form to IRS—15 minutes
Estimated Total Reporting/ Recordkeeping Burden: 292,800 hours.
Clearance Officer: Garrick Shear (202) 535–4297, Internal Revenue Service, room 5571, 1111 Constitution Avenue, NW., Washington, DC 20224
OMB Reviewer: Milo Sunderhauf (202) 395–6880, Office of Management and Budget, room 3001, New Executive Office Building, Washington, DC 20503

Dale A. Morgan,

Departmental Reports Management Officer.

[FR Doc. 91–23158 Filed 9–25–91; 8:45 am]

BILLING CODE 4830–1–M

Public Information Collection Requirements Submitted to OMB for Review

Date: September 20, 1991.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, room 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

U.S. Customs Service

OMB Number: New
Form Number: None
Type of Review: New collection
Title: Card Survey on Global Trade Talk Magazines
Description: This information collection is a survey of readers of the Global Trade Talk for their opinions on ways to improve the publication or topics they would like to see covered.
Respondents: Businesses or other for-profit, Federal agencies or employees, Small businesses or organizations
Estimated Number of Responses: 200
Estimated Burden Hours Per Response: 15 minutes
Frequency of Response: Annually
Estimated Total Reporting Burden: 50 hours
Clearance Officer: Ralph Meyer, (202) 566–4019, U.S. Customs Service, Paperwork Management Branch, room 6316, 1301 Constitution Avenue, NW., Washington, DC 20229
OMB Reviewer: Milo Sunderhauf, (202) 395–6880, Office of Management and Budget, room 3001, New Executive Office Building, Washington, DC 20503

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 91–23199 Filed 9–25–91; 8:45 am]

BILLING CODE 4820–02–M

Public Information Collection Requirements Submitted to OMB for Review

Date: September 18, 1991.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Pub. L. 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, room 3190 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

Internal Revenue Service

OMB Number: 1545–
Form Number: None
Type of Review New
Title: Coordinated Examination Program Examination Post Closing Survey
Description: Information gathering for program evaluation and operation. The data collected will be used to evaluate the level of satisfaction of the largest corporate taxpayers examined by the IRS Examination Function, to identify possible areas of program improvement, and thereby, improve the quality and effectiveness of the Coordinated Examination Program.
Respondents: Businesses or other for-profit
Estimated Number of Respondents/ Recordkeepers: 300
Estimated Burden Hours Per Respondent/Recordkeeping: 1 hour and 30 minutes
Frequency of Response: One time at conclusion of taxpayer examination
Clearance Officer: Garrick Shear (202) 535–4297, Internal Revenue Service, room 5571, 1111 Constitution Avenue, NW., Washington, DC 20224
OMB Reviewer: Milo Sunderhauf (202) 395–6880, Office of Management and Budget, room 3001, New Executive Office Building, Washington, DC 20503

Dale A. Morgan,

Departmental Reports Management Officer.

[FR Doc. 91–23159 Filed 9–25–91; 8:45 am]

BILLING CODE 4830–01–M

Sunshine Act Meetings

Federal Register
Vol. 56, No. 187
Thursday, September 26, 1991

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

FEDERAL ELECTION COMMISSION

DATE AND TIME: Tuesday, October 1, 1991, 10:00 a.m.

PLACE: 999 E Street, N.W., Washington, D.C. (Ninth Floor)

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 2 U.S.C. § 437g.
Audits conducted pursuant to 2 U.S.C. § 437g, § 438(b), and Title 26, U.S.C.
Matters concerning participation in civil actions or proceedings or arbitration.
Internal personnel rules and procedures or matters affecting a particular employee.

DATE AND TIME: Thursday, October 3, 1991, 10:00 a.m.

PLACE: 999 E Street, N.W., Washington, D.C. (Ninth Floor)

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED:

Final Audit Report—Bush-Quayle '88 and George Bush for President, Inc./ Compliance Committee
Advisory Opinion 1991–22: Mr. Douglas A. Kelley on behalf of Senator David Durenberger, Representative Jim Ramstad, Representative Vin Weber, and others.
Proposed Revisions to Bank Loan Regulations (continued from meeting of August 29, 1991)
Administrative Matters

PERSON TO CONTACT FOR INFORMATION: Mr. Fred Eiland, Press Officer, Telephone: (202) 376–3155.

Delores Harris,

Administrative Assistant, Office of the Secretariat.

[FR Doc. 91–23402 Filed 9–24–91; 2:43 pm]

BILLING CODE 9-24-91

POSTAL RATE COMMISSION

TIME AND DATE: 10:00 a.m., September 26 and September 27, 1991.

PLACE: Conference Room, 1333 H Street, NW, Suite 300, Washington, DC 20268.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Issues in Docket No. R90–1.

CONTACT PERSON FOR MORE INFORMATION: Charles L. Clapp, Secretary, Postal Rate Commission, Room 300, 1333 H Street, N.W., Washington, D.C. 20268–0001, Telephone (202) 789–6840.

Charles L. Clapp,

Secretary.

[FR Doc. 91–23327 Filed 9–24–91; 10:42 am]

BILLING CODE 7710–FW–M

Corrections

Federal Register
Vol. 56, No. 187
Thursday, September 26, 1991

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. TM91-1-31-001]

Arkla Energy Resources, A Division of Arkla, Inc.; Corrections to Tariff Filing

Correction

In notice document 91-14899 appearing on page 28754 in the issue of Monday, June 24, 1991, in the third column, in the file line at the end of the document, "FR Doc. 91-14889" should read "FR Doc. 91-14899".

BILLING CODE 1505-01-D

DEPARTMENT OF TRANSPORTATION

Maritime Administration

Change of Name and Removal From Roster of Approved Trustees

Correction

In notice document 91-15207 appearing on page 29305 in the issue of Wednesday, June 26, 1991, in the third column, in the file line at the end of the document, "FR Doc. 91-15202" should read "FR Doc. 91-15207".

BILLING CODE 1505-01-D

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Parts 10, 171, and 172

[T.D. 91-71]

RIN 1515-AA91

Delegation of Authority To Decide Penalties and Liquidated Damages Cases

Correction

In rule document 91-19609 beginning on page 40776 in the issue of Friday, August 16, 1991, make the following corrections:

§ 10.39 [Corrected]

1. On page 40779, in the second column, in amendment 2., in the first line "word" was misspelled.

§ 171.21 [Corrected]

2. On the same page, in the third column, in § 171.21, in the second line"finds" should read "fines".

§ 171.33 [Corrected]

3. On page 40780, in the first column, in § 171.33(b)(1), in the ninth line, "directory" should read "director".

4. On the same page, in the same column, in the 14th line, "In the district believes" should read "If the district director believes".

5. On the same page, in the same column, in § 171.33(d), in the heading, in the first line "*Appeals of*" should read "*Appeals to*".

PART 172 [CORRECTED]

6. On the same page, in the same column, in the authority citation for part 172, "1634" should read "1624".

§ 172.22 [Corrected]

7. On the same page, in the same column, in § 172.22(e), in the heading, in the second line "in--bond" should read "in-bond".

8. On the same page, in the same column, in § 172.22(e), in the 11th line "delegation" should read "delegations".

BILLING CODE 1505-01-D

federal register

Thursday
September 26, 1991

Part II

Department of Health and Human Services

Health Care Financing Administration

42 CFR Part 431, et al.

Medicare and Medicaid; Requirements for Long Term Care Facilities and Nurse Aide Training and Competency Evaluation Programs; Final Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 442, 447, 483, 488, 489 and 498

[BPD-396-F]

RIN 0938-AD 12

Medicare and Medicaid; Requirements for Long Term Care Facilities

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

ACTION: Final rule.

SUMMARY: These final regulations revise and consolidate the requirements that facilities furnishing long term care are required to meet to participate in either or both the Medicare and Medicaid programs. They revise our February 2, 1989 (54 FR 5316) final regulations to reflect our response to comments submitted by the public and to conform them to statutory provisions that were not in effect when we issued the prior rule, and to include various minor and technical changes in the requirements made by the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101-508).

EFFECTIVE DATES: These regulations are effective April 1, 1992. We would note, however, that these regulations reflect a number of provisions that are currently in effect as a result of their publication in a final rule on February 2, 1989 (54 FR 5316) and also provisions that were enacted in OBRA '90 and made effective by Congress as if they were enacted in the Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100-203). State agencies have until 90 days after receipt of a revised State Plan preprint to submit their plan amendments and required attachments. We will not hold a State to be out of compliance with the requirements of these final regulations if it submits the necessary plan materials by that date.

FOR FURTHER INFORMATION CONTACT: Bill Ullman (301) 966-5667.

SUPPLEMENTARY INFORMATION:

I. Background

Prior Rulemaking Activity

On February 2, 1989, we published in the **Federal Register** (54 FR 5316) final regulations that specified new and revised requirements that long term care facilities (skilled nursing facilities (SNFs) under Medicare, and SNFs, intermediate care facilities (ICFs), and, effective October 1, 1990, nursing facilities under Medicaid) must meet in order to receive Federal funds for the care of residents who are Medicare beneficiaries or Medicaid recipients. We invited comments on the regulations if submitted by May 3, 1989.

Many of the requirements in the February 2 regulations implemented provisions of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) (Pub. L. 100-203). An effective date of August 1, 1989 was specified for the regulations except for provisions that relied on a later statutory effective date. (Some OBRA '87 requirements have effective dates of January 1, 1990, April 1, 1990, and October 1, 1990.) However, we later determined that the August 1, 1989 effective date did not give States and others adequate implementation time, and on July 14, 1989 we delayed the August 1, 1989 effective date to January 1, 1990 (54 FR 29717).

On December 19, 1989, the Omnibus Budget Reconciliation Act of 1989 (OBRA '89, Pub. L. 101-239) was enacted. Section 6901(a) of OBRA '89 changes the January 1, 1990 effective date of the nursing home regulations to October 1, 1990. As a result, on December 29, 1989 we published in the **Federal Register** (54 FR 53611) a final rule to revise the effective date of our February 2, 1989 regulations to October 1, 1990.

On November 5, 1990, the Omnibus Budget Reconciliation Act of 1990 (OBRA '90, Pub. L. 101-508) became law. Sections 4008(h) (for the Medicare program) and 4801 (for the Medicaid program) contained technical amendments to the nursing home reform provisions contained in the previously cited statutes. Section 4207(k) of the same act gave the Secretary authority to issue regulations "on an interim or other basis" to implement the provisions of the relevant title. Conference Committee Report language for both Medicare and Medicaid provisions indicated the conferees view that the amendments made by OBRA '90 were "minor and technical changes to the nursing home reform statute as originally enacted in 1987. The managers are aware that the Secretary will soon issue regulations implementing portions of the original law. The managers do not intend that the amendments below result in any further delay in forthcoming regulations." (H12661, Congressional Record, October 26, 1990.) As a result, we have incorporated the OBRA '90 changes into this final regulation. In the interests of issuing this final regulation as quickly as possible, we have inserted the OBRA '90 changes in the regulations text and discussed them in the preamble at places where comments and responses for the amended provisions appear.

Effect of Proposed Rule

The February 2, 1989 revision of the nursing home regulations was the most extensive set of Federal regulatory changes in this area of the health care industry in 15 years. We revised the requirements that long term care facilities must meet in order to receive Federal funds for the care of residents who are Medicare beneficiaries or Medicaid recipients. We issued the regulations following a notice of proposed rulemaking (NPRM) (52 FR 38582, October 16, 1987) to refocus the requirements for participation in both programs to actual facility performance in meeting residents' needs in a safe and healthful environment. The previous set of requirements had focused on the capacity of the facility to provide appropriate care. In addition, we needed to simplify Federal enforcement procedures by using a single set of requirements that apply to all activities common to SNFs, ICFs, and NFs.

As discussed in the preamble to the proposed rule (52 FR 38582), our NPRM reflected the recommendations of the Institute of Medicine (IoM). OBRA '87 was written with both the recommendations of the IoM and our NPRM as a model. OBRA '87 departs from previous Congressional practice by specifying many details which prior law leaves to the authority of the Secretary. It also contains entirely new requirements which are also specified in detail.

In drafting the final regulation, we attempted to adapt the language used in OBRA '87 in all cases in which we believed that the requirements in question are supportable under the statute as it existed prior to inclusion of OBRA '87 requirements and reasonably flow from proposals published in the October 16, 1987 NPRM. We did this because we had comments on the NPRM that have recommended this course of action. Consequently, in the February 2, 1989 rule, we included many of the provisions of our NPRM (revised as appropriate) and, when possible, the new requirements contained in OBRA '87 that are effective October 1, 1990. Provisions that were not specifically addressed by elements of OBRA '87 but which met requirements of the Administrative Procedure Act that would permit issuance of a final rule, were made effective on October 1, 1990. It was our intention that the final regulations reflect, to the extent possible, the comments on the NPRM

and the requirements of titles XVIII and XIX of the Act as modified by OBRA '87.

As a result of comments and the legislative changes, we incorporated the following major OBRA '87 requirements:

- Assuring residents' privacy rights with regard to accommodations, medical treatment, personal care, visits, written and telephone communications, and meetings with resident and family groups;
- Maintaining confidentiality of personal and clinical records;
- Guaranteeing facility access and visitation rights;
- Issuing a notice of rights at the time of admission;
- Implementing admissions policy requirements;
- Assuring proper use of physical and chemical restraints;
- Protecting resident funds being managed by a facility;
- Ensuring transfer and discharge rights and issuing notices required of a facility;
- Providing twenty-four hour licensed nursing services, and services of a registered nurse at least 8 consecutive hours a day, 7 days a week, subject to waivers;
- Furnishing comprehensive assessments and being subject to civil money penalties for falsification of an assessment;
- Requiring minimum training of nurse aides, competency evaluation programs, and regular in-service education;
- Prohibiting admission to SNFs and NFs of individuals with mental illness and mental retardation, except when they need SNF and NF services and have been prescreened by a State authority of mental illness or retardation;
- Providing or obtaining routine and emergency dental services;
- Employing a full time social worker if a facility has more than 120 beds; and
- Meeting disclosure of ownership requirements.

Due to the extensive revisions from our NPRM, we invited public comments and offered to undertake revisions if warranted.

Content of February 2, 1989 Rule

Inasmuch as the February 2, 1989 rule totally restructured the regulations with respect to long term care facility requirements, no brief summary of its content could adequately present technical material exhaustively presented in previous documents. Readers with interest in specific background information on items included in this rule should refer to the preambles of the NPRM (52 FR 38582) or final rule (54 FR 5316).

It is important to note that the February 2, 1989 long term care requirements significantly departed from the format traditionally used, thus creating an effect in enforcement activities that measure adherence to the requirements. The condition of participation (COP) format traditionally used by Medicare and Medicaid consisted of condition and standard level statements. It was based on the principle that each condition level statement would be a statutory requirement while standard level requirements were reflective of regulatory standards. In determining compliance with our requirements, a State survey agency could find a facility with deficiencies at the standard level and making efforts to correct them acceptable to continue to participate in the Medicare program. The State agency would, however, recommend a facility be subject to termination if it failed to meet a condition level (i.e., statutory) requirement. Regardless of the significance of the requirement, that is, whether the requirement was a COP or a standard within a condition, the facility was responsible for fully complying with all requirements.

Notwithstanding this long standing agency policy, we believe that, to the extent that Federal requirements were set forth in what appeared to be a qualitative hierarchy, there was some misunderstanding that violations of the "lesser" requirements would not be subject to Federal enforcement.

Additionally, the OBRA '87 requirements have recast substantive requirements so as not to use the traditional "conditions" and "standards" terminology.

Accordingly, in the final rule published February 2, 1989 we retained the organization of the various proposed requirements, and designated them as Level A and Level B requirements.

It was never intended that the Level A and Level B designations imply a hierarchy of importance. In the final rule we included a preamble statement at 54 FR 5318 indicating that the Level A and Level B "designations are intended to communicate that all the nursing facility requirements are binding and are not part of a qualitative hierarchy." Moreover, sections 1819(h) and 1919(h) of the Act as amended by OBRA '87 make all nursing facility requirements binding. Thus a facility must be in compliance with all the requirements of sections 1819(b) through (d) and 1919(b) through (d) in order to participate in the Medicare and Medicaid programs.

Every requirement in these regulations must be enforced and penalties must be assessed in accordance with regulations issued pursuant to sections 1819(h) and 1919(h) of the Social Security Act (the Act).

II. Overview of Final Rule, Comments and Responses and Summary of Changes

We received more than 800 comments in response to the February 2, 1989 final rule with a comment period. Comments were submitted from various associations and organizations representing nursing homes, and the various medical and other professional employees that make up long term care facility staff also submitted comments. Individual States and major third party payers also submitted comments. In that the majority of comments and issues dealt with the content of new part 483, Requirements for Long Term Care Facilities, we deal with these items first. Commenters also expressed views on part 442, Standards for Payment for Skilled Nursing and Intermediate Care Facility Services and part 447, Payment for Services. Below, we summarize briefly the provisions of the rule generating the comments, indicate individual comments and responses, and summarize changes to our rules.

Comments on Part 483, Requirements for Long Term Care Facilities

Comment: A number of commenters, especially those dealing with resident activities and social services, objected to the Level A and Level B designations used in the organization of these requirements. Their principal objection centered around a belief that Level B requirements were less important than Level A requirements.

Response: In order to prevent any further confusion over this issue, we have decided to delete from part 483 all references to Level A and Level B requirements.

The deletion of Level A and Level B designation has led to one complication, however. The OBRA '87 enforcement regulation was not issued in final form on October 1, 1990, and 42 CFR parts 442, 488 and 489 (the current enforcement rules) were amended to refer to Level A and Level B requirements. (The current enforcement system refers to Level A and Level B requirements and adverse actions are taken as a result of noncompliance with Level A requirements.) It is therefore necessary from an administrative standpoint to continue to use the Level A and Level B designations for all surveys until a few enforcement system

and accompanying forms and procedures are in place. This policy is reflected by the reference to Level A and Level B in parts 442, 488, 489, and 498. These references to Level A and Level B will be removed in the OBRA '87 enforcement rule. Accordingly, the following listing of requirements designated as Level A or Level B, as published in the February 2, 1989 **Federal Register**, is repeated here for informational purposes.

Section	Level A requirement	Level B requirement
483.10	Resident rights.....	(a) Exercise of rights.
		(b) Notice of rights and services.
		(c) Protection of resident funds.
		(d) Free choice.
		(e) Privacy and confidentiality.
		(f) Grievances.
		(g) Examination of survey results.
		(h) Work.
		(i) Mail.
		(j) Access to facility.
		(k) Access and visitation rights.
		(l) Telephone.
		(m) Personal property.
		(n) Married couples.
		(o) Self administration of drugs.
483.12	Admission, transfer and discharge.	(a) Transfer and Discharge.
		(b) Notice of bed-hold policy and readmission.
		(c) Equal access to quality care.
		(d) Admissions policy.
		(e) Resident care policies.
483.13	Resident behavior and facility practices.	(a) Restraints.
		(b) Abuse.
		(c) Staff treatment of residents.
483.15	Quality of life	(a) Dignity.
		(b) Self-determination and participation.
		(c) Participation in resident and family groups.
		(d) Participation in other activities.
		(e) Accommodation of needs.
		(f) Activities.
		(g) Social Services.
		(h) Environment.
483.20	Resident assessment.	(a) Admission orders.
		(b) Comprehensive assessments.
		(c) Accuracy of assessments.
		(d) Comprehensive care plans.
		(e) Discharge summary.
		(f) Preadmission screening for mentally ill individuals and individuals with mental retardation.
483.25	Quality of care.....	(a) Activities of daily living.
		(b) Vision and hearing.
		(c) Pressure sores.
		(d) Urinary incontinence.
		(e) Range of motion.
		(f) Psychosocial functioning.
		(g) Naso-gastric tubes.
		(h) Accidents.
		(i) Nutrition.
		(j) Hydration.
		(k) Special needs.
		(l) Drug therapy.
		(m) Medication errors.
483.28	Nursing services--skilled nursing facilities.	(a) Director of nursing services.
		(b) Charge nurse.
		(c) Twenty-four hour nursing service.
483.29	Nursing services--intermediate care facilities.	
483.30	Nursing services.....	(a) Sufficient staff.
		(b) Registered nurse.
		(c) Nursing facilities: Waiver of requirement to provide licensed nurses on a 24-hour basis.
		(d) SNFs: Waiver of the requirement to provide services of a registered nurse for more than 40 hours a week.
483.35	Dietary services.....	(a) Staffing.
		(b) Sufficient staff.
		(c) Menus and nutritional adequacy.
		(d) Food.
		(e) Therapeutic diets.
		(f) Frequency of meals.
		(g) Assistive devices.
		(h) Sanitary conditions.
483.40	Physician services....	(a) Physician supervision.
		(b) Physician visits.
		(c) Frequency of physician visits.
		(d) Availability of physicians for emergency care.
		(e) Physician delegation of tasks.
483.45	Specialized rehabilitative services.	(a) Provision of services.
		(b) Qualifications.
483.55	Dental services.....	(a) Advisory dentist.
		(b) Outside services.
		(c) Skilled nursing facilities.
		(d) Nursing facilities.
483.60	Pharmacy services..	(a) Methods and procedures.
		(b) Procedures.
		(c) Pharmaceutical services committee.
		(d) Service consultation.
		(e) Drug regimen review.
		(f) Labeling of drugs and biologicals.
		(g) Storage of drugs and biologicals.
483.65	Infection control	(a) Infection control programs.
		(b) Preventing spread of infection.
		(c) Linens.
483.70	Physical environment.	(a) Life safety from fire.
		(b) Emergency power.
		(c) Space and equipment.
		(d) Resident rooms.
		(e) Toilet facilities.
		(f) Resident call system.
		(g) Dining and resident activities.
		(h) Other environmental conditions.
483.75	Administration.....	(a) Licensure.
		(b) Compliance with Federal, State and local laws.
		(c) Compliance with Federal, State and local laws and professional standards, effective October 1, 1990.
		(d) Relationship to other HHS regulations.
		(e) Governing body.
		(f) Institutional plan and budget.
		(g) Required training of nurse aides.
		(h) Proficiency of nurse aides.
		(i) Staff qualificatio
		(j) Use of outside resources.
		(k) Medical director.
		(l) Laboratory services.
		(m) Radiology and other diagnostic services.
		(n) Clinical records.
		(o) Disaster and emergency preparedness.

Section	Level A requirement	Level B requirement
		(p) Transfer agreement. (q) Utilization review. (r) Quality assessment and assurance. (s) Disclosure of ownership. (t) Independent medical evaluation and audit.

Section 483.05 Definitions

Summary of Provisions

Section 483.05 specifies the definition of "facility" for purposes of subpart B.

Comments and Responses

There were no public comments on § 483.05. Nonetheless, we are making a clarification to the definition of "facility". We believe that the change in the definition is necessary because of the misunderstanding that gave rise to the statutory requirement relating to intrafacility transfers in sections 4008(h)(2)(G) and 4801(e)(8) of OBRA '90. The statutory authority under which a "distinct part" is considered to be a SNF or NF is the language in sections 1819 and 1919 of the Act, at the beginning. However, the term facility is often used to denote not just a participating entity but also a larger institution of which the participating entity is a part.

Summary of Change to § 483.05

We have added a sentence to the definition of "facility to clarify the fact that, for purposes of Medicare and Medicaid eligibility, coverage, and certification, and payment. this term refers to the entity that participates in the program, whether or not the participating entity is comprised of the entire institution or a distinct part of the institution.

Section 483.10 Resident Rights

Summary of Provisions

Section 483.10 specifies that the resident has a right to a dignified existence, self-determination, and communication with and access to persons and services inside and outside the facility. Section 483.10 also specifies that the facility must assert, protect, and facilitate the exercise of these rights. Under present rules, resident rights are categorized as an individual provision within a condition.

Section 483.10(a) specifies that (1) The resident has the right to exercise his or her right as a resident of the facility, and as a citizen or resident of the United States, including the right to file complaints; (2) the resident has the right to be free of coercion or reprisal from the facility in exercising his or her rights; and (3) an individual appointed under State law may exercise a resident's rights when a resident has been adjudicated to be incompetent.

Section 483.10(b) requires that the facility must inform the resident of his or her rights and all rules governing resident conduct and responsibilities during the stay in the facility. The notice must include the State's notice of rights and obligations of residents of nursing facilities (and spouses of such residents) under the Medicaid program. States are required to develop this notice by section 1919(e)(6) of the Act. Section 4801(e)(10) of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90, Pub. L. 101–508) requires that these statements be included in the facility's notice to the resident and so we have included that requirement here.

Section 483.10(c) specifies that a resident is not required to deposit personal funds with the facility, and the resident may designate another party to manage his or her finances.

Section 483.10(d) specifies that a resident has the right to choose an attending physician, be informed in advance of care and treatment, and to participate in development of his or her plan of care.

Section 483.10(e) provides that a resident has the right to refuse the release of personal and clinical records to any individual outside of the facility, except when required to release to another health care institution by law, or third party payment contract.

Section 483.10(f) specifies that a resident has a right to treatment or care, and the right to prompt efforts by the facility to resolve a grievance.

Section 483.10(g) provides that a resident has the right to examine the results of the most recent survey of the facility conducted by Federal and State surveyors.

Section 483.10(h) specifies the work requirement and the resident's right to perform services for the facility when the need or desire for work is documented in the plan of care.

Section 483.10(i) specifies that a resident has the right to privacy in written communication including the right to send and receive unopened mail promptly.

Section 483.10(j), Level B requirement: Access to the facility, was only effective only until October 1, 1990. Therefore we propose to eliminate it. All subsequent paragraphs are redesignated.

Section 483.10(k) (redesignated to § 483.10(j)) specifies that a resident has a right to receive immediate family members or other relatives at any hour, and other visitors at a reasonable hour by arrangement with the facility.

Section 483.10(l) (redesignated to § 483.10(k) in this final rule) provides that a resident has the right to be provided use of a telephone.

Section 483.10(m) (redesignated to § 483.10(l) in this final rule) specifies that a resident has the right to retain and use personal possessions, unless to do so would infringe upon rights or health and safety of other residents.

Section 483.10(n) (redesignated to § 483.10(m) in this final rule) specifies that a resident has the right to share a room in a facility with a spouse when both spouses consent to the arrangement.

Section 483.10(o) (redesignated to § 483.10(n) in this final rule) provides that an individual may self-administer drugs only if the interdisciplinary team determines that it is safe.

Section 483.10(o) specifies the resident's right to refuse transfer from a room on one distinct part of a facility to a room in another distinct part of the facility for purposes of obtaining Medicare of Medicaid eligibility or without medical justification (to create vacancies for purposes of admitting other individuals who may be eligible for these programs to distinct parts to which payments may be made).

Comments and Responses

Comment: A number of commenters representing mental health interests requested that we add to the opening statement for resident rights that each resident has the right to treatment for the mental and physical conditions identified in his or her comprehensive plan of care.

Response: We do not believe the recommended changes would have the intended result. Instead, we believe that the appropriate means to assure that residents with mental or other illnesses receive the treatment they need is through enforcement of the requirements relating to properly assessing care given and comparing the provision of services actually furnished to those required to meet the resident's identified needs. We address several mental health treatment issues in additional responses. (See §§ 483.20(b)(2)(iii) and (vii); 483.20(f); 483.25(f); and 483.45(a)).

Comment: The regulations addressing resident incompetence and devolution of rights elicited over twenty responses;

commenters overwhelmingly opposed the proposed wording of § 483.10(a)(3). Almost all commenters asked that the rule address non-adjudicated determinations of incompetency as well as adjudicated cases because they asserted that residents often are not adjudicated incompetent but are too confused or ill to exercise their rights effectively without the assistance of others. Because the OBRA '87 provision concerning competency fails to address non-adjudicated situations, we did not include a provision in the February 2, 1989 final rule specifically addressing these cases. Commenters charged that this omission has the effect of requiring adjudication before anyone else can exercise a resident's rights. Also, they claimed that this omission either conflicts with State laws or excludes from consideration a variety of State-authorized means of handling resident incapabilities through non-judicial designation of legal surrogates, such as durable powers of attorney, living wills, or natural death laws. By ruling out these advance directives, we would effectively restrict a resident's right to self-determination.

Response: In order to avoid such ambiguity, we accept commenters' recommendations that we include a statement dealing with non-adjudicated cases of incompetence. Because of the variance in State laws concerning the issue of exercise of resident rights, we are deferring entirely to State law in these cases as we have already done with adjudicated cases. We are adding a provision at § 483.10(a)(4) which recognizes State mechanisms to designate legal surrogates through non-judicial means. To the extent that State-designated mechanisms for either adjudicated or non-adjudicated residents rely on a physician's determination of incapacity or incompetence, we bow to the State's authority to regulate in what has traditionally been a State matter.

Comment: Thirteen commenters responded to the preamble discussion on informing the resident of rights and responsibilities of the meaning of "in the language that he or she understands", which was contained in regulations at § 483.10(b)(1). The requirement is that facilities must notify residents of their rights. Several commenters objected to the many forms in which we suggested the notice of rights should be given (e.g., use of written foreign language translations and interpreters for non-English speaking residents and large print or sign language interpretation for those with visual or hearing impairment). Some suggested that we clarify in the interpretative guidelines that using family members or other appropriate third party representatives to provide translations for the resident would be sufficient. Other commenters praised this clarification and requested that it be included in the regulations text.

Response: We are retaining the regulation as it was presented in the February 2, 1989 final rule. We believe the approach we recommended in the preamble to that rule was sufficiently flexible not to place an undue burden upon facilities. That is, for foreign languages commonly encountered in the facility's locale, the facility should have written translations of its statement of rights and responsibilities and should make the services of an interpreter available. In the case of uncommon foreign languages, however, a representative of the resident may sign that he has interpreted the statement of rights to the resident prior to the resident's acknowledgment of receipt. For hearing impaired residents who communicate by signing, the facility would similarly be expected to provide an interpreter. Large print texts of the facility's statement of resident rights and responsibilities should also be available for the many residents who need them. We do not believe a facility should avoid its responsibility to see that the resident knows what his or her rights are and what is expected of him or her.

Comment: Fifteen commenters asked for clarification of either "during a resident's stay" or "all rules and regulations" in the regulation at § 483.10(b)(1).

Response: We believe that "during a resident's stay" means that any time State or Federal laws relating to resident rights or facility rules changes, residents must promptly be apprised of these changes. "All rules and regulations" relates to facility policies governing resident conduct. A facility cannot reasonably expect a resident to abide by rules about which he or she has never been told. Whatever rules the facility has formalized and by which it expects residents to abide should be included in the statement of rights and responsibilities.

Comment: We received over 60 comments on § 483.10(b)(2), which deals with the resident's right to inspect and purchase photocopies of his or her records. A sizable number of resident advocates asked for the right to inspect records immediately upon request. They were willing, however, to wait 48 hours to obtain photocopies. This group of commenters pointed out that current records are available immediately to staff, consultants, and Federal and State inspectors. They believe that residents should also have immediate access. Several commenters also believed that requiring a written request disadvantaged some residents with disabilities and that an oral request should be sufficient.

An equally sizable group of provider-based commenters claimed that 48 hours was not long enough to produce records. They pointed out that in the case of some long term residents, medical records can be extremely voluminous. Current records are periodically thinned. Older records may be warehoused away from the unit or even the facility, and several days might be required for retrieval. Facility-based commenters asked for from 2 to 7 working days to fulfill a request to see records.

Response: In keeping with the Institute of Medicine (IoM) recommendation that residents should be as informed and in control of their care as possible, we concur with the view of resident advocates that a resident should have the same right of access to his or her current records that staff, consultants or inspectors have and that an oral request should suffice. We also recognize the validity of the facilities' position concerning older records. We are therefore amending § 483.10(b)(2) to grant residents access within 24 hours to records which would include clinical records as specified in OBRA '90 and according to commenters request. We are not allowing immediate access to current records so as not to go beyond the OBRA '90 provisions which allow 24 hours for facilities to obtain clinical records. Upon provision of the records, new or old, a facility would be allowed two working days in which to provide photocopies at the resident's expense.

Comment: Several commenters responded to the statement in § 483.10(b)(2) that a resident should have access to "all records pertaining to the resident." Some asked that we limit records to medical records while others applauded the inclusiveness of this statement. Two commenters asked that facility incident reports not be considered a part of resident records.

Response: We are leaving the term "all records" as stated in the February 2 rule because we agree with those commenters that believe that a resident should have access to all records pertaining to him or her such as trust fund ledgers, contracts with the facility, and facility incident reports which involve him or her. This also includes clinical records as specified by the

provisions of OBRA '90 and, for consistency, we are allowing facilities 24 hours to grant access to all listed records.

Comment: As was the case with comments on the October 16, 1987 proposed rule, a handful of commenters again asked that we qualify the right to inspect records with the statement "unless medically contraindicated."

Response: As we explained in the preamble to the February 2, 1989 rule, we have eliminated this qualifier from all rights. This decision was based on the overwhelming response of commenters to the October 16, 1987 proposed rule who favored deletion of such phrases and upon our belief that each resident should have as much control as possible over his or her care. Other provisions relating to the exercise of resident rights should assure that incompetent residents do not have inappropriate access to records relating, for example, to their treatment.

Comment: Thirteen commenters, mostly representing facilities, expressed the belief that the role of informing the resident of both his or her medical condition and health status clearly belongs to the physician, not the facility. Some commenters believed the facility should only be responsible for responding to a resident's questions concerning what he or she had been told by the physician, but another group of commenters believed that, even in responding to questions, the facility could be placed in jeopardy for miscommunicating medical information that requires a physician's professional opinion. In such cases, they stated it would be improper for facility staff to answer specific questions.

Response: We note that proposed regulations at § 483.10(b)(3) would have qualified the right to be fully informed with "by a physician." We did not place this qualifier in the final rule because we did not wish to absolve the facility of all responsibility for communicating with the resident concerning his or her health status. We do not feel the change is appropriate now. This provision is consistent with § 483.10 (d)(2) and (d)(3), which require that the resident be informed of changes in his or her care or treatment and, unless a State authorized surrogate decision maker is involved, be allowed to participate in the planning of his or her care. While professional ethics would dictate that discussion of some matters requires a physician, the in-house interdisciplinary care-planning process should be discussed with the resident. The facility has always been in the position of contacting the physician when only a physician's judgment will suffice. In sensitive areas of discussion with the resident, the facility staff would not act in violation of this requirement should they refer the resident's questions to the attending physician or a facility physician. However, we expect facility staff, especially medical social workers, to routinely communicate in layman's terms information about health status to the resident.

Comment: Nine commenters responded to the requirement at § 483.10(b)(4) that residents have the right to refuse treatment and participation in experimental research. Several of them were concerned that the statement does not deal with incompetent, yet non-adjudicated residents incapable of making informed decisions. They believed that to allow such individuals to refuse food and water when not in mental control is irresponsible. Some of these commenters questioned our solution, in non-adjudicated cases, that if the refusal of all treatment is persistent and consistent, the facility may have grounds for discharge of the resident. One commenter suggested that we consider adding to the regulation our interpretation that a petition for a court-appointed guardian be considered in such cases. Another suggested that the regulations should emphasize the facility's obligation to offer the least restrictive treatment modality to patients in need of some form of treatment and should require the facility to offer rehabilitative alternatives in the face of persistent refusal.

Response: We are clarifying in a new § 483.10(a)(4) that we defer to whatever legal processes a State has adopted for dealing with incompetence or incapacity on the part of a resident. Some of these legal processes may involve the use of the courts to adjudge an individual incompetent and appoint a guardian or conservator. Other State designated instruments, such as a durable power of attorney, are non-adjudicative because they do not involve the use of the courts to permit another person to act on behalf of the resident. Some State processes discriminate between areas where a resident is competent and areas where a surrogate is empowered to make divisions. We recognize any legal surrogate designated in accordance with State law, whether appointed by adjudicative or non-adjudicative means and to any extent designated.

We believe that, whether or not a resident is incompetent, consistent refusal of treatment over time must be honored, but in compliance with State law and case law. The resident has the right to refuse treatment. This refusal and the facility's response to it must be consistently documented before a facility can legitimately consider discharge as an option. A pattern of failure to document the resident's refusal of treatment and the facility's efforts to employ alternate modalities of treatment before resorting to discharge as the ultimate solution could lead to a deficiency for discharging without adequate grounds and/or for a failure to provide an adequate quality of care.

Comment: Fourteen commenters responded to § 483.10(b)(5) and (b)(6), which concern notification of residents about Medicare and Medicaid and about services offered by the facility but not covered by Medicare and Medicaid. The largest number of commenters requested clarification of "periodically" in § 483.10(b)(6). Two commenters termed these requirements onerous because the number of items in the State plan or offered by facilities are numerous and change often. They believed a list of what the Medicaid-eligible resident is responsible for or a notice of changes in the cost of services used by a private pay resident should be sufficient. Another commenter urged us to publish a list of items and services that are included in nursing facility services and for which the resident may not be charged. Still other commenters asked for 30 days written notice of any changes in the list of services covered by the State plan and charges for uncovered services.

Response: These two requirements (§ 483.10(b)(5) and (b)(6)) are taken directly from section 1919(c)(1)(B)(iii and iv) of the Act as amended by OBRA '87. When the two provisions—one relating to Medicaid recipients and the other relating to non-Medicaid recipients—are considered together, the thrust of these provisions becomes clear: Residents should be told in advance when changes will occur in their bills. Therefore, we interpret "periodically" to mean whenever changes are being introduced that will affect the resident's liability. The items and services which may be charged to a resident's personal funds are being clarified as part of a separate regulation published as a notice of proposed rulemaking on March 20, 1990 at 55 FR 10258.

Comment: Three commenters asked that § 483.10(b)(7)(ii), which requires a facility to notify residents of their right to file complaints in certain instances, be expanded to include notice of the resident's right to complain to the State licensure office, the ombudsman program, the protection and advocacy network, the adult protective services, and the Medicaid fraud control unit. They asked that the names, addresses, and phone numbers of each of these

advocacy groups be included in the notice of rights as well as be required to be posted so that this information is easily accessible to residents and visitors.

Response: We agree with these commenters that the notice of rights is an appropriate place to present information about the various State agencies acting as client advocates. Section 483.10(f)(1) assures that residents have the right to voice grievances, and § 483.10(g)(2) requires that residents receive information about such organizations and be afforded the opportunity to contact these agencies. However, nowhere do we currently require that detailed information about how to contact these agencies (i.e. name, mailing address and telephone number) be placed in every resident's hands at the time of admission. We are therefore amending § 483.10(b)(7) to include a requirement that the statement of rights contain the name, mailing address and telephone number of relevant advocacy agencies. By relevant advocacy agencies we mean, the State survey and certification agency, the State licensure office (usually synonymous with the survey and certification agency), the ombudsman program established by the State under the Older Americans Act of 1965; the protection and advocacy system for developmentally disabled individuals established under the Developmental Disabilities Assistance and Bill of Rights Act; the protection and advocacy system established under the Protection and Advocacy for Mentally Ill Individuals Act; and the Medicaid fraud control unit established under section 1903(q) of the Act, as amended by the Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977.

Our rationale for imposing this requirement is that we believe it does a resident or his or her representative little good to tell him or her that he or she can complain without supplying specific information concerning relevant advocacy agencies. The written statement of rights given at the time of admission is likely to be retained by the resident or representative and is, therefore, an appropriate place to list these client advocacy agencies. Section 1919(c)(1)(x) gives the Secretary the authority to establish other rights. We believe this requirement is an extension of the rights specified in section 1919(c).

We do not believe this requirement is overly burdensome since most of this information should be readily available to the facility. For instance, in order to transfer or discharge a resident, OBRA '87 amended section 1919(c)(2)(B)(iii) of the Act to require that the NF include in the transfer or discharge notice identical information about the State ombudsman and, as appropriate, the protection and advocacy systems for individuals with mental retardation/developmental disabilities and mental illness.

Comment: Two commenters responded that § 483.10(b)(8), which requires facilities to tell residents how to contact their physicians, as presented in the February 2 rule, implies that the facility chooses the physician responsible for the resident's care. They asserted that in fact, the reverse is usually the case. The resident or responsible party chooses the physician and should inform the facility as to whom the treating physician is and when a change occurs. They stated that only in rare instances should the facility have to secure a physician without prior consultation with the resident or responsible party.

Response: This provision was added to the list of resident rights because commenters on the proposed rule alleged that many residents have no knowledge who is their attending physician or how to contact him or her. While the resident has the right to choose a physician, and most residents may do so, the resident may not have exercised this right and may not know whom to contact. When a resident has selected an attending physician, it is appropriate for the NF to confirm that choice when complying with this requirement. When a resident has no attending physician, it is appropriate for the NF to obtain one and inform the resident.

Comment: Several commenters asked that we specify "primary" or "attending" physician in § 483.10(b)(8) because some residents have several different physicians. Other commenters noted that facilities often use clinics and that the name, address, and telephone number of the clinic should be sufficient.

Response: We believe "the physician responsible for his or her care" means the attending or primary physician or clinic, whichever is responsible for managing the resident's plan of care and excludes other physicians whom the resident may see from time to time.

Comment: Ten commenters responded to the requirement at § 483.10(b)(9) based on OBRA '87 that facilities provide information about Medicare and Medicaid. Several commenters objected to having to provide oral information to potential residents. They asked that this requirement be limited to referring individuals to the appropriate agency for explanation if the individual could not read or understand the written material presented. Another commenter asked us to define the parameters of a "potential" resident. Other commenters believed that the State or Federal government should prepare the written materials on how to apply for Medicaid and Medicare.

Response: Since OBRA '87 requires that the facility provide residents or individuals applying to reside in the facility with oral and written information, we cannot alter this requirement. Written materials issued by the State Medicaid agency and the Federal government relating to these benefits may be used. Also, we believe that facilities may fulfill their obligation to inform orally residents or applicants for admission about how to apply for Medicaid or Medicare by assisting them in contacting the local Social Security Office or the local unit of the State Medicaid agency. Nursing facilities cannot be expected to know and are not responsible for orally providing detailed information on the often complex Medicare or Medicaid eligibility rules. In accordance with the OBRA '87 provision, we have substituted the term "applicants for admission" for the less precise "potential residents."

Comment: Two commenters requested that the notice given under § 483.10(b)(9) should include information about how to appeal if Medicaid or Medicare benefits are denied.

Response: Since other rules specify that all denial notices contain information about appeal rights, we believe that requiring an NF to discuss how to file an appeal on a resident right is unnecessary. Furthermore, the OBRA '87 provision upon which this requirement is based does not include notice of appeal procedures.

Comment: One commenter asked if the phrase "how to receive refunds for previous payments covered by such benefits" in § 483.10(b)(9) is a reference to refunds which might be due based on publication of the list of items and services furnished by a nursing facility which are not chargeable to the personal funds of a resident.

Response: We expect to publish in a forthcoming proposed rule the list of items and services which cannot be charged to a resident's personal funds. We do not anticipate that these requirements, even when published as a final rule, would be applied retroactively. Rather, the reference relates to refunds due as a result of Medicaid payments when eligibility has been determined retroactively.

Comment: Over 50 commenters responded to the requirement concerning notification of changes in the

resident's health condition. Several commenters suggested this requirement be rewritten. As it is currently worded, they pointed out, it means that in a medical emergency or in the case of a competent individual the facility does not have to tell the resident what is happening to him or her. Nor, in these two situations, does the facility have to contact the resident's physician and the legal representative or family to notify them of the changes.

Response: The interpretation of the commenters is not what we intended. We are clarifying the wording of this provision to indicate that in all cases, whether or not there is a medical emergency, the facility must notify the resident; his or her physician; and any legally-appointed representative or an interested family member, if known. In the case of an incompetent individual, the legal representative would make any decisions that might have to be made, but we believe the resident should still be told what is happening to him or her even though he or she is not capable of fully understanding. In the case of a competent individual, the facility must still contact the resident's physician and notify an interested family member, if known.

Comment: A number of commenters raised questions about who must be notified. Some felt that we should not use the term "interested family member" because it has no legal status, because some families are very large and many members may be "interested", and because a competent resident should either be expected to notify the family himself or be afforded the choice of whether he or she wants to approve or deny notification of the family. Other commenters pointed out that the definition of a "legal representative" varies from State to State or even within a State, depending upon the instrument used. Another commenter asked why the facility should "consult" with the resident and only "notify" the physician, rather than the other way around.

Response: We agree that the facility should inform the resident of the changes that have occurred but consult with the physician about actions that are needed. As we indicated in § 483.10 (a)(3) and (a)(4) we defer entirely to any State requirements relating to designation of legal surrogates that may be in effect. By using the term "interested family member" we expect that a family that wishes to be informed would designate one member to receive calls. Even when a resident is mentally competent, we believe such a designated family member should be notified of significant changes in the resident's health status because the resident may not be able to notify them personally, especially in the case of sudden illness or accident.

Comment: Twelve commenters objected to granting the facility up to 24 hours in which to notify the resident's physician and the legal representative or family. As some noted, a resident could be dead or beyond recovery in that time and the family would be denied the opportunity of being with their loved one during the time of crisis.

Response: We agree and have amended the regulation to require that the physician and legal representative or family be notified immediately.

Comment: Fifteen commenters requested that we qualify "injury" to include only those which are "substantial" or "require physician intervention." Commenters also asked us to define a "significant" change in health status or treatment.

Response: We recognize that judgment must be used in determining whether a change in the resident's condition is significant enough to warrant notification, and accept the comment that only those injuries which have the potential for needing physician intervention must be reported to the physician. We have defined "significant change" to mean deterioration in health, mental, or psychosocial status in either life-threatening conditions (for example, heart attack, stroke) or clinical complications (for example, development of a stage II pressure sore, onset or recurrent periods of delirium). A need to alter treatment "significantly" means a need to stop a form of treatment because of adverse consequences (for example, an adverse drug reaction) or commence a new form of treatment to deal with a problem (for example, the use of any type of restraint, medical procedure, or therapy which has not been used on that patient before).

Comment: Seventeen commenters responded to the requirement concerning change in room or roommate assignment at § 483.10(b)(10)(ii)(A). Several asked what the purpose of notification of roommate change is. Some consumer advocates stated that the notice is meaningless if the resident does not have the right to request, approve, or refuse a change in room or roommate. One such commenter proposed that the residents subject to involuntary intra-facility transfer should have the same rights available to them under the transfer and discharge provisions in § 483.12. On the other hand, facility representatives indicated that they must have the right to make practical and reasonable roommate changes since they are ultimately held accountable for the welfare of all the facility's residents. Emergency room changes may need to be made to isolate a resident, or a change in pay status may require movement to a different bed. While they could understand the importance of notifying the family of a room change, some facility commenters felt that it was not practical to notify families when a roommate is changed. Some facility-based commenters also questioned why they should have to notify both the resident and a legal representative. A number of commenters also asked us to define "promptly."

Response: This requirement is based on sections 1819(c)(1)(v)(II) and 1919(c)(1)(v)(II) of the Act, which requires that the resident be given prior notification of both room and roommate changes. The statute does not give the resident more than the right to be informed that the change will take place. Therefore, we did not expand upon this right to accord residents veto powers over facility decisions. Changes in room or roommates is not subject to the same rights as inter-facility transfers or discharges. Far from being meaningless, the right to notification of room or roommate changes should reduce stress for residents. For example, a commenter on the proposed rule noted that too often a resident will come back from lunch to find that his or her room or roommate has been changed. Anyone would find such a discovery unsettling. Even many incompetent residents can be presumed to benefit from being informed in advance of the changes. We have therefore specified in the regulation that both the resident and the resident's representative or family be informed. The interpretive guidelines explain that "promptly" generally means the resident should be informed as soon as the facility determines that a change in room or roommate is to be made.

With respect to the issue of inter-facility but intra-physical plant transfers (**Note**: For a more detailed discussion of intra and inter-facility transfer, see discussion for the second response to comment under section 483.12 Admission, Transfer, and Discharge rights, Comments and Responses.) relating to payment status, we would note that such transfers are inappropriate in the context of the Medicaid program. When a resident occupies a bed in a distinct part of a NF which participates in Medicaid and not in Medicare, he or she may not be moved by the facility (or be required to be moved by the State) solely for the purpose of assuring Medicare eligibility for payment. Such inter-facility but

intra-physical plant movements are only appropriate when they take place at the request of the resident as might occur, for example, when a privately paying Medicare beneficiary believes that admission to a bed in a Medicare participating distinct part of the facility may result in Medicare payment. This point was made explicitly in sections 4008(h)(2)(G) and 4801(e)(8) of OBRA '90, which prohibit intra-facility transfers for purposes of qualifying patients for Medicare payment. A discussion of these two sections occurs later, where new § 483.10(o) is described and explained.

Comment: Two commenters believe nursing facilities should receive reimbursement for having to provide the banking services required at § 483.10(c)(2) or be allowed to charge residents for the services.

Response: Section 1902(a)(13)(A) of the Act provides for title XIX payment for meeting the requirements of section 1919(b) (other than paragraph (3)(F) thereof), (c), and (d). The provision requiring an accounting of resident funds is found at section 1919(c)(6). Therefore, the expense of providing these services should be included in the State's Medicaid payment rates which must be calculated pursuant to 42 CFR part 447.

Comment: Twenty-four commenters responded to the deposit of funds requirement in § 483.10(c)(3), which was taken directly from OBRA '87. Many of the commenters objected to the burden of having to keep full, complete, and separate accountings for 2 accounts (interest-bearing and non-interest-bearing) for each resident entrusting his or her funds to the facility. They claimed that facilities will be moving funds back and forth between the two accounts with no real gain for the resident. Many commenters also complained that the threshold of $50 is too low. They pointed out that banks are increasingly unwilling to offer interest-bearing accounts on such small sums or levy service charges that exceed the interest. Other commenters recommended as a solution to this problem that the facility be allowed to have one pooled trust account for all residents having a balance of $50 or more.

Response: This requirement is based on sections 1819(c)(6) and 1919(c)(6) of the Act. After further examination of the statute, we have determined that it does not prohibit placement of resident funds less than $50 in interest-bearing accounts. Instead, it gives facilities flexibility in managing resident funds less than $50. Thus, while a facility must place resident funds greater than $50 in an interest-bearing account, it may opt to place funds less than $50 in an interest-bearing, a non-interest-bearing account, or a petty cash fund. We have made this change in the regulations.

Also, the February 2 final rule contained a typographical error which led to some misunderstanding on the part of commenters. The preamble also erroneously stated that the facility must keep the "resident's" (as opposed to "residents' ") funds in separate accounts. We are modifying § 483.10(c)(3) to reflect the statutory language which permits both petty cash and the interest-bearing funds to be pooled, so long as residents' funds are not commingled with any of the facility's operating accounts and separate accounting is made of each resident's share of the assets and earnings (in the case of interest-bearing accounts). We understand that computer programs for performing these functions are available to NFs. If a pooled account is used, each resident must be individually identified and the interest prorated on a basis of actual earnings or end-of-quarter balance.

Comment: Eight commenters responded to the accounting and records requirement in § 483.10(c)(4). Six of them asked for quarterly statements rather than reporting upon request.

Response: Because the majority of commenters who addressed this requirement in both the proposed rule and final rule with comment overwhelmingly requested quarterly statements, we have amended § 483.10(c)(4) to require them.

Comment: Nine commenters, all representing facilities, asked that we limit the requirement to notify residents when the amount of money in their accounts reaches certain balances to funds for which the facility has responsibility.

Response: We agree that a facility would have no way of knowing what other resources an individual might have other than those deposited with the facility. The interpretive guidelines clarify that a facility is not responsible for knowing about assets not on deposit with the facility.

Comment: Seven commenters responded to § 483.10(c)(6), which requires a facility to convey promptly a resident's funds to his or her estate administrator upon death. Some asked us to define "promptly". Others asked that we establish a procedure for cases in which there is no individual available to administer the estate.

Response: We consider within 30 days to be generally acceptable as a definition for "promptly" and have made this substitution. We also have clarified that the final accounting must be conveyed to the "individual or probate jurisdiction" administering the estate in response to commenter's concerns.

Comment: Four commenters noted that the limitations on personal funds addressed in § 483.10(c)(8) are already illegal and that HCFA should issue regulations defining what services are covered by Medicaid and what services cannot be charged to a resident's personal funds.

Response: The statutory provisions in sections 1819(f)(7) and 1919(f)(7) relating to the requirement for regulations defining the items and services that may be charged to resident funds and the items and services included in nursing facility payments is being implemented in another rule. In the interim, States are required to assure that residents are not charged for routine personal hygiene items and services. Section 483.10(b)(7) currently contains the requirements relating to a facility's responsibility for informing the resident about the facility's charging practices.

Comment: Twenty-two commenters responded to the requirement of free choice of an attending physician. The vast majority of commenters argued in favor of having this resident right balanced by a facility right to grant or withdraw staff privileges to physicians. These commenters argued that the facility is required to ensure good care and must be able to deny privileges to physicians who do not deliver the level of care that meets the level of physician services required of the facility or who do not follow facility policies.

Response: We believe the right of the resident to choose a physician is not absolute. In the interpretative guidelines we explain that if a physician of the resident's choosing fails to fulfill a given Medicaid or Medicare requirement, the facility has the right, after informing the resident, to seek alternate physician participation to assure the provision of appropriate and adequate care and treatment.

Comment: One commenter pointed out that continuing care retirement centers (CCRCs) generally have a panel of physicians under contract and structure the medical and financial program around the physician panel.

Response: In the case of CCRCs, a resident has already exercised a certain degree of choice in selecting this type of living arrangement. If the resident is allowed to choose his or her physician from among panel members, the requirements for free choice is being met.

Comment: Two commenters asked that we expand the right to choose an attending physician to include the right

to choose other providers such as pharmacists.

Response: We have not amended the regulation to include a right of a resident to select other providers because we believe that the resident has already exercised freedom of choice in selecting the facility. The facility has the responsibility of maintaining appropriate methods of dispensing and administering drugs in the facility. With that responsibility goes the right to define certain methods and procedures with which the pharmacist must comply. These methods and procedures are essential to assuring that the patient is protected from medication errors. Therefore, the facility has the right to restrict the variety of drug labeling and packaging practices that can result from using multiple pharmacies in an effort to reduce or eliminate medication errors.

Comment: Two commenters expressed the opinion that the responsibility of informing the resident about care and treatment should belong to the physician, not the facility. One of these asked who has to bear ultimate responsibility when there is a disagreement among the resident, the physician, and the facility staff over implementation of the plan of care.

Response: As we indicated in the response to comments submitted on § 483.10(b)(3), we believe the facility shares with the physician responsibility for communicating with the resident about care and treatment. We have explained in the interpretive guidelines that the facility is expected to discuss options and alternatives with the resident or his or her legal representative; the resident selects and approves the specific plan of care before it is instituted. This requirement does not apply to application of emergency procedures in life-threatening situations unless advance directives are in effect. If the resident objects to any proposed changes in the plan of care, the facility should allow the resident to discuss his or her objections with the physician and note the final decision in the medical record.

Comment: Two commenters asked us to clarify who may participate in care planning on behalf of incapacitated residents or expressed the concern that the use of the phrase "adjudicated incompetent" was too strong and that the requirement should allow for the use of less restrictive mechanisms.

Response: The rest of the phrase in question reads ". . . or otherwise found to be incapacitated under the laws of the State . . ." We note that under § 483.10(a)(3) and (a)(4) we have deferred to State law in the matter of acceptable legal surrogates for both adjudicated and non-adjudicated incompetent persons, and believe that position is appropriate here also.

Comment: Two commenters asked that we clarify the regulation which states that the facility is not required to provide a private room in relationship to the resident's right to have privacy in accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups. The commenters believed that the qualifier only applied to resident accommodations and did not apply to rooms for meetings of residents and family groups, visits, written and telephone communications, personal care, and medical treatment.

Response: Sections 1819(c)(1)(A)(iii) and 1919(c)(1)(A)(iii) require privacy in accommodations, medical treatment, and meetings of family and resident groups. The provision at the end of sections 1819(c)(1)(A)(x) and 1919(c)(1)(A)(x) state that "clause (iii) shall not be construed as requiring the provisions of a private room" and we have so clarified the regulation. We believe this statement applies to accommodations and all the activities listed under sections 1819(c)(1)(A)(iii) and 1919(c)(1)(A)(iii). Thus, the ultimate rule the facility must follow is the practice of assuring an individual's privacy rights. How they accomplish that privacy is not mandated by the statute or these regulations. With the exception of the explicit requirement for privacy curtains in all initially certified facilities (see § 483.70(d)(1)(v)) the facility is free to innovate in order to provide privacy for its residents. This may but need not be through the provision of a private room.

Comment: One respondent asked that we eliminate the provision in § 483.10(e)(3) that restricts the rights of patients to refuse release of personal and clinical information to third party payors because persons in the community have the right to refuse to release records to such payors.

Response: We concur and have deleted this reference. A third-party payment insurance contract may be contingent upon the resident's consent to release information but the rules should not permit a facility to release the information without the resident's consent.

Comment: Five commenters responded to the grievance requirements in § 483.10(f). One believed that the right to voice grievances should not be restricted to those pertaining to treatment or care. The right to file any grievances (for example, those concerning mismanagement of finances or violation of rights) should also be protected.

Response: We agree and have amended the text of the regulations to avoid making the list we present exclusive so that the resident has the right to voice any grievances, including those about treatment and care.

Comment: Two other commenters asked that we substitute "address" for "resolve" on the grounds that the facility cannot guarantee that all grievances will be resolved to the resident's complete satisfaction since the facility is also responsible to other residents and must uphold their rights as well. A third commenter, however, supported the statement in § 483.10(f)(2) as worded.

Response: The regulation reguires the facility to assure the resident the right to "prompt efforts" to resolve grievances. This is OBRA '87 language at sections 1819(c)(1)(A)(vi) and 1919(c)(1)(A)(vi) of the Act and in no way requires the facility to resolve all grievances, cnly to make prompt effort to do so.

Comment: Eighteen commenters responded to the requirement that residents have the right to examine survey results and that facilities must post these results. The majority did not object to having the survey results accessible in their entirety, but they felt that "posting" these results, which are lengthy and cumbersome, would not contribute to ease in reading or a homelike atmosphere. They proposed, instead, that the facility be allowed to post a notice on a wall or bulletin board that the results are available for inspection and that the survey results be readily available (perhaps organized in a binder] at the same location as the notice. Under this arrangement, a resident or visitor would not have to ask to see the results. A minority of commenters believed, however, that the results of a survey could be misinterpreted. They wanted to have the results available "upon request."

Response: While the wording of this requirement in OBRA '87 would allow for examination of survey results "upon reasonable request," we retained the "posted" language, used in the proposed rule and in the February 2 final rule because of the favorable response of commenters. The majority of commenters on both the proposed rule and the February 2 final rule supported our view that individuals wishing to examine the results should not have to ask to see them. We accept their suggestion that the results be made available in a more readable form such as a binder and have revised the wording of § 483.10(g)(1) to state that the results must be "made available for

examination" in the facility in a place readily accessible to residents.

Comment: A few commenters requested that more information than the results of the most recent annual survey and any plan of correction in effect be made available. For example, they asked that past surveys, citations produced as a result of State complaint investigations, and notices of any adverse actions imposed by the survey agency also be required to be made available. They also asked that the separate statement of deficiencies be posted as well as the survey report form. One commenter believed that rather than posting the complete survey report form, a facility should be required to post only the statement of deficiencies if one exists.

Response: Sections 1819(c)(1)(A)(ix) and 1919(c)(1)(A)(ix) give the resident the right to examine the results of the most recent survey of the facility. We are interpreting the "results" of the most recent survey to include both the survey report form and any statement of deficiencies, however these deficiencies were generated (whether by a standard or extended survey or as a result of a complaint investigation). Since OBRA '87 addresses only the "most recent survey," we did not require facilities to make available surveys previous to the most recent survey.

Comment: The three commenters who responded to the requirement that residents be permitted to contact and receive information from a client advocate asked that we require posting of a complete list of the names of all available regulatory enforcement and client advocacy agencies and their addresses and telephone numbers. Many of these organizations have 800 numbers.

Response: We note that commenters on the October 16, 1987 proposed rule objected to posting this list because it detracts from a homelike atmosphere, However, we were persuaded by the recent commenters who argued that on balance the benefits of having this information readily available (posted) would be greater since timid or frightened residents may be reluctant to request it from facility staff. Thus, we have included a provision for posting the names, addresses, and telephone numbers of regulatory and advocacy agencies.

Comment: Nine commenters responded to the work requirement in § 483.10(h). Three of them supported making all work arrangements, whether paid or voluntary, reviewable in the plan of care. Some commenters, however, objected to any references to work for pay. Others expressed fears that facilities would be required to offer work for pay to any resident who wanted it or that all voluntary work performed by residents would cease due to the inability of facilities to pay a "prevailing wage." Another commenter asked what a "prevailing wage" means (whether prevailing in the facility or in the community) and whether a facility would have to pay taxes for FICA or workman's compensation if it offered work for pay. This commenter also suggested that if a community prevailing rate is required, the work performed should be of a quantity and quality comparable to that performed in the community before similar pay would have to be offered.

Response: We do not believe the work requirement as presented in the February 2 rule requires a facility to offer paid work. By making all work reviewable under the plan of care, we believe we have created a bargaining table at which the voluntary or paid nature of therapeutic work can be discussed and terms can be negotiated if pay is to be offered.

Comment: Nineteen commenters responded to the mail requirement. Nearly all of them either supported or objected to the February 2 preamble discussion which clarified that the requirement for the sending or receiving of mail "promptly" means that delivery to the resident of incoming mail must be within 24 hours of arrival within the facility and delivery of outgoing mail to the post office must be within 24 hours. The majority wanted some allowance made for weekends and holidays.

Response: The interpretive guidelines specify that we continue to support the concept of delivery to the resident within 24 hours of delivery by the post office, but we will relax the 24 hour guideline for outgoing mail on weekends and holidays when there is no regularly scheduled postal delivery and pick-up service.

Comment: Several commenters asked that we define "at any reasonable hour," "reasonable access," and "reasonable restrictions" as used in § 483.10(k) redesignated in these rules as § 483.10(j), Access and visitation rights. (Section 483.10(j), which deals with access to facilities and visitations rights contains provisions that expire October 1, 1990, hence it is deleted and § 438.10(k) through (o) are redesignated as § 483.10(j) through (n), respectively.

Response: In the interpretive guidelines we indicate that "at any reasonable hour," means that the facility must allow access to the resident at least 8 hours per day, arranged in such a way that daytime, evening, and weekend visitation times are available to meet the schedules of most potential visitors who are subject to visiting hours. The only individuals who are not subject to visiting hour limitations are State and Federal Health and Human Services (HHS) representatives and representatives of the State ombudsman system and the protection and advocacy agencies for mentally ill and mentally retarded individuals.

The law delineates somewhat differing access rights for 3 groups. First, immediate family or other relatives will no longer be subject to visiting hour limitations or other restrictions. Second, non-family visitors must also be granted immediate access to the resident; however, the facility may place "reasonable restrictions" upon this right. "Immediate access subject to reasonable restrictions" means that the facility may not limit the timing of the visit by a non-relative but may establish other reasonable limitations to facilitate care giving for the resident or to protect the privacy of other residents. For example, the facility may require that non-family visits not take place in a resident's room if a roommate is asleep or receiving care. Third, the facility must provide "reasonable access" to any resident by any entity or individual that provides health, social, legal, or other services to the resident. "Reasonable access" by service providers means that the facility may establish rules that establish permissible times and circumstances of the visit such as location or duration of the visit.

Comment: Four commenters requested that we amend the requirement at redesignated § 483.10(j) to allow residents the right to grant or deny access by State or Federal surveyors on the grounds that a resident should have the right to deny access to anyone of his or her choosing.

Response: The statutory language of sections 1819(c)(3)(A) and 1919(c)(3)(A) does not allow residents the right to deny access by State or Federal HHS representatives, by representatives of the State ombudsman and protection and advocacy systems for the mentally ill or mentally retarded, or by the resident's individual physician. All other parts of sections 1819(c)(3) and 1919(c)(3), which grant access to variou other categories of visitors (that is subparagraphs B through E), contain clauses such as "subject to the resident's right to deny or withdraw consent at any time" or "with the permission of the resident". Subparagraph A contains no such qualifier. Because of the presence of such limitations in all other subparagraphs, we cannot interpret the

absence of such a qualifier in subparagraph A as a mere omission. We therefore hold that a resident cannot refuse to see these specified government officials or his or her own physician.

Comment: Seventeen facility representatives objected to granting immediate access to the immediate family and other relatives on the ground that 24-hour-a-day open access conflicts with the facility's caregiving responsibilities. It could interfere with meals, sleep, or treatment. It could pose security risks during the late evening or night. Moreover, it could deprive roommates of privacy.

Response: The statute provides no basis for adding "reasonable restrictions" to this right to access by family and relatives. Sections 1819(c)(3)(B) and 1919(c)(3)(B), (§ 483.10(j)(1)(vii) of the regulation), which grant immediate access to immediate family and other relatives contain no such qualifier. By contrast, the next subparagraph C (§ 483.10(j)(1)(viii) of the regulation) which grants access to others visiting the resident contain the clause "subject to reasonable restrictions."

Comment: Three commenters objected to the limitations placed on the examination of residents' clinical records by representatives of the State ombudsman. One ombudsman commenter objected to having to obtain a resident's permission. Another wanted all the resident's records, not just clinical ones, open for examination by ombudsmen with the permission of the resident. The third commenter thought that written consent of the resident or his or her representative should be required.

Response: The statute at sections 1819(c)(3)(E) and 1919(c)(3)(E) clearly requires permission of the resident and restricts access to the resident's records to clinical records. Therefore, we have not expanded upon this requirement.

Comment: Thirteen commenters responded to the requirement on telephones. Several commenters asked that the text of the regulation specifically require wheelchair accessibility and availability of adaptive equipment. One commenter suggested that we change "regular" to "reasonable" access to the private use of a telephone on the grounds that regular could mean once a week. Another commenter applauded the requirement, stressing the importance of telephone calls when family members live at considerable distance: Frequent calls are the next best thing to visits. A number of commenters also questioned the degree of privacy that must be accorded. Some pointed out that pay phones and even private phones in shared rooms are not totally private. Others felt that the facility should not be required to provide a specific phone for patient access or that we should specify that the use of a phone is a resident expense.

Response: We do not believe that the regulation needs to be expanded to address the comments relating to telephones. The right to privacy is a resident right clearly spelled out in § 483.10(e)(1). Section 504 of the Rehabilitation Act of 1973 assures that handicapped persons also have this right. We have, however, clarified the language in section 483.10(k) to make it clear the resident must have reasonable access to a telephone where calls can be made without being overheard. We have made no further changes in the rule.

Comment: Five commenters responded to the personal property requirement of redesignated § 483.10(1). One requested that facilities be required to replace lost prosthetic items such as glasses and hearing aids that are essential to independent functioning. Another commenter urged that we require facilities to keep an inventory of a resident's possessions and to institute search and investigation procedures. The remaining commenters asked that either the facility administrator or the resident have more control over what furnishings were acceptable.

Response: We believe the OBRA '87 requirement at sections 1819(g)(1)(C) and 1919(g)(1)(C) of the Act concerning reporting of misappropriation of property should help to deal with cases of theft or loss of property. While we do not have the authority to require facilities to maintain inventories of all resident possessions, we recommend such a practice. In response to those commenters who believe either the facility administration or the resident ought to have more power to decide what furnishings are acceptable, we believe that the wording presented in the February 2 rule strikes a workable balance between resident and facility rights. On grounds of space and health or safety concerns, the facility may legitimately deny a request. On the other hand, residents are entitled to have some familiar possessions and furnishings to make their rooms homelike.

Comment: We received ten comments on the requirement that married couples in the same facility be allowed to share a room. Five of them urged that we reinstate an "unless medically contraindicated" provision to deal with spousal abuse while another supported our deletion of such a limitation.

Response: As we explained in the preamble to the February 2 rule, the overwhelming response to the proposed rule favored the deletion of medical contraindications to all rights. We continue to believe that our response to this issue is appropriate. In the February 2 rule we added the qualifier that both spouses must consent to the room sharing and that, in verifiable cases of spousal abuse, facilities should use their social work staff to resolve difficulties or encourage the abused spouse to withdraw consent.

Comment: The few remaining commenters opposed this requirement on the ground that it places a burden on case mix reimbursement systems. One commenter proposed that reimbursement be made at the higher rate.

Response: As we stated in the preamble to the February 2 rule, we believe that the incidence of cases in which both spouses are in the same facility at very different levels of care is low enough that facilities will not incur inordinate financial losses.

Comment: States, facilities and consumer advocates have also asked how we view the priority of rights in situations where a resident's spouse wants to share a room in the facility, but the resident's current roommate does not want to be relocated to accommodate the admission of the spouse.

Response: The regulations at redesignated § 483.10(n), effective October 1, 1990, state that the resident has the right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement. We do not believe that this provision gives a resident the right to compel another resident to relocate to accommodate a spouse. It means that when a room is available for a couple to share, the facility must permit them to share it if they choose. However, it does not compel a facility to relocate anyone to accommodate the wishes of the married couple.

Comment: Approximately 30 commenters complained about the provision at redesignated § 483.10(n) of the final rule which gives residents the right to self-administer drugs unless an interdisciplinary team has decided that this practice is unsafe.

The commenters maintain that about 95 percent of the residents are not physically, mentally, or visually capable of this task, and if the interdisciplinary team has to document why 95 percent of the residents cannot self-administer drugs, a very large paperwork burden

will exist. Furthermore, commenters pointed out that those residents who are capable of self-administration of drugs represent a potential danger to other residents if they do not maintain proper security of their drugs. Wandering residents are highly likely to find these supplies and help themselves.

Response: The right to self-administer drugs was promoted as a way to help residents maintain as much self-control and self-determination as possible. This is particularly important for residents on a discharge plan who are preparing to become independent in their homes again. As commenters have pointed out, however, this right does not weigh favorably against the potential hazard it may cause to other residents and the paperwork burden it can create for facilities. Thus, we have changed the requirement so that a resident has the right to self-administer a drug only if the interdisciplinary team determines that it is safe.

Summary of Changes to § 483.10

In response to comments, in addition to minor technical or editorial changes, we are making the following changes:

- We are revising all the sub-headings of the regulations to simply state the subject matters that follows. For example, §§ 483.10(f) and 483.10(j), formerly designated as Level B requirements, will now read "Grievances" and "Access and visitation rights", respectively. Similarly, those 2 sub-headings are grouped under the heading "Resident Rights", formerly designated as a Level A requirement. Headings will be italicized. The use of italics is intended only to aid identification of categories or groupings of rights, not to indicate a hierarchy of importance.
- In § 483.10(a)(4) we are clarifying that we defer to the State in dealing with individuals determined incapacitated or incompetent through either adjudicative or non-adjudicative means.
- In § 483.10(a)(4) we are adding a provision which recognizes State mechanisms to designate legal surrogates through non-judicial means.
- In § 483.10(b)(2) we are granting residents access to records within 24 hours including clinical records. Facilities are allowed two working days to provide photocopies at the resident's expense.
- In § 483.10(b)(7) we include a requirement that the statement of rights contain detailed information about how to contact relevant advocacy agencies.
- In § 483.10(b)(9) we clarified that the requirement applies to applicants for admission to a facility.
- In § 483.10(b)(10) we clarified the requirement concerning notification of changes in the resident's health condition.
- In § 483.10(c)(4) we now provide that residents be informed of the status of any funds held in account quarterly.
- In § 483.10(c)(6) we require a facility to convey a resident's funds to the estate administrator within 30 days after the resident's death.
- In § 483.10(c)(7) we are revising this provision to reflect the exact wording of sections 1819(c)(6)(C) and 1919(c)(6)(C) of the Act, thus eliminating "or provide self-insurance." We are replacing that language with "provide assurance satisfactory to the Secretary." Under most circumstances we expect NFs will obtain a surety bond since these bonds are inexpensive and readily available and the total amount they will need to cover is relatively small. In the interpretive guidelines we will spell out circumstances under which we would accept self-insurance but the facility would have to meet strict criteria for fiscal solvency.
- In § 483.10(e)(3) we remove the restriction on residents to deny access of third party payors to personal and clinical information.
- Section 483.10(j), Level B requirement: Access to facility, is effective only until October 1, 1990. We would eliminate this paragraph and redesignate all subsequent paragraphs.
- In § 483.10(n) (redesignated from § 483.10(o)) we have changed the requirement so that a resident has the right to self-administer a drug only if the interdisciplinary team determines that it is safe.
- In § 483.10(o), Refusal of certain transfers, we are adding a new residents' right provision to reflect changes made by sections 4008(h)(2)(G) and 4081(e)(8) of OBRA '90. Specifically these provisions allow a resident to refuse transfer from a room in one distinct part of a facility to a room in another distinct part of the facility for purposes of obtaining Medicare eligibility or without medical justification.

We are also amending § 483.10(b)(7) to reflect a change made by section 303(a)(2) of the Medicare Catastrophic Coverage Act (MCCA) of 1988 which was overlooked in the February 2 rule. Section 303(a) of MCCA is generally referred to as the spousal impoverishment provision. The statute applies to institutionalized persons who have spouses living in the community. The provisions establish new income and resource eligibility methods and provide for more generous deductions from income of institutionalized spouses to meet the need of their community spouses and other family members when calculating how much institutionalized spouses contribute to the cost of their care.

Section 303(a) of MCCA, amended section 1919(c)(1)(B)(i) by adding an additional requirement that nursing facilities inform, orally and in writing, each resident at the time of admission of the requirements and procedures for establishing Medicaid eligibility, including the right (in the case of married couples where only one spouse is institutionalized) to request and have the appropriate agency within the State assess couples' resources. Resource assessments requested under this provision are assessments described in section 1924(c)(1)(B) of the Act and may be requested by either member of a couple or a representative acting on behalf of either spouse. Such assessments are evaluations of resources held by couples as of the beginning of continuous periods of institutionalization to determine the type and value of resources which would be used to determine Medicaid eligibility if the institutionalized member of a couple applied for Medicaid. Countable resources held by couples as of the beginning of the most recent period of institutionalization are used in part of the Medicaid eligibility determination process, regardless of when a Medicaid application is filed.

Thus, such arrangements will be useful to couples in financial planning and should produce a more accurate accounting of each spouse's resources should a Medicaid application be filed some time in the future. States are permitted to charge reasonable fees for assessments requested by couples who have not applied for Medicaid. No charge is permitted when a computation of a couple's resources is made in conjunction with a Medicaid application. Therefore, residents must be made aware of any fees associated with such assessments. At the completion of an assessment, each spouse will be provided a copy of the assessment and the documentation used to make it. Such persons are also provided notices advising couples that they do not have the right to appeal the assessment findings at the time the assessments are made but have the opportunity to appeal findings if and when the institutionalized spouse applies for Medicaid.

Section 483.12 Admission, Transfer, and Discharge Rights

Summary of Provisions

In the final rule we created a new requirement called Admission, transfer and discharge rights, § 483.12, based on wording from OBRA '87 provisions.

Paragraph (a), Transfer and discharge, defines transfer and discharge of a resident. The paragraph also specifies the requirements and documentation needed for transfer or discharge of a resident and specifies that a facility must notify the resident and a family member or legal representative of a transfer or discharge.

New paragraph (b), Notice of bed-hold policy and readmission, largely incorporates OBRA '87 provisions in new section 1919(c)(2)(D) of the Act. This paragraph requires that facilities provide written information to the resident and a family member or legal representative that specifies the duration of the bed-hold policy, if any, under the State plan, and the facility's policies on bed hold periods before a resident is transferred to a hospital or for therapeutic leave, and at the time of transfer.

Paragraph (c), Equal access to quality care, implements the OBRA '87 provision in new section 1919(c)(4) of the Act, which provides that a facility must establish and maintain identical policies and practices regarding transfer, discharge, and the provision of services under the State plan for all individuals regardless of source of payment.

Paragraph (d), Admissions policy, incorporates OBRA '87 provisions in section 1919(c)(5) of the Act, which prohibit facilities from—

- Requiring a third party guarantee of payment as a condition of admission, expedited admission, or continued stay in the facility; and
- Charging, soliciting, accepting or receiving, in addition to any amount required to be paid under the State plan, any gift, money, donation or other consideration as a condition of admission, expedited admission or continued stay in the facility.

A facility must not—

- Require residents or potential residents to waive their rights to Medicare or Medicaid, and
- Require oral or written assurance that residents or potential residents are not eligible, or will not apply for, Medicare or Medicaid benefits. These provisions are intended to prevent discrimination against individuals entitled to Medicare or Medicaid benefits.

Comment and Responses

Comment: A commenter wanted to know what would prevent facilities from "dumping" residents whom they viewed as undesirable and requested the regulation assure that facilities do not justify this type of transfer or discharge by not providing a service normally covered by the statutory definitions of nursing facility or skilled nursing facility services. Another commenter specifically addressed the situation of residents with dementia, who may be viewed as a threat to the safety of other residents, and opposed their discharge where the facility fails to provide appropriate care.

Response: The facility must not transfer or discharge a resident unless it is necessary for the resident's welfare and the resident's needs cannot be met in the facility (§ 483.12(a)(1)(i)); the transfer or discharge is appropriate because the resident's health has improved sufficiently so that the resident no longer needs the services provided by the facility (§ 483.12(a)(1)(ii)); the safety or health of individuals in the facility is endangered (§ 483.12(a)(1) (iii) and (iv)); or the resident has failed, after reasonable notice, to pay his/her bill (§ 483.12(a)(1)(v)).

The facility must provide services according to the provisions of sections 1819(b)(4)(A) (i) through (vi) and 1919(b)(4)(A) (i) through (vi) of the Act to the extent needed to fulfill all plans of care; nursing and related services and specialized rehabilitative services to allow or maintain the highest practicable physical, mental, and psychosocial well-being of each resident; pharmaceutical services; dietary services; an ongoing program of activities; and routine dental services. Thus, a facility would be out of compliance if it refused to provide a statutorily defined service in order to eliminate certain residents under one of the transfer reasons stated above.

Comment: Several commenters urged that the applicability of the OBRA '87 transfer and discharge provisions be clearly explained. They specifically wanted to clarify that these provisions apply to inter not intra facility transfer and discharge.

Response: OBRA '87 clearly intends that the transfer and discharge provisions apply to residents who are transferred or discharged "from the facility". There are two statutory references that support this contention. One is at section 1919(c)(2)(A) of the Act which states that "A nursing facility must permit each resident to remain in the facility and must not transfer and discharge the resident *from the facility* (emphasis added) unless * * *." There is an identical Medicare provision at section 1819(c)(2)(A) of the Act. Similar language at sections 1819(c)(2)(C) and 1919(c)(2)(C) makes reference to transfer *from the facility*. Thus, the transfer and discharge provisions must refer to movement of the resident from one facility to another facility and not within a facility.

Another provision of OBRA '87 supports this view in another way. Sections 1819(c)(1)(A)(v)(II) and 1919(c)(1)(A)(v)(II) of the Act give the resident the right "to receive notice before room or roommate of the resident in the facility is changed." If the law had intended for the transfer and discharge provisions to apply to intra facility transfer, there would have been no reason for this provision. Further, sections 1819(a) and 1919(a) define a participating facility in terms of being * * * "an institution (or a distinct part of an institution)." Thus, if a resident is transferred from a nursing facility unit (i.e., distinct part) to a skilled unit (i.e., distinct part) of the same physical plant, they are being transferred outside of one facility (in this case, the intermediate care unit) and into another, and the transfer and discharge provisions of OBRA '87 would apply.

We have clarified this issue by adding a definition of transfer and discharge to § 483.12(a) at paragraph (1). This definition states that "transfer and discharge" includes the movement of a resident to a bed outside of the certified facility whether that bed is within the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility. As a result of this addition, all subsequent paragraphs are redesignated.

We have also added a new residents' right at § 483.10(o) to reflect the provisions of sections 4008(h)(2)(G) and 4801(e)(8) of OBRA '90. These two sections of the law made explicit an existing right of patients to avoid transfers from "distinct part" SNFs to "distinct part" NFs or vice versa for purpose of manipulating payments under Medicare or Medicaid.

Briefly, both Medicare and Medicaid permit a SNF or NF to be a "distinct part" of an institution, and institutions often choose to designate one distinct part for Medicare, or a distinct part for Medicaid, or both. Since Medicare payment can only be made when the beneficiary is in a SNF (or distinct part of an institution that is participating as a SNF) and Medicaid payment can only be made to a NF (or a distinct part of an

institution that is participating as a NF) States and institution operators often have the incentive to relocate residents from one distinct part to another, for example:

- A facility with a small Medicare distinct part may wish to move residents whose Medicare coverage is exhausted to distinct part that does not participate in Medicare so that a new Medicare patient can be placed in the vacated bed; or
- A State may wish a dually entitled beneficiary (i.e , a beneficiary who is eligible for both Medicare and Medicaid payments) to be transferred to a distinct part of a facility that participates in the Medicare program so that payment would not be made under the State's Medicaid program. (This program occurred frequently before the repeal of MCCA '88, when there was no Medicare requirement for a 3 day hospital stay for SNF entitlement and the benefit was calculated on an annual basis. It was alleged that residents were transferred from one distinct part (Medicaid) to another (Medicare) to shift liability from one program to another.)

Both types of transfers were inappropriate under existing rules; however, there were reports of inappropriate transfers which led to the inclusion of this explicit right in OBRA '90.

The language in the new right includes a statement that a refusal to consent to a transfer does not affect Medicaid eligibility or entitlement. This language means only that a State may not refuse to make Medicaid payment because a resident declines to be admitted to a distinct part in which the Medicare program could make payment. It does not create new Medicaid entitlement or expand entitlement to individuals who are in facilities (or distinct parts of facilities) that do not participate in the Medicaid program as NFs.

Comment: Seven commenters objected to the provision at § 483.12(a)(2)(v), which prohibits facilities from transferring or discharging a resident for 30 days in cases where the resident has not paid his or her bill or has not had his or her bill paid by Medicare or Medicaid. They wanted to add a provision that would allow them to transfer or discharge a resident without 30 days notice when Medicare, Medicaid, or other third party payor abruptly terminated payment for the resident. Without this provision, they claim they would have to provide up to 30 days of free care when payment is denied without notice by Medicare, Medicaid, or third party payor.

Response: The provision at § 483.12(a)(5) requiring a 30 day notice before transferring or discharging a resident because of nonpayment of services is a statutory requirement found at sections 1819(c)(2)(A)(v) and 1919(c)(2)(A)(v) of the Act. Congress specifically intended a 30 day notice because at sections 1819(c)(2)(B)(ii) and 1919(c)(2)(B)(ii) it exempted a 30 day notice for a number of reasons (e.g., the transfer or discharge is necessary for the health, safety, or welfare of the resident or the resident has not lived in the facility for 30 days) but not for nonpayment of services. We interpret this exemption as leaving the Department without discretion to consider the commenter's suggestion.

Comment: Two commenters addressed the requirement at § 483.12(a)(3)(i) (redesignated to § 483.12(a)(4)(i)) which provides that the facility notify the resident and, if known, a family member or legal representative of the transfer or discharge and the reasons for the move. One suggested that we include the word "written" to conform to the requirement in § 483.12(a)(5) (written notice). The other commenter suggested that we also modify this provision by adding to the end of the statement "in a language and manner that the resident understands."

Response: We agree, for clarification purposes, to modify this provision to include the suggested revisions to read as follows: "Notify the resident, and, if known, a family member or legal representative of the resident of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand."

Comment: A commenter asked whether a facility must provide notice of transfer or discharge to residents who have resided less than 30 days in the facility, and another noted that this seems to be a discriminatory practice against new residents. The provisions of redesignated § 483.12(a)(2) (i) through (vi) describe the circumstances in which a resident may be given 30 days notice. These dates do not apply when the resident has lived in the facility less than 30 days (§ 483.12(a)(4)(ii)(E) redesignated as § 483.12(a)(5)(ii)(E)).

Response: The facility has no obligation to notify residents who have lived in the facility less than 30 days. The regulation at redesignated § 483.12(a)(5)(ii)(E) implements the statutory provision at sections 1819(c)(2)(B)(ii)(IV) and 1919(c)(2)(B)(ii)(IV) of the Act, which excludes residents with less than 30 days residency from the requirement of providing advance transfer or discharge notice.

Comment: A commenter noted that the transfer and discharge requirements are overly cumbersome, particularly because facilities are already overburdened with paperwork.

Response: We are not able to eliminate or make major modifications to these requirements since they are specifically required by OBRA '87 provisions. However, we welcome any suggestions for ways that the law could be amended to make these requirements less cumbersome.

Comment: A commenter recommended inclusion of a requirement that any determination of need to transfer, except in an emergency, should be made in consultation with a multidisciplinary assessment and care planning team.

Response: We require at § 483.12(a)(2)(i) (redesignated from § 483.12(a)(1)(i)) that when a facility transfers or discharges a resident under any circumstances as described under § 438.12(a)(2) (i) through (v), documentation must be made by the resident's attending physician (§ 483.12(a)(3)(i)) or, as required at § 483.12(a)(3)(ii), a physician. This does not prevent an interdisciplinary team from making a recommendation for discharge or transfer but makes the physician the final arbiter of the appropriateness of the decision.

Comment: A commenter expressed the belief that a resident should be allowed to return to the facility under bed-hold provisions in cases where an acute episode of mental illness (MI) occurs.

Response: The requirement at § 483.12(b)(3) already provides that the facility must establish and follow a written policy under which a resident whose hospitalization or therapeutic leave exceeds the bed-hold period under the State plan is admitted to the facility immediately upon the first availability of a bed in a semi-private room if the resident requires the services provided by the facility and is eligible for Medicaid. If this situation follows an acute episode of MI, then the bed-hold provisions apply. Thus, we see no need for additional regulations.

Comment: One commenter suggested that a resident's notice of transfer or discharge as required under redesignated § 483.12 (a)(3) should be given immediately in those circumstances where the 30-day notice is not possible. It was also recommended that upon a resident's successful appeal after transfer, a resident should be returned immediately to the facility or, in those cases where the appeal is made before transfer, any action should be stayed pending determination of the appeal.

Response: We have outlined those circumstances under which a 30-day notice would not have to be given for a transfer or discharge under redesignated § 483.12 (a)(5)(ii) (A) through (E). The notice may be made as soon as practicable before transfer or discharge when the safety of the individuals in the facility is endangered, the resident's health improves to allow for an immediate discharge, or the resident has not resided in the facility for 30 days.

With regard to a resident's appeal rights for transfers and discharge, we are currently establishing in a separate regulation requirements the States must meet to provide a fair mechanism for hearing appeals on transfer or discharges from skilled nursing facilities. Comments about these appeals that we received in connection with this regulation have been considered in the process of drafting the NPRM on appeals which will also be subject to public comment when it is published.

Comment: Ten commenters responded to the notice of bed-hold requirements in § 483.12(b). Most commenters questioned how or why a facility could, or should have to, give notice both before and at the time of transfer. Particularly in the case of an emergency transfer, many commenters believed the second notice was inappropriate. They asked us to clarify in the interpretive guidelines that the first notice could be provided well in advance of any transfer (e.g., at the time of admission) and that the second notice could be given after an emergency transfer in order not to delay the transfer. Another commenter could see no reason for notifying both the resident and the legal representative or family member if the resident is competent.

Response: This requirement is taken directly from OBRA '87, which requires that two notices be issued, both before and at the time of transfer. The statute also requires that the written notice be given to both the resident and the family or legal representative. We believe the first notice could be given well in advance of any transfer. However, reissuance of the first notice would be required if the bed-hold policy under the State plan or the facility's policy were to change. We intend to explain in the interpretive guidelines that, in cases of emergency transfer, notice "at the time of transfer" means that the family or legal representative could be provided with the written notification within 24 hours of the transfer. We accept the requirement is met if the resident's copy of the notice is sent with other papers accompanying the resident to the hospital.

Comment: Five commenters responded to the readmission requirement in paragraph (b)(3) with a variety of comments. One commenter pointed out that a transfer to a hospital or therapeutic leave frequently indicates a significant change in the resident's health status. Readmission to the facility must be contingent upon the facility's continued ability to provide appropriate care. Another commenter objected to having to readmit a resident who has an outstanding balance for Medicaid cost-sharing when he or she goes out on bed-hold. This commenter felt that forced readmission constituted a major infringement on the facility's property rights. Another facility-based commenter asked what the facility should do if the next available bed in a semiprivate room is in a room already occupied by a person of the opposite sex. Still another commenter believed that this provision, which applies only to Medicaid recipients, discriminates against private pay residents.

Response: This requirement is contained in section 1919(c)(2)(D)(iii) of the Act. If, after a stay in a hospital, a resident requires nursing facility services, the facility must readmit the resident. The law makes no reference to or exception for unsatisfied balances. Therefore, the facility must readmit such an individual. We believe the "next available bed in a semiprivate room" can be construed to mean a bed in a room shared by another resident of the same sex. In response to the final objection that this provision is discriminatory, we note that the statute requires that the notice of bed-hold and readmission policies must be given to all residents who transfer or go out on therapeutic leave. The statute requires readmission only of Medicaid recipients after the bed-hold period expires.

Comment: A few commenters asked whether the prohibition against third party guarantees in § 483.12(d)(2) applies to private pay admissions as well as to Medicare beneficiaries and Medicaid recipients.

Response: We note that the statute makes a distinction when referring to specific individuals or residents (e.g., section 1919(c)(5)(A)(iii), "in the case of an *individual* who is entitled to medical assistance for nursing facility services * * *", and section 1919(b)(1)(A), "A nursing facility must care for its *residents* in such a manner * * *"). Thus, in this instance, since no similar distinction is made, the prohibition against third party guarantees applies to all residents and prospective residents regardless of the payment source in both Medicaid NFs and Medicare SNFs.

Comment: Several commenters asked that we clarify that the prohibition against third party guarantees does not include gathering information about eligibility for payment by Medicare, Medicaid, or private insurance. If the facility cannot assure that once admitted the resident will indeed pay his or her bills at least through insurance, the facility is put at risk to recover payment for services rendered, particularly if the resident becomes incompetent. These commenters believed that unless facilities are allowed to establish information about third party payment sources, they will be reluctant to accept individuals who are not Medicaid eligible unless they have sufficient assets to guarantee payment for a long stay.

Response: The wording of this provision is taken directly from OBRA '87. We agree that the term "third party guarantee" needs definition. The legislative history reveals that Congress was concerned with prohibiting SNFs and NFs from requiring a person, such as a relative, to accept responsibility for the charges incurred by a resident, unless that person is authorized by law to disburse the income or assets of the resident. In such allowable cases, the person providing the guarantee assumes no personal liability. He or she only promises to make payment out of the resident's financial holdings. We do not believe that Congress intended to limit in any other way the facility's right to obtain information necessary for collecting payment from third party payors (not guarantors). Therefore, we will explain in the interpretive guidelines that a "third party guarantee" is not the same thing as a "third party payor" and that this provision does not preclude the facility from obtaining information about Medicare or Medicaid eligibility or the availability of private insurance. The provision does, however, prohibit the facility from requiring a person other than the resident to assume personal responsibility for any cost of the resident's care. We would also note that the prohibition against requiring a third party guarantee of payment would not prohibit a third party voluntarily from making payment on behalf of a resident.

Comment: Several other commenters were concerned that this provision would prevent continuing care retirement communities (CCRCs) from requiring members to take out long term care insurance to cover costs of nursing facility care they might need. These commenters pointed out that CCRCs

offer life care services, ranging from independent living accommodations to NF care. Residents sign contracts for this extensive package of housing and health care services and pay an entrance fee and monthly fees. In return, the community assumes the financial risk of providing some or all of the services the resident needs for the rest of his or her life. At a minimum, the contract guarantees access to NF services. At a maximum, it covers the full cost of NF services. These commenters believed that this requirement, as written, would prohibit CCRCs from including participation in a group long-term care insurance program for those who can afford to do so, as a contract provision. They therefore urged that the facility and community be considered separately.

Response: As we established above, insurance is a third party payor, not a third party guarantor. In addition, the CCRC member usually makes this commitment by his or herself, rather than having someone else make it for him or her.

Comment: Seven commenters objected to § 483.12(d)(3) which regulates nursing facility solicitation and acceptance of gifts, because they believed that the requirement severely restricts fund raising for nonprofit facilities. They also pointed out that residents sometimes donate large items such as organs or pianos to be used by the residents during their stays and left to the facility after death or discharge. They believe this requirement would prohibit a facility from accepting any unconditional gift from a resident or potential resident. Also, these commenters pointed out that in soliciting funds, non-profit facilities appeal to their entire religious or community organization. They should not be expected to purge their mailing lists of any relatives of current residents or any potential residents. In a broad sense, nearly everyone in their organizations is a "potential" resident.

Response: This requirement is derived almost verbatim from section 1919(c)(5)(A)(iii) and (8)(iv) of the Act, which apply this prohibition only to Medicaid eligible recipients in nursing facilities certified under Medicaid. Section 1819(c)(5)(A) contains no comparable requirement for skilled nursing facilities under Medicare. Therefore, we have revised the text of the regulation to reflect this limitation. We have also restructured this section to make the intent of the OBRA admissions provisions more readily understandable.

In clarifying that revised § 483.12(d)(3) applies only to Medicaid recipients in Medicaid NFs, we note that, by contrast, the proceeding two requirements in sections 1819(c)(5)(A) and 1919(c)(5)(A) which prohibit facilities from requiring individuals to waive their rights to Medicare or Medicaid benefits (revised § 483.12(d)(1)) or from requiring a third party guarantee of payment (revised § 483.12(d)(2)) apply to all residents, not just Medicaid recipients, in both Medicare SNFs and Medicaid NFs.

We believe that revised § 483.12(d)(3) only prohibits the nursing facility from charging/soliciting or accepting/receiving gifts from or on behalf of a Medicaid recipient when these gifts are intended to purchase preferential treatment for a Medicaid recipient, presumably over other Medicaid recipients. Gifts given by or on behalf of Medicaid recipients for purposes other than to gain admission, expedited admission or continued stay are not prohibited. Nor are any donations from or on behalf of non-Medicaid eligible individuals, given for whatever reason, prohibited.

Thus, non-profit nursing facilities may continue to appeal to their traditional sources of support with few limitations (i.e., only with respect to Medicaid-eligible residents or potential residents and only with respect to donations given to gain for the Medicaid recipient preferential treatment with respect to admission, expedited admission or continued stay).

We note that, while section 1819(c)(5)(A) of the Act contains no corresponding statement on gifts or donations to Medicare skilled nursing facilities, other parts of the statute and regulations are relevant. Under section 1866(a) of the Act, a participating Medicare provider must agree not to charge a Medicare beneficiary (or other person on his or her behalf) for services covered by Medicare, except for any deductible and coinsurance amounts that may be applicable. This provision operates to preclude acceptance by a Medicare SNF of donations from or on behalf of Medicare beneficiaries in return for preferential treatment with respect to admission or continued care. The implications of the section 1866 agreement are spelled out, in part, in regulations at 42 CFR 489.22. In addition, regulations at 42 CFR 489.53(a)(2) prohibit any participating Medicare provider that accepts both Medicare and Medicaid patients from imposing restrictions on the acceptance of Medicare patients for treatment which are more severe than those it imposes on all other persons seeking care. Because section 1866(a) is already implemented elsewhere in the regulations, as indicated, we are not repeating these requirements here.

Comment: Five commenters asked why the requirement at § 483.12(e) which requires the facility to have resident care policies will be removed after October 1, 1990.

Response: This requirement is based on section 1861(j)(2) of the Act, which was repealed by OBRA '87, effective October 1, 1990.

Summary of Changes to § 483.12

In response to comments, we have made the following changes:

- In § 483.12(a) we have added at paragraph (1) a definition of transfer and discharge to clarify that the determinant is whether a resident is moved to another certified facility, whether or not the bed is in the same physical plant. This results in redesignating all following paragraphs and correcting appropriate cross references.
- In § 483.12(a)(4) (redesignated from (a)(3)) we clarify that notification for a move must be in writing and in a language and manner that the resident understands.
- In § 483.12(b), since this section applies only to Medicaid as specified in section 1919(c)(2)(D) of the Act, it is necessary to specify *nursing facility* as opposed to *facility*.
- In section 483.12(d) we clarify the admission policy for a facility to conform the regulation more closely to the statute.

We also made minor editorial or technical changes to conform the regulation more closely to the statute. In a few instances we removed obsoleted material, i.e., not in effect after September 30, 1990. We also deleted the reference to the "State agency designated by the State for such appeals" at § 483.12(a)(6)(iv) since we are designating the use of the Medicaid fair hearing system at § 483.200ff in another regulation.

Section 483.13 Resident Behavior and Facility Practices

Summary of Provisions

Section 483.13(a) specifies that a resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience.

Section 483.10 (b) and (c) provide that a resident has the right to be free from abuse, corporal punishment and involuntary seclusion and that a facility must develop and implement written policies and procedures that prohibit mistreatment, neglect and abuse of a resident, and misappropriation of resident property.

Comments and Responses

Comment: A large group of commenters raised issues on the physical and chemical restraint requirement at § 483.13(a).

Response: As we pointed out in the preamble (54 FR 5323) to the final regulation, we plan to publish a separate regulation detailing specific requirements on physical and chemical restraints in emergency and non-emergency situations. While we are using the comments received on this regulation to assist in preparing this proposed rule, we will accept and review further comments when it is published in the Federal Register.

Comment: Five commenters objected to the location of the restraint requirement. They felt that it would be better located under § 483.10, Resident rights. This would ensure that the right to be free from restraints would be among those rights of which residents are informed pursuant to § 483.10(b).

Response: The organizational location of this requirement in no way frees the facility from notifying a resident of all his or her rights as established by these regulations. The rights of residents are established in three sections, § 483.10 Resident Rights, § 483.12 Admission, Transfer and Discharge Rights, and § 483.13 Resident Behavior and Facility Practices.

Comment: Several commenters felt that the references to a right to be free from involuntary seclusion in § 483.13(b) and (c) should be removed. They pointed out that involuntary seclusion can be a form of treatment to minimize the use of physical restraints by removing a resident from a source of agitation.

Response: We agree with the commenters that involuntary seclusion can be used in some circumstances. We are, however, unable to remove the prohibition against its use from the regulations because it is statutorily required by sections 1819 and 1919(c)(1)(A)(ii) of the Act as amended by OBRA '87.

Comment: Several commenters pointed out that in revising § 483.13(c), which requires the facility to take several steps to protect residents from mistreatment, neglect, and abuse of residents by staff, we did not take into account all of the relevant OBRA '87 provisions. Sections 1819 and 1919(g)(1)(C) of the Act require the State, through its survey and certification agency, to have a process for receipt, timely review, and investigation of all allegations of resident abuse or neglect or misappropriation of resident property by a nurse aide or other individual used by the facility. The State survey and certification agency must also enter all adverse findings into the nurse aide registry or notify the appropriate licensure authority in the case of other staff (non-nurse aides). Sections 1819 and 1919(e)(2)(B) require the nurse aide registry to include specific documented findings by the State survey and certification agency concerning resident neglect, abuse, or misappropriation of resident property by an individual listed in the registry. Also, sections 1819 and 1919(b)(5)(C) require a nursing facility to inquire of the registry as to information concerning an individual before allowing him or her to serve as an aide.

Commenters noted that § 483.13(c):

- Contains no mention of misappropriation of resident property;
- Omits explicit reference to the State survey and certification agency's role in investigating all alleged violations;
- Leaves the reporting of alleged violations to "other officials in accordance with State law" optional (by using "or" instead of "and" in § 483.13(c)(2) and (c)(4)), thus rendering the operation of the registry ineffective; and
- Uses a different standard than proposed in OBRA (i.e., § 483.13(c) limits the prohibition against hiring to individuals who have been "convicted," presumably by a court of law, rather than to those who are "found" by the survey and certification agency to have neglected or abused a resident or misappropriated resident property).

Response: In addition to this regulation, the nurse aide registry and enforcement provisions of OBRA '87 are the subject of other proposed rules which are under development. In those rules, we will explain more fully how these staff treatment requirements relate to the workings of the nurse aide registry and the survey and certification process. See for example, 55 FR 10938 in the March 23, 1990 issue of the Federal Register for our proposed rule on nurse aide registry requirements. (See § 483.75(g) for other nurse aide training and competency requirements.)

Also as a result of these comments we have reevaluated the wording of § 483.13(c) which was first proposed in the October 16, 1987 proposed rule at § 483.25(n) as a close parallel to § 483.420(d) in the regulations for intermediate care facilities for the mentally retarded (ICFs/MR). Section 483.420(d) requires that the ICF/MR not employ any individual who has been "convicted" of abuse, neglect, or mistreatment of a resident. We have been advised that "found guilty by a court of law" is a more inclusive term and should be used. This term includes situations in which the accused pleads guilty, or is found guilty while having pleaded innocent, or pleads *nolo contendere.*

While the survey and certification agency is charged under OBRA '87 with investigating and producing findings on all allegations of resident abuse, neglect and misappropriation of resident property by staff, we continue to believe that the facility has an important responsibility for identifying and investigating all incidents of suspected resident abuse, neglect, or mistreatment or misappropriation of property, whether by staff or others. Often the source of the offense will be initially unknown. Other residents or visitors, rather than staff, could be involved. Once the facility's preliminary investigation implicates staff, the facility is responsible for notifying the State survey and certification agency. If an incident appears to involve a criminal act, the facility is also responsible for notifying the appropriate law enforcement agencies.

Comment: A number of commenters responded to the requirement at § 483.13(c)(1)(ii) which prohibits the facility from employing individuals who have been convicted of abusing, neglecting, or mistreating individuals. Most of the commenters were concerned that this information is not and will not always be available to the facility. These commenters pointed out that even though States are required to maintain nurse aide registries, not all staff will be included in the registry. Also, access to police records is often limited and may not be available at all from sources outside the State. These commenters requested that the regulation be changed to read that the facility must not knowingly employ individuals who have been convicted of abusing, neglecting, or mistreating residents.

Response: The intent of the regulation is to prevent the abuse of residents by staff who have a history of abuse. To add the word "knowingly" would dilute the intention of the regulation and give facilities an opening not to be thorough in their investigations of the past histories of individuals they are considering hiring. In addition to inquiring of the State nurse aide registry or other licensing authorities, the facility should check all references and make reasonable efforts to uncover information about any past criminal prosecutions. If the nursing facility should learn of a history of criminal acts by an employee (past, present, or prospective), we are requiring that it

report such knowledge to the State registry or other licensing authority.

Comment: Another group of commenters suggested that the regulation could result in many employees unfairly losing their jobs. They stated that the regulation does not describe what protection must be afforded employees who are accused of neglect or mistreatment, nor does it inform facilities of the investigation and due process procedures with which all parties must comply.

Response: The regulation prohibits the facility from hiring individuals who have been found guilty of abusing, neglecting or mistreating residents or misappropriating resident property either by a court of law or by the State survey and certification agency. Court actions would provide safeguards to protect the innocent. Furthermore, OBRA '87 requires that the investigatory role of the survey and certification agency is to include opportunities for a fair hearing and for the individual to rebut adverse information contained in the registry. Therefore, we believe due process rights are protected and ample safeguards are in place to protect the innocent whether in a court of law or before a survey and certification agency.

Comment: Several commenters suggested that the requirement at § 483.13(c)(4) which states that the results of all investigations must be reported to the administrator or his or her designated representative within 5 working days of the incident did not allow the facility enough time for investigation in cases where an allegation is not made until several days after the incident. They suggest that the requirement be changed to read within 5 working days of knowledge of the incident.

Response: We have not accepted these comments. We think that 5 days is a reasonable time in view of the fact that a resident may be in jeopardy of repeated abuse in the meantime. To make the change requested would weaken the intent of the regulation, which is to protect patients from abuse.

Summary of Changes

In order to make the staff treatment provisions of this rule consistent with these other OBRA '87 provisions, as a result of these comments we are:

- Adding "misappropriation of property" to the list of violations in § 483.13(c)(1) against which the facility must protect the resident.
- Changing "convicted" in § 483.13(c)(1)(ii) to read "found guilty by a court of law" and must not employ individuals for whom findings indicate a past history of abuse, neglect, or mistreatment of residents or misappropriation of resident property.
- Changing the "or" to an "and" in § 483.13(c)(2) and (c)(4) to make reporting of allegations and findings of the facility's own investigation to the State survey and certification agency and any other officials, as required by State law, obligatory.
- Requiring the facility to report to the State nurse aide registry and other licensing authority any knowledge it has of criminal actions taken against a past, present, or prospective employee which might indicate unfitness for service as a nurse aide or other staff.

Section 483.15 Quality of life

Summary of Provisions

Section 483.15 Quality of Life, specifies that the facility must ensure that residents receive care in a manner and in an environment that maintains or enhances their quality of life without abridging the safety and rights of others by (a) treating each resident with dignity and respect and (b) maintaining each resident's privacy.

Section 483.15(c) specifies that residents have a right to choose activities, schedules and health care, consistent with their interests, assessments and plans of care, and also to interact with members of the community both inside and outside the facility.

Section 483.15(f) provides that the facility must provide for an ongoing program of activities appropriate to residents' needs and interests designed to promote opportunities for engaging in normal pursuits, including religious activities of their choice.

Section 483.15(g) specifies that a facility must provide medically related social services to attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident.

Section 483.13(h) requires that the facility provide a clean, comfortable, and homelike environment for the resident.

Comments and Responses

Comment: Section 483.15(c)(6) requires that, "when a resident or family group exists, the facility must listen to the views and act upon grievances and recommendations of residents and families concerning proposed policy and operational decisions affecting resident care and life in the facility." A commenter noted that "listening to and acting upon" is too vague and suggested requiring written responses from the administration about grievances or recommendations and forwarding unresolved grievances to the licensing bureau.

Response: We do not believe it is necessary to regulate the means by which the facility should respond to grievances by requiring a written response. Our regulations allow facility flexibility and we do not wish to impose any additional burden upon the facility.

Comment: Section 483.15(f)(2) requires the activities program to be, "directed by a qualified professional who is a qualified therapeutic recreation specialist who is licensed or registered if applicable, by the State in which practicing; and eligible for certification as a therapeutic recreation specialist by a recognized accrediting body on October 1, 1990." Several commenters recommended that the National Association of Activity Professionals (NAAP) be included in the qualifications for the person who directs the activity program because they believe their certification criteria are appropriately based on the educational and experiential background needed for a person to be able to provide a quality activity program to an elderly population. It also emphasizes the importance of providing a variety of activity programs, not a specific type of program, such as music, art recreation, etc.

Response: We chose not to specify particular accrediting associations or organizations but rather leave it to the majority membership of the particular discipline to determine which association or organization they recognize.

Comment: Section 483.15(f)(2)(B)(iv) requires that an activities program must be directed by a qualified professional who "has completed a training course approved by the State." Approximately 80 commenters addressed this section. Some commenters supported this requirement; others suggested that the State-approved course be used in conjunction with other qualifications (i.e., degree and appropriate certification as an art, dance, music, or recreation therapist). Several commenters opposed this requirement for a number of reasons:

- State approved programs do not include components necessary to implement a successful therapeutic activity program.
- State programs differ in length, content, and qualifications, thus there are not national uniform standards.
- Regulations do not provide any evaluation method for these programs. Many State training courses provide 30 to 50 contact hours of training. Given multiple responsibilities of the activity

professional, the limited training provides a bare minimum even in the best of circumstances.

• When State-approved certification programs are in place, they may not include consultation by an occupational or recreational therapist to ensure that high standard programs are in place.

• State approved programs provide too much flexibility for the States or for facilities.

• State approved programs should be required for all activity assistants or activity aides.

Response: Based upon the provisions of OBRA '87, we are requiring an ongoing program of activities directed by a qualified professional designed to meet the interests and the physical, mental, and psychological well-being of each resident. We do not believe it is necessary to eliminate the option of State approved programs as we are continuing to focus on outcome measures rather than the method by which these objectives are accomplished. We have no evidence that the residents participating in activities programs directed by individuals who have completed State approved programs are less likely to achieve the desired objective than when the program is directed by other individuals.

Comment: Many of the commenters wanted to retain the requirements at 42 CFR 405.1131(a) which state that a member of the facility's staff is designated as responsible for the patient activities program.

Response: Upon the effective date of the February 2, 1989 rule (October 1, 1990) 405.1131(a), which allows a member of the facilities staff to be responsible for the patient activities program, is eliminated. Similarly, we eliminate the requirement that if the staff member is not a qualified patient activities coordinator, he or she must function with frequent, regularly scheduled consultation from a person so qualified. We believe that effective October 1, 1990, the consultation requirement is unnecessary since we have stated that the activities must be directed by a qualified professional.

Comment: Several commenters addressed the qualifications section of this requirement and recommended that the activities program be directed by a qualified professional who is a qualified therapeutic recreation specialist who is licensed or registered if applicable, by the State in which practicing; and eligible for certification as a therapeutic recreation specialist by the National Council for Therapeutic Recreation Certification; or has two years experience in a social or recreational program within the last 5 years, one of which was full-time in a patient activities program in a health care setting; or is a qualified occupational therapist.

Response: As stated in the previous response, we are accepting the recommendations for the qualified professional who directs the activities programs as stated at § 483.15(f)(2). We chose not to include a specific certification body eligibility but are revising the language at § 483.15(f)(2)(i)(B) to state "eligible for certification as a therapeutic recreation specialist by a recognized accrediting body on October 1, 1990."

Comment: In the preamble to the February 2 rule, it was noted that the commenters had recommended adding another requirement to the activities section which would contain three types of therapeutic activities; supportive, maintenance, and empowerment. We had responded by noting we would present this material in the interpretive guidelines. Many commenters opposed presenting this in the interpretive guidelines as they stated these terms are used only by a small percentage of activities professionals and not at all by therapeutic recreation specialists. They felt incorporation of these classifications into the survey or regulatory system could jeopardize many activities programs that base their programs upon the individual needs of residents.

Response: We believe that the source of the controversy surrounding this material is the disagreement among various activities professionals over the appropriateness of this terminology. Rather than attempting to mediate this dispute, we will delete this terminology from the interpretive guidelines and leave this aspect of the activities requirement to the surveyor's discretion.

Comment: There were approximately 80 comments addressing the social services requirements. Over one half of the total comments addressed the new requirements pertaining to the qualifications of the social worker. Many of these believed that the social worker qualification standard at § 483.15(g)(4)(ii) (i.e., two years of social work supervised experience in a health care setting working directly with individuals) is a less stringent standard and is a lower standard than that of OBRA '87. The OBRA '87 states a social worker must have at least a bachelor's degree in social work or similar qualifications. Other comments addressing the qualifications requirements were:

• Social services should be provided by individuals with a master's degree in social work.

• Maintain current requirements for social workers. as listed at 42 CFR 405.1130(b) (a member of the facility designated as responsible for services. If the designated person is not a qualified social worker, the facility has a written agreement with a qualified social worker or recognized social agency for consultation and assistance).

• Require a nonsocial worker providing social services who is not a graduate or licensed social worker to receive at least 200 hours per year of consultation from a licensed social worker or a social worker with a degree from an accredited school of social work and at least one year of health care experience.

• Do not require a social worker consultant to be a graduate of a particular discipline since social worker consultants come from all disciplines (i.e., psychology, sociology, and mental health education).

• Require social workers to have a bachelor's degree in gerontology with substantial course work in social work.

• Clarify "similar professional qualifications" as stated at § 483.15(g)(4)(iii).

• Define "similar professional qualifications" as a bachelor's degree in a related field such as human services field (i.e., applied sociology, with at least 1 year of previous supervised experience in meeting psychosocial needs).

• Recommend as social worker qualifications either a bachelor's degree from an accredited school of social work, or a bachelor's degree in a related human services field plus 1 year of previously supervised experience in a health care setting, or two years of supervised experience providing social services in a nursing facility prior to October 1, 1990.

• Clarify whether the bachelor's degree requirement is met only by a bachelor's degree in social work from a program accredited by the National Association of Social Workers or by a social work major from any program.

• Delete § 483.15(g)(4)(ii) "2 years of social work supervised experience in a health care setting working directly with individuals."

Response: Regarding comments recommending that we require a master's degree social worker to provide social services, the provisions of OBRA '87 require that in the case of a skilled nursing facility with more than 120 beds the facility must have at least one social worker (with at least a bachelor's degree in social work or similar professional qualifications) employed full-time to provide or assure the

provision of social services in sections 1819(b)(7) and 1919(b)(7). Thus, requiring individuals with master's degrees would go beyond the statute. This does not preclude facilities from employing social workers with master's degrees.

With regard to commenters who wanted to maintain the current requirements for social workers as listed at 42 CFR 405.1130(b), we may not retain these requirements as they do not reflect the statutory requirement of "at least a bachelor's degree".

We do not believe that commenter requests for requiring non social workers providing social services to receive at least 200 hours per year of consultation from a licensed social worker would benefit resident rights. Under our regulations, facilities with 120 beds or more must have a qualified social worker. Facilities with less than 120 beds must assure that the facility provides medically related social services to attain or maintain the highest practicable physical, mental, or psychosocial well-being of each resident.

We agree to define the statutory requirements found at sections 1819(b)(7) and 1919(b)(7) of the Act, "similar professional qualifications" as a bachelor's degree in a human services field (including but not limited to sociology, special education, rehabilitation, counseling, and psychology).

We agree to delete the requirement at § 483.15(g)(4)(ii) describing a social worker as someone with a bachelor's degree or 2 years of social work supervised experience in a health care setting. Instead, we will require a bachelor's degree and 1 year experience of supervised social work as commenters requested.

Comment: Several commenters suggested that the social worker should be identified as part of the interdisciplinary team as described in § 483.20(d)(2)(ii). A comprehensive care plan must be prepared by an interdisciplinary team that includes the attending physician, a registered nurse with responsibility for the resident, and other appropriate staff in disciplines as determined by the resident's needs and with the participation of the resident, the resident's family, or legal representative to the extent practicable.

Response: We do not agree to specify the social worker as part of the interdisciplinary team but rather leave it to the discretion of the interdisciplinary team to decide when social work involvement in care planning is needed by a resident.

Comment: A number of commenters noted that Congress in the Medicare Catastrophic Coverage Act of 1988 (MCCA) required that the standards for social service workers be "at least as stringent" as those in effect prior to the enactment of OBRA. They argue that because the previous regulation contained provisions which are not included in the final rule, the standards for social workers in this final rule are therefore contrary to the statute.

Response: We disagree. First, we recognize that the "at least as stringent" language, which did not appear in the MCCA, does appear in OBRA '90. It is our opinion, however, that the standards for social workers in the final rule are in full accordance with the statute. In fact, the United States District Court for the District of Columbia specifically concluded that the standards appearing in the final rule are at least as stringent as those in existence prior to the enactment of OBRA '87. See *Gray Panthers Advocacy Committee, et al.* v. *Sullivan,* Civil Action No. 89 0605–NHJ (D.D.C. Sept. 17, 1990). Simply because the final rule does not include every word of the regulations in effect prior to the enactment of OBRA '87, does not mean that the final rule could not be as stringent as the old regulations. Congress specifically did not require that the final rule contain the identical language as in the previous regulations. In fact, we believe that the final rule is more stringent than the previous regulation. The final rule by focusing on quality of care, rather than the mere capacity to provide such care, emphasizes outcome. With the previous regulations, it was possible that while the facility might have been in technical compliance, the care received was not adequate or appropriate. Specifically, the fact that an individual may have satisfied the credential requirements of the regulations provided no assurances that the care actually rendered was of high quality. Under these rules, however, since high quality services are the standard, this weakness in the old rule has been removed. Consequently, the objective of the final rule is to look at the quality of care actually received by each resident, and thus to prevent any undue reliance on staff qualifications that may have existed in the previous rule.

Comment: Several commenters opposed the setting of temperature ranges of 71–81° F on initially certified facilities:

- One commenter noted that the temperature range is contrary to HCFA comments in the preamble in the February 2 rule pertaining to food temperature where we refused to define a temperature range because we thought it was a subject for interpretive guidelines, not regulations.
- Commenters suggested that we revise § 483.15(h)(6), in part, to reference recommendations by the American Society of Heating, Refrigerating, and Air Conditioning Engineers. They believe that specifying temperature ranges does not take into account mechanical ability of various systems nor the resident's choice of temperature.
- Other commenters suggested requiring facilities to provide comfortable and safe humidity levels.

Response: The temperature ranges indicated in § 483.15(h)(6) are for facilities initially certified after October 1, 1990, the effective date of these regulations, not for existing facilities. Currently certified SNFs and ICFs that are initially certified under these requirements as NFs and SNFs after October 1, 1990 would not be required to modify their heating and cooling systems to maintain the specified temperature ranges. Even though we deferred from specifying temperature ranges in the "Quality of Life" requirement on food, we indicated that we intend to issue guidelines to ensure that the food is served at the proper temperature and under sanitary conditions. We decided in this instance to provide specific temperature ranges in response to many comments to the proposed rule that expressed concern for appropriate temperature ranges within nursing facilities and indicated how residents' comfort in this area affected quality of life. We derived our temperature ranges from standards recommended by the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE standard, Thermal Environmental Conditions for Human Occupancy, ANSI/ASHRAE 55–1981) with a few degrees of variation in consideration of lower metabolism rate of the nursing facility population, who are mostly elderly and/or less active than individuals in other settings.

We do not believe alternative wording suggested would provide any clearer assistance or guidance to surveyors in identifying noncompliant facilities. We do, however, plan to specify within guidelines exceptional circumstances under which a facility may be briefly outside the specified ranges. Thus, we believe this would accommodate concerns about situations in which the temperature may deviate a degree or two in either direction.

We did not accept the suggestion to add "humidity levels" as we believe that referring to safe and comfortable

temperature levels would encompass too much or too little moisture in the air.

Summary of Changes to § 483.15

As a result of our evaluation of comments, we are making the following changes:

• In § 483.15(g) we established as an alternative qualification for a social worker, a bachelor's degree in a human services field including, but not limited to sociology, special education, rehabilitation counseling and psychology with one year of supervised social work experience in a health care setting working directly with individuals. We deleted as qualifications two years of supervised social work experience or similar professional qualifications.

Section 483.20 Resident Assessment

Summary of Provisions

Section 483.20 specifies that a facility must conduct initially and periodically thereafter a comprehensive assessment of each resident's medical, functional and psychosocial needs. OBRA '90 amends this section to specify that the assessment must be conducted not later than 14 days after admission rather than 4 days as previously required.

Section 483.20(d) requires that the comprehensive care plan be prepared by an interdisciplinary team which includes the resident, the resident's family or resident's legal representative, a physician, a registered nurse, and other staff in disciplines determined by the resident's needs.

Section 483.20(f) provides that on or after January 1, 1989, a facility must not admit an individual with mental illness or mental retardation unless the State mental health authority or the State mental retardation or developmental disability authority has determined that the individual requires this level of care furnished by the facility.

If the individual requires such level of services, the State mental health or mental retardation authority must also have determined whether the individual needs active treatment. In the case of individuals with mental illness, the State mental health authority's determinations must be based on an independent evaluation performed by a person or entity other than the State mental health authority. This requirement implements the statutory requirement of section 1919(b)(3)(F) of the Act. In § 483.20(f)(2) we define mental illness and mental retardation based on the statutory provisions of section 1919(e)(7)(G).

Comment and Responses

Comment: Several commenters suggested that the requirement for resident assessment should be expanded by adding the phrase "physical and mental" before the word functional status at § 483.20(b)(2)(iii) and by adding "mental and psychosocial" status at § 483.20(b)(2)(vii). The same commenters asked that we specify at § 483.20(c)(1)(ii) that qualified mental health professionals must participate in the performance of the mental status portions of the comprehensive assessment.

Response: We agree with commenters that the mental status of a resident is an important component of any assessment and we had intended this concept to be conveyed in the term "psychosocial" in the current § 483.20(b). Baseline data on the mental status of all residents must be available to enable facilities to determine which residents need mental health services, including mental health rehabilitative services (see § 483.45(a)) and to enable mental health professionals to develop appropriate plans of care. To clarify this issue we have revised § 483.20(b)(2)(iii) to state physical and mental functional status, § 483.20(b)(2)(vii) to state mental and psychosocial status, and § 483.20(d)(1) to state mental and psychosocial needs.

We believe that, as currently stated, the requirement at § 483.20(c)(1)(i) that each assessment must be conducted or coordinated with the appropriate participation of health professionals already requires involvement of qualified mental health professionals in the performance of mental status examinations to the extent that they are needed. (See also the preamble discussion of mental health needs in § 483.20(f)).

Comment: Approximately six commenters thought that the requirement at § 483.20(b)(4)(ii) that individuals admitted on or after October 1, 1990 should have a comprehensive assessment no later than 4 days after the date of admission should be changed to give the facility more time to meet this requirement. Suggestions for change ranged from 7 working days to 21 working days.

Response: OBRA '87 made a 4 day assessment statutory at sections 1819 and 1919(b)(3)(C)(i)(I) of the Act. However, OBRA '90 amends these sections and now requires comprehensive assessment not later than 14 days for individuals admitted on or after October 1, 1990.

Comment: Commenters asked for clarification as to whether or not the physician needed to participate in person in the preparation of the comprehensive care plan required by § 483.20(d)(2)(ii).

Response: It is not the intention, nor does the regulation specify, that physician involvement in the interdisciplinary team process must be personal presence at a team meeting. The physician can participate through other means, such as one to-one discussions. This will be further clarified in interpretive guidelines for the regulation.

Comment: Approximately 20 commenters responded to § 483.20(f)(1) which requires that, on or after January 1, 1989, a nursing facility must not admit any new resident with mental illness or mental retardation unless the State mental health or mental retardation authority (as appropriate) has determined prior to admission that, because of the individual's physical and mental condition, he or she requires the level of services provided by a nursing facility.

In general, commenters on this preadmission screening provision felt that the regulations failed to address a major aspect of OBRA '87 NF reform provisions: responsibility to the resident who needs these services in order to attain the highest level of mental and psychosocial well-being as required by sections 1919(b)(2) and 1919(b)(4)(A) (i), (ii) and (v) of the Act. Commenters proposed a number of measures for correcting this perceived failure.

More specifically related to this preadmission screening provision, many of the commenters believed it is essential that HCFA provide clear definitions for and a delineation between special services for mental illness and the normal level of ongoing treatment for mental health problems that a resident is entitled to receive under the general rubric of services aimed at attaining or maintaining the highest level of mental and psychosocial well-being. (Specialized services was formerly called active treatment prior to enactment of OBRA '90 which substituted terms). Commenters stressed that services mandated by these long term care facility requirements must not be regarded as specialized services for mental illness. Otherwise, they believed a contradiction would exist between the requirements for psychosocial assessment and maintenance of psychosocial function and the preadmission screening and annual resident review (PASARR) requirements of OBRA '87 (i.e., Proper attention to a resident's mental and psychosocial needs would inevitably put the resident

at risk of being discharged or would put the facility at risk of not being reimbursed by Medicaid since section 1919(e)(7)(G)(iii) of the Act excludes specialized services from nursing facility services).

Many of the commenters very strongly urged that we define specialized services as being limited to those services that are required by individuals experiencing an acute episode of severe mental illness and should clearly be limited to the delivery of intensive, specialized mental health services on a 24-hour a day basis by trained mental health personnel. These commenters also pointed out that while the types of services provided might be the same or similar in both cases, the intensity of the services in a program of specialized services is much greater than that provided as a part of a normal level of care.

Another group of commenters also urged that, in defining mental health services, we include services for all individuals who require them, whether or not they have a formal diagnosis of mental illness. These same commenters felt that if a nursing facility takes anyone with mental health needs, it must assure that those needs are met.

Response: We must begin this response by noting that OBRA '90 contained 3 provisions with direct relevance to the issues which gave rise to many of the comments.

- The term "mentally ill" was directly keyed to the listing of mental illness in DSM–III, a comprehensive compendium of mental illnesses.
- Section 4801(b)(7) of OBRA '90 changed this term to read—"serious mental illness (as defined by the Secretary in consultation with the National Institutes for Mental Health)."
- As a result of section 4801(b)(8), the term "active treatment" was replaced each place where it occurred with the term "specialized services," to avoid confusing the needed services with the mode of treatment.
- The law was clarified for both Medicare SNFs (section 4008(h)(2)(D)) and Medicaid NFs (section 4801(e)(4)) by adding to the list of services a facility must provide, "treatment and services required by mentally ill and mentally retarded residents not otherwise provided or arranged for (or required to be provided or arranged for) by the State."

Before OBRA '90 was enacted, we had responded to the comments by clarifying the final regulation to make it clear that mental health rehabilitation services are required and by reflecting provisions relating to such services in the regulations provisions relating to resident assessment and quality of care. Commenters should note, also, that we reflected our intent to clarify these issues in the preamble to our March 23, 1990 proposed regulation relating to the preadmission screening and annual resident review (PASARR) requirements.

The bulk of the requirements relating to these provisions are contained in the PASARR regulations which, as in the case of the NPRM, will be published as a separate rule. In the paragraphs below, however, we describe the changes we made in this final regulation as a result of the comments we received and as a result of the OBRA '90 requirements.

In response to the more general comment that we failed to deal adequately with the OBRA requirements concerning the responsibility of the NF to deliver mental health services to residents who need them in order to attain the highest level of mental and psychosocial well-being, we believed that the references to psychosocial services in the February 2 rule were sufficient. Nursing facilities and their predecessors, SNFs and ICFs, have always been required to meet the physical and mental needs of their residents. The types of comments we received have, however, persuaded us that the regulation text needs to contain more specific references to mental health in the assessment, quality of care, and specialized rehabilitation services sections so that the intent of the regulation, now explicitly confirmed in OBRA '90, is clear. In this final rule we have, therefore, made changes to the wording of the assessment requirements at § 483.20(b)(2) (iii) and (vii) and the quality of care requirement concerning psychosocial functioning at § 483.25(f).

We have changed the references in those sections from "psychosocial" to "mental and psychosocial" since it seems clear from the comments that each term has separate nuances, all of which we wish to capture. For instance, the concept of mental status appears to include the mental dysfunction present in a sad or anxious mood as well as overt disruptive behavioral manifestations such as wandering, verbal abuse, and physical abuse. The concept of psychosocial well-being appears to relate to how people feel about themselves and their lives. This includes involvement in life around them, having satisfactory relationships with others as well as self-respect and a sense of satisfaction with life.

In § 483.45(a) we have also added rehabilitative services for mental illness and mental retardation, to the specialized rehabilitative services for which the nursing facility is responsible and which are covered NF services under Medicaid.

Since other nursing facility services such as nursing, dental, or medical-related social services are not defined in detail in these regulations, we are not defining mental health services in the regulation text. However, because there may be some ambiguity over terms such as "services for mental illness and mental retardation," we wish to clarify in this preamble what types of activities we believe are commonly understood to be included among mental health services:

- Crisis intervention services;
- Individual, group, and family psychotherapy;
- Drug therapy and monitoring of drug therapy;
- Training in drug therapy management; and
- Other rehabilitative services such as—

—Structured socialization activities to diminish tendencies toward isolation and withdrawal;
—Development and maintenance of necessary daily living skills including grooming, personal hygiene, nutrition, health and mental health education, money management, and maintenance of the living environment; and
—Development of appropriate personal support networks.

Some of these services may be delivered by nurses and social workers or through the activities program or pharmacy services while others may require the expertise of individuals with specialized training in psychology or psychiatry. In keeping with our focus on outcomes of care, we are not specifying who should perform the services. We do specify, however, in the quality of care requirement in § 483.25(f) that all NF residents who display mental or psychosocial adjustment difficulties must receive appropriate treatment and services to correct the assessed problem. This requirement also mandates that all residents who do not display psychosocial adjustment difficulties at the time of assessment do not develop these difficulties, unless their clinical condition demonstrates that such a pattern was unavoidable.

We also clarify that rehabilitative services for mental illness or mental retardation as required in § 483.45(a), are not synonymous with specialized services (previously called active treatment). We view these types of rehabilitative services as meeting the needs of individuals with mental illness or mental retardation whether or not

they are required to be subject to the PASARR process and whether or not they require additional services provided or arranged for by the State as specialized services. For example, individuals may need social services, activities, or medication to treat moderate depression. Sections 1819 and 1919(b)(4) of the Act as amended by OBRA '90, clearly indicate that mental health needs must be served by NFs, while section 1919(e)(7)(G)(iii) of the Act clearly indicates that certain specialized services are outside the scope of nursing facility mental health services. We believe that specialized services can only be ordinarily delivered in the NF setting with difficulty because the overall level of services in NFs is not as intense as needed to address these needs. If the State's PASARR program determines that an individual with mental retardation or mental illness may enter or continue to reside in the NF, even though he or she needs specialized services, and the individual does so, then the State must provide or arrange for the provision of additional services to raise the level of intensity of services to the level needed by the resident.

Readers should review the regulation expected to be published to make final provisions discussed in the March 23 proposed rule or the proposed PASARR requirements for a detailed discussion of these issues.

Comment: The remaining comments on the PASARR provision reflected a variety of objections, mainly to the statute itself, over which we have no discretion in implementation. Specifically, commenters objected to the application of PASARR requirements to private pay individuals, to the broad statutory definition of mental illness, to the lack of community alternatives which commenters feared would result in placement problems for individuals with mental illness who are not admitted to NFs, and to the lack of federal guidelines. A number of these commenters alluded to PASARR litigation which has ensued since enactment of the law.

Response: In the absence of language in the statute limiting the cope of PASARR, we have no alternative but to conclude that the statute requires that preadmission screening applies to "any new resident," regardless of the method of payment (see section 1819(b)(3)(F) and 1919(b)(3)(F)). Congress has twice considered an amendment exempting private pay individuals, in 1989 and 1990. In both years, this amendment was defeated. By contrast, OBRA '90 substituted a much narrow definition of mental illness, limited to serious mental illness as defined by the Secretary in consultation with NIMH.

With regard to fear that these requirements will result in placement problems, we note that Congress did allow States to submit alternative disposition plans (ADPs) through which States may gain extra time for creating community placements for current residents of skilled nursing facilities who must be relocated, but not for new applicants who are deflected from entering nursing facilities. For potential new residents, we recognize States will need to make other provisions for care for this population.

We note, in response to those who commented on the lack of Federal guidelines, that OBRA '87, as originally enacted, did not require issuance of final regulations, only criteria. This requirement was contained in section 1919(f)(8). By contrast, the preceding requirement at section 1919(f)(7) specifically instructs the Secretary to issue regulations on charges to residents' funds. In developing PASARR criteria, we consulted extensively and issued guidelines informally in September 1988. In May 1989, after further analysis and experience, we formally issued State Medicaid Manual part 4 Transmittal No. 42. We further note that the statute clearly required States to implement the preadmission screening requirements even in the absence of Federal criteria. This position was upheld in two Federal courts in May 1989. (See *Idaho Health Care Assoc., et al.* v. *Sullivan,* No. 88–1425 (D. Idaho May 11, 1989); (*Rayford, et al.* v. *Bowen,* No. 89–0418 (W.D. La. May 25, 1989). As a result of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89, Pub. L. 101–239), we are now required to publish these criteria as a proposed rule.

Summary of Changes to § 483.20

As a result of our evaluation of comments we have made several clarifying changes, as identified above.

We also are revising the wording of § 483.20(b)(1)(i) to reflect the provisions of sections 1819(e)(5)(B) and 1919(e)(5)(B) of the Act which require the State to specify an assessment instrument which is consistent with minimum data set and is approved by the Secretary. In the February 2, 1989 rule, we inadvertently omitted reference to the Secretary's approval.

We are also revising § 483.20(b)(4) (i) and (ii) so that it is consistent with sections 1819(b)(3)(C)(i)(I) and 1919(b)(3)(C)(i)(I) of the Act and OBRA '90 requirements relative to deadlines for assessing current residents of a facility as of October 1, 1990. Assessments must be conducted not later than 14 days after admission. Assessments of current SNF residents must be conducted between October 1, 1990 and January 1, 1991 (a three-month period). For residents, this period is one year (between October 1, 1990 and October 1, 1991).

Section 483.25 Quality of Care

Summary of Provisions

Section 483.25 specifies that each resident must receive the necessary nursing, medical and psychosocial services to attain and maintain the highest possible mental and physical functional status, as defined by the comprehensive assessment and plan of care.

Section 483.25(a) specifies that a resident's ability to ambulate, dress, eat, groom, bathe, toilet, transfer (i.e., from bed to chair) does not diminish unless reasonable justification is documented.

Section 483.25(b) provides that a facility must, if necessary, assist the resident in making appointments and arranging for transportation to and from a medical practitioner specializing in the treatment of vision and hearing impairments or vision or hearing assistive devices.

Section 483.25(c) specifies that a facility must ensure that a resident entering a facility without pressure sores does not develop them unless a physician certifies they were not reasonably avoidable, and a resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.

Section 483.25(d) requires that a facility ensure that a resident who is incontinent of bladder receive the appropriate treatment and services to restore normal bladder functioning; a resident is not catheterized unless it is necessary; and a resident who uses a urinary catheter receives appropriate treatment to prevent infections.

Section 483.25(e) requires that a facility must ensure that a resident who enters a facility without contractures does not experience an unpredictable reduction in range of motion without justifiable cause, and a resident with contractures receives appropriate treatment to increase range of motion and prevent further decrease in range of motion.

Section 483.25(f) requires that a facility must ensure that a resident who displays mental and psychosocial adjustment difficulty receives appropriate treatment and services to achieve remotivation and reorientation,

and a resident whose assessment did not reveal a mental and psychosocial adjustment difficulty does not display a pattern of decreased social interaction or increased withdrawn, angry or depressive behavior without justifiable cause.

Section 483.25(g) requires that a facility must ensure that a resident who has been able to feed or partially feed himself or herself is not fed by naso-gastric tube unless reasonable justification is documented, and that the resident receives appropriate treatment and services to prevent complications and to restore normal feeding function.

Section 483.25(k) requires that a facility must ensure that residents receive proper treatment and care for the following special services (to the extent covered under the program): Injections; parenteral fluids, colostomy or ileostomy care; tracheostomy care; tracheal suctioning, foot care, and respiratory therapy.

Section 483.25(l) requires that the facility must ensure that each resident's drug regimen is free of unnecessary drugs, inadequate drug monitoring, unnecessary dose levels, undue adverse consequences (i.e., side effects), and significant medication errors or significant medication error rates.

Section 483.25(m) requires that facilities not have significant error rates and that residents be free of significant medication errors.

Comments and Responses

Comment: A number of commenters objected to the use of the word "ensure" to describe a facility's responsibility for certain outcomes in various provisions of this section and suggested substitute words such as "provide" or "enable." They argued that a facility cannot reasonably be expected to "ensure" that a desired outcome will occur, especially with respect to all of the factors that may affect frail, aged nursing home residents.

Response: As we noted in our discussion of this issue in the preamble to the February 2, 1989 final rule (see 54 FR 5332), resident care outcomes can sometimes be affected by factors other than the treatment and services furnished, such as the degree of a resident's cooperation (i.e., the right to refuse treatment) and disease processes. However, we do not believe it is unreasonable to make the facility responsible for ensuring that basic treatment and services are provided since this is the reason for the resident's stay in the facility, as well as for program payment. We believe that the current wording of this section acknowledges the limitations imposed by the resident's right to refuse treatment, as well as by recognized pathology and the normal aging process, by enabling the facility to demonstrate that based on available clinical evidence, a negative resident care outcome was unavoidable.

Comment: Various provisions of this section allow a facility to cite a resident's clinical condition in establishing that specific negative resident care outcomes (including the use of certain otherwise inappropriate medical interventions) were unavoidable. Two commenters expressed support for these provisions. Two others, however, felt that the wording of these provisions would have the effect of forcing a facility to withhold these types of medical interventions when they are appropriate if supporting documentation for the intervention is absent. One commenter suggested that the language be amended to specify that the clinical justification must be documented in the medical record by the R.N. and the physician.

Response: With regard to the specific medical interventions discussed in this section (urinary catheters, naso-gastric tubes, etc.), the intent of this language is simply to ensure that these interventions are used only when there is valid medical justification for doing so. Since medical factors supporting their use would always be present whenever these types of interventions are used appropriately, these provisions would not require a facility to withhold the intervention under such circumstances; rather, the facility would merely be expected to record the medical factors that should already be present. Therefore, we are not revising the language to specify the precise manner of documentation since we believe that this would be unnecessarily prescriptive. Further, we note that the issue of adequate documentation of the resident's clinical record is already dealt with in regulations at § 483.75(l)(1) and (l)(6).

Comment: Two commenters suggested the addition of a specific requirement dealing with daily oral hygiene.

Response: We believe that a separate requirement is not necessary since oral hygiene is already addressed in § 483.25(a)(3).

Comment: Some commenters recommended revising the language in several parts of the section which currently requires the facility to furnish various services to the resident, so that the facility would be required only to "offer" such services to the resident.

Response: We believe that such revisions are not necessary since the regulations already make clear that the resident has the right to refuse treatment (see § 483.10(b)(4)) and the discussion of that provision in the February 2 preamble to the final rule (see 54 FR 5321) makes this clear.

Comment: Two commenters expressed support for the section as a good example of an outcome-oriented process. Two others objected to the facility being held accountable for the actions of other professionals, such as physicians.

Response: This comment is responded to in our later discussion of physician services (§ 483.40) where we discuss the issue of accountability of physicians and other individual practitioners.

Comment: One commenter noted that the mere presence of dementia alone does not justify a decline in a resident's ability to perform activities of daily living (ADLs).

Response: We agree that the mere presence of a clinical diagnosis of dementia cannot, in itself, justify a decline in a resident's ability to perform ADLs; rather, it is necessary to look at the resident's actual functional status, as determined by the resident assessment (see § 483.20 (b)(1)(ii) and (b)(2)(iii)).

Comment: We received numerous comments requesting clarification of the facility's responsibility to pay for the items and services discussed in § 483.25(b), particularly with regard to Medicaid facilities and services that are not covered under a State's Medicaid program.

Response: In order to respond to this comment, we believe it is appropriate to clarify the intent of the introductory paragraph's requirement for a facility to "*provide the necessary care and services* to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care" (emphasis added.) The specific types of "care and services" that the facility is responsible for providing under this requirement are the ones listed in section 1819(b)(4)(A)(i) through (vii) of the Act (for Medicare SNFs) and in section 1919(b)(4)(A)(i) through (vii) of the Act (for Medicaid NFs.) If a service appears in the applicable portion of the Act the facility is obligated to provide it to all residents who need the service; the nonavailability of program funding for private pay residents, for example, does not relieve the facility of this obligation. The sole exception would be routine dental services in Medicaid NFs, which are required under section 1919(b)(4)(A)(vi) of the Act only to the extent that they are covered under the

State plan (section 1819(b)(4)(A) does not relieve Medicare SNFs of responsibility for their residents' dental services, but does allow them to impose an additional charge for these services).

For types of care and services (such as assistive devices for vision and hearing) that are not specified in the applicable portion of the Act, the facility's responsibility is simply to assist residents and their families in locating and utilizing any available resources (Medicare or Medicaid program payment, local health organizations offering items and services which are available free to the community, etc.) for the provision of the services that the resident needs. This would include assisting the resident with activities such as making appointments and arranging transportation necessary to obtain the needed services.

Comment: One commenter concurred with the requirement in § 483.25(c) which requires that a resident with pressure sores receive necessary treatment to promote healing and prevent infection or the development of new sores. Two others requested that § 483.25(c)(2) be revised, allowing a facility to be exempted from this requirement by claiming that a resident's clinical condition makes such treatment impossible.

Response: We are not making the requested revision because we believe that the facility should always furnish the necessary treatment and services to prevent the development of pressure sores or, at the least, to promote the healing of sores that have developed.

Comment: One commenter indicated that § 483.25 (d)(1) and (d)(3), which require an incontinent resident to receive appropriate care, are redundant.

Response: We agree with this comment, and are deleting § 483.25(d)(1).

Comment: One commenter argued that, in order to establish that no reduction in range of motion has occurred during a resident's stay, it would be necessary to conduct a baseline assessment for each resident upon admission, which might be burdensome for some facilities.

Response: We note that the regulations at § 483.20(b)(2) (iii) and (xi) already include functional status and rehabilitation potential as prescribed parts of the required resident assessment. This should provide an adequate baseline for determining whether a reduction in a resident's range of motion has occurred.

Comment: A number of commenters believed that we failed to address as quality of care issues a major aspect of OBRA '87 NF reform provisions: responsibility of the NF to deliver appropriate mental health services to the resident who needs these services in order to attain the highest level of mental and psychosocial well-being as required by sections 1919(b)(2), and 1919(b)(4)(A) (i), (ii) and (v) of the Act. They asked that we add explicit requirements for both mental health and psychosocial services.

Response: We agree and have changed the title to this requirement to "mental and psychosocial" functioning and have made other appropriate changes to encompass both mental health and psychosocial services. (See also the preamble discussion of mental health needs in § 483.20(f)).

Comment: A number of commenters questioned the use of the terms "remotivation" and "reorientaton" for a resident who displays psychosocial adjustment difficulty in § 483.20(f)(1). As an alternative, several suggested rewording the last portion of this section to require treatment and services "to correct the assessed problem."

Response: We accept this comment, and are revising this provision accordingly.

Comment: Several commenters suggested deleting the list of possible complications from § 483.25(g)(2).

Response: We are not accepting this comment. We believe that the specific language here is needed in the regulations themselves in order to give surveyors guidance in this area.

Comment: One commenter endorsed the recognition of podiatric care in § 483.25(k)(7), which deals with special needs, as a type of care that residents must receive when needed. Several others suggested that the reference to podiatric care should be changed to "foot care" since the use of the term "podiatric" implies that this care can be furnished only by a podiatrist.

Response: We accept the suggestion to revise this provision since it was not our intention to limit its applicability to care furnished by podiatrists. Foot care could, for example, be appropriately furnished by a Doctor of Medicine or a Doctor of Osteopathy as well as by a podiatrist.

Comment: Several commenters suggested that certain elements of § 483.25(k) be revised to clarify that the facility is required to ensure that residents receive services only to the extent that they are covered under the Medicaid State plan.

Response: We do not accept this comment. As noted in the discussion of vision and hearing services (see § 483.25(b)), and with the exception of dental services for residents of Medicaid NFs, the nonavailability of program funding does not relieve a facility of its obligation to ensure that its residents receive all needed services listed in section 1819(b)(4)(A) of the Act (for Medicare SNFs) and section 1919(b)(4)(A) of the Act (for Medicaid NFs). For those services that are not listed in the applicable section of the Act, a facility is only required to assist the resident in securing any available resources to obtain the needed services.

Comment: In the notice of proposed rulemaking published on October 16, 1987, we received twenty comments requesting that we define "unnecessary drug." We defined "unnecessary drug" in the preamble to the final rule with comment published February 2, 1989, (54 FR 5334) as follows:

> "Unnecessary drugs" are drugs that are given in excessive doses, for excessive periods of time, without adequate monitoring, or in the absence of a diagnosis or reason for the drug. An unnecessary drug is a drug for which monitoring data, or undue adverse consequences indicate that the drug should be reduced or discontinued entirely. An unnecessary drug is also one which is prescribed only in anticipation of an adverse consequence of another prescribed drug.

Commenters on the final rule objected to two of these definitions and argued that the rule interfered with the practice of medicine and that the Secretary lacked the statutory authority to promulgate such a rule (see the following comment and response for a discussion of these issues).

Response: Because we feel that it is important to establish a clear definition of unnecessary drug in order to deal with the problem of drug misuse in nursing homes, we have decided, as commenters requested in the NPRM of October 16, 1987, to define "unnecessary drug" in the regulation text rather than in the preamble to the February 2, 1989, final rule with comment. For categories of drugs commonly used in nursing homes, we will develop specific guidelines for further definition of excessive dose, excessive periods of time, without adequate monitoring, in the absence of a diagnosis, and when adverse consequences indicate the drug dose should be reduced or discontinued. Where surveyors detect potential violations of these guidelines, they will be instructed to review existing evidence that justifies the drug's use before making a decision about whether a violation of the unnecessary drug requirement exists. The term "unnecessary drug" will be reserved for drug therapy circumstances in which HCFA guidelines (to be based on medical and behavorial sciences

literature and expert opinion) have established that such circumstances are a potential threat to the resident's health and safety, and for which the facility is unable to justify why using a drug under such circumstances is in the best interest of the resident. In justifying drug use the facility can certainly rely on physician justification of the risk-benefit of the drug use, but the facility would not be allowed to justify the drug use on the basis of "the doctor ordered it." This justification would "render the regulation, and the statutory underpinnings for it, meaningless.

Comment: With respect to § 483.25(l)(1), which concerns drug therapy, one commenter objected to the definition of an unnecessary drug which is presented in the preamble to the February 2, 1989 final rule. The preamble, in part, said that an unnecessary drug is one that is prescribed in anticipation of a side effect caused by another drug. The commenter pointed out that there are many circumstances in which these are perfectly legitimate prescriptions. For example, prescribing an antacid with a drug which is known to cause acid secretion as a side effect is acceptable.

Response: We agree with the commenter, and we will not consider drugs prescribed for this reason to be unnecessary.

Comment: A number of commenters complained about the definition of unnecessary drugs because they did not believe that an inadequately monitored drug could be called an unnecessary drug. They argued that a drug may be necessary even if it is not adequately monitored. These commenters, however, conceded that without adequate monitoring, one could not determine if a drug had achieved desired results, and therefore could not determine if it was or was not a necessary drug. Commenters also conceded that, without adequate monitoring for potential adverse effects, the risk-benefit ratio of the drug might be so unfavorable that it could be considered an unnecessary drug.

Response: As mentioned previously, we have changed the regulations at § 483.25(l) to define unnecessary drug as it is defined in the preamble to the February 2, 1989 rule, and this includes a provision for adequate monitoring.

Comment: Nine commenters were concerned about the prohibition against unnecessary drugs (as defined in the preamble (54 FR 5335) to the February 2 final rule). They believed that the regulation inappropriately holds facilities responsible for controlling drug use when it is physicians who prescribe drugs and control their use. They argue that under State Law only the physician may prescribe and discontinue drugs, order laboratory monitoring tests for drug use, and generally arrange the drug therapy of the resident.

Response: Section 1919(c)(1)(A)(ii) of the Act establishes the right of a resident to be free from chemical restraints imposed for the purpose of discipline or convenience and not for treatment of medical symptoms. Moreover, a physician who attends residents in a long-term care facility is essentially an outside professional resource and the facility must assume responsibility for the quality of his or her services. This is required by sections 1819 and 1919(d)(4)(A) of the Act and these regulations at § 483.75(h)(2)(i) which require that a skilled nursing facility or nursing facility must obtain services that meet professional standards and principles that apply to professionals providing services in such a facility. These provisions clearly make the facility responsible for the quality of drug therapy provided in the facility. They do not require the facility to act in place of the physician, but they do, in accordance with the statute, hold the facility responsible for the health and safety of the resident.

Comment: A number of commenters believed that the prohibition against unnecessary drugs exceeds our statutory authority. They argued that because Congress has established very detailed requirements in the statute, HCFA is precluded from imposing additional requirements in the regulations.

Response: We disagree. First, there is no indication either in the statute or legislative history that would support this view. Second, in addition to our general rulemaking authority to prescribe regulations which may be necessary to carry out the purposes of the Medicare and Medicaid programs, there is specific authority within the provisions of nursing home reform to support the additional drug therapy requirements (see e.g., sections 1819(c), 1819(d)(4), 1819(f), 1919(c), 1919(d)(4), 1919(f)). Specifically, sections 1819(c)(1)(A)(ii) and 1919(c)(1)(A)(ii) assure a resident's right to be free from "physical and mental abuse," and any "chemical restraints imposed for purposes of discipline or convenience and not required to treat the resident's medical symptoms." Thus, Congress essentially required that nursing facilities ensure that drugs, which when improperly utilized, could be characterized as physical abuse or chemical restraints, not be prescribed unless required to treat medical symptoms. The regulations, requiring that a resident's drug regimen be free from unnecessary drugs, merely implement this specific prohibition.

Moreover, the statute provides that nursing facilities must ensure any other rights which we establish (see sections 1819(c)(1)(A)(x) and 1919(c)(1)(A)(x); see also sections 1819(d)(4) and 1919(d)(4)). As noted in the proposed and final rule, in order to assure patient health and safety, each resident's drug regimen must be free from unnecessary drugs and significant medication errors. Accordingly, a facility must ensure that drugs are not given to residents unless necessary or required to treat a specific medical condition.

Comment: Several commenters contend that the drug therapy regulations constitute Federal interference with the practice of medicine. They contend that the regulations establish rules which will require nursing facilities to exercise medical judgments that would interfere with a physician's treatment decisions.

Response: We disagree. The rules, in defining unnecessary drugs, essentially call for physicians, not nursing facilities, to make judgments as to what drugs are indicated, or needed to treat in the first instance a specific medical condition. (see 54 FR 5335). The regulations do not require nursing facilities to exercise such medical judgments in place of physicians. Rather, they require that facilities enforce Medicare and Medicaid standards for the use of drugs on residents and ensure that physicians make reasonable medical judgments that these standards have been met before prescribing drugs to the facility's residents.

Comment: One commenter expressed concern that this regulation prohibits the use of antipsychotic drugs unless an antipsychotic drug is necessary to treat a specific condition. One commenter suggested that a provision be added which requires that the specific condition for which the drug is used must be documented in the clinical record.

Response: We agree and we have modified § 483.25(1)(2)(i) accordingly. It now reads, "Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record."

Comment: Several commenters suggested changing the provision which requires residents who are taking antipsychotic drugs to receive gradual dose reductions, drug holidays, and behavioral programming. The commenters stated that although a drug

holiday is a form of dose reduction, it is not necessarily "gradual."

Others stated that drug holidays are not well defined in the regulations and that gradual dose reduction is the concept that we should capture in these regulations. Several other commenters stated that behavioral programming is not appropriate for use with demented residents because it depends on reservoirs of memory which they do not have. The key to dealing with demented residents, commenters state, is a change in the "environment," including physical environment and staff behavior.

Response: We agree with the commenters who want to delete the requirement for drug holidays, and have done so. We also agree with the commenters who would like to change the term "behavioral programming." We have changed this term to "behavioral interventions," which can include changed staff behavior toward residents but can also mean behavioral programming for those clients for which this is an appropriate intervention.

Comment: With regard to medication errors in § 483.25(m), a number of commenters wanted "significant" defined. Three commenters, representing both consumer and provider groups, specifically suggested that significant medication error rates should not exceed five percent.

Response: Regarding a facility's responsibility to prevent significant error rates, we have modified § 483.25(m) to state that facilities may not have error rates of five percent or greater. This definition has been used in interpretive guidelines by HCFA since May of 1984 (appendix N, part 2 State Operations Manual Transmittal No. 165). It is used as a measure of a facility's drug distribution system, which encompasses the entire spectrum of ordering, transcribing, dispensing, preparing, and administering drugs to residents. It has enabled HCFA to establish an outcome measure for the entire process of drug distribution in long-term care facilities. HCFA does not regulate who may prescribe, dispense, or administer drugs. HCFA does not regulate what type of drug distribution system must be used (e.g., unit dose, floor stock). HCFA has only minimal requirements for drug labeling and no requirement as to how an individual administering drugs must go about preparing drugs for administration. HCFA has left a facility free to create and manage its own system in any way it sees fit as long as it does not make "significant" medication errors and has an overall medication error rate of less than five percent.

The impact this outcome-oriented standard has had on facilities has been very positive. Historically, facilities would correct various perceived defects in the drug distribution system when they were faulted by surveyors. These corrections had little to do with medication error rates, as judged by a medication error rate study HCFA conducted in 1980 (Medication Errors in Nursing Homes and Hospitals; Am. J. Hosp. Pharm., 1982; 39:987–91). In May, 1984, when HCFA began applying this five percent error rate, facilities began to examine their systems of drug distribution, the staff that operate the systems, the pharmacies that provide the drugs, and myriad other issues in order to reduce medication error rates. Anecdotal data indicate that medication error rates are falling as a result of this policy.

Since medication errors vary in their significance (e.g., from significant errors such as a double dose of a potent cardiac drug like digoxin to a small error in the dose of an antacid like milk of magnesia), we have based sanctions on two different criteria. First, if a facility has a significant medication error, then it is sanctioned. This policy satisfies consumers, who maintain that a five percent tolerance in medication errors is too lenient and that one medication error could be disastrous for a resident. Second, a facility is sanctioned if it has an error rate of five percent or greater. This satisfies providers who maintain that there must be some tolerance of errors because all systems have some errors. The five percent limit on medication errors applies to both significant and non-significant errors. When a facility experiences a five percent or greater medication error rate, even if all errors are insignificant, it is a sign that the system has flaws that may eventually lead to a significant, perhaps disastrous error.

A significant medication error is judged by a surveyor, using factors which have been described in interpretive guidelines since May 1984. The three factors are: (1) Drug category. Did the error involve a drug that could result in serious consequences for the resident? (2) Resident condition. Was the resident compromised in such a way that he or she could not easily recover from the error? (3) Frequency of error. Is there any evidence that the error occurred more than once? Using these criteria, an example of a significant medication error might be as follows: A resident received twice the correct dose of digoxin, a potentially toxic drug. The resident already had a slow pulse rate, which the drug would further lower. The error occurred three times last week.

Summary of Changes to § 483.25

As a result of our evaluation of comments, in addition to minor editorial changes, we are making the following changes:

- In § 483.25(d), we are removing paragraph (d)(1) as redundant and redesignating the following two paragraphs.
- In § 483.25(f), we are clarifying terminology to emphasize that the requirements concern mental and psychosocial functioning and to require treatment and services to correct the assessed problem.
- In § 483.25(k), we have revised "podiatric" care to "foot" care to remove emphasis on who may provide the proper treatment.
- In § 483.25(l)(1), we define unnecessary drug and add a provision that each resident's drug regimen must be adequately monitored. In paragraph (1)(2)(a), concerning antipsychotic drugs, we added a requirement that the need for an antipsychotic drug be diagnosed and documented in the clinical record. We also deleted, as suggested, the requirement for drug holidays.
- In § 483.25(m), we require that facilities ensure medication error rates are below five percent.

Section 483.28 Nursing Services—Skilled Nursing Facilities and Section 483.29 Nursing Services—Intermediate Care Facilities

These two sections contain requirements effective through September 30, 1990. They were established in the February 2, 1989 rule, which, initially was to be effective August 1, 1989. As described elsewhere in this preamble, the effective date of the rule is now October 1, 1990. Accordingly, we are deleting them as out-of-date.

Section 483.30 Nursing Services

Summary of Provisions

Section 483.30 specifies that the facility must have sufficient nursing staff to provide nursing and related services to attain or maintain the highest practicable physical, mental and pyschological well-being of each resident, as determined by resident assessments and individual plans of care. Sections 483.30 (a) and (b) specify need for sufficient staff and for a registered nurse.

Section 483.30(c) provides for waiver of the requirement that a facility provide a registered nurse for at least 8 hours a day, 7 days a week, and licensed nurses

on a 24-hour basis to the extent that a facility is unable to meet these requirements. Section 483.30(c) also specifies that the State agency granting a waiver of the requirements provides notice of the waiver to the State long term care ombudsman and the protection and advocacy system in the State for the mentally ill and mentally retarded.

Section 483.30(d) provides for waiver of the requirement to provide service of a registered nurse, for more than 40 hours a week. Sections 483.30 (c) and (d) also specify that the facility that is granted such a waiver notifies residents of the facility and members of their immediate families.

Comments and Responses

Comment: Several commenters objected to the requirement that facilities requesting waivers must demonstrate that they are offering wages at the community prevailing rate for nursing facilities.

Response: The words "offering wages at the community prevailing rate for nursing facilities" are taken verbatim from sections 1819(b)(4)(C) and 1919(b)(4)(C) of the Act. We therefore are not altering the requirement.

Comment: Several commenters suggested that HCFA has not provided enough regulatory guidance to facilities on the exact criteria that will be used in implementing the waiver requirements.

Response: HCFA is currently in the process of developing a proposed rule to address these issues. There will be an opportunity for public comment on the proposed criteria before the final rule is developed.

Summary of Changes to § 483.30

We are making the appropriate changes to § 483.30(c) as required by OBRA '90 to specify that a State may waiver 24-hour nursing service if the facility is unable to meet the requirements of paragraphs (a)(2) and (b)(1) of this section.

We are adding § 483.30(c)(6) as required by section 4801(e)(5)(D)(iv) of OBRA '90 to specify that the State agency granting a waiver of the requirements provides notice of the waiver to the State long term care ombudsman and the protection and advocacy system in the State for the mentally ill and mentally retarded.

We are adding § 483.30(c)(7) as required by section 4801(e)(5)(D)(v) of OBRA '90 to specify that the nursing facility that is granted such a waiver by a State notifies residents of the facility and members of their immediate families

We are adding § 483.30(d)(iv) as required by sections 4801(e)(5)(D)(v) and 4008(e)(v) of OBRA '90 to specify that the facility that is granted a waiver notifies residents of the facility and members of their immediate families.

We are also making minor editorial changes to delete unnecessary dates.

Section 483.35 Dietary Service

Summary of Provisions

Section 483.35 requires that a facility must provide each resident with a nourishing palatable, well-balanced diet including modified and specially prescribed diets.

Section 483.35(a) requires that a facility must employ a qualified dietitian either full-time, part-time, or on a consultant basis.

Section 483.35(b) requires that a facility must employ sufficient support personnel competent to carry out the functions of the dietary services.

Section 483.35(d) specifies the requirements of the facility for food preparation and service for each resident.

Section 483.35(f) specifies the facility must provide each resident at least three meals daily, at regular times comparable to normal mealtimes in the community.

Comments and Responses

Comment: There were approximately 40 comments addressing the dietary services requirements. The majority of these comments opposed staffing qualifications at § 483.25 (a)(1) and (a)(2). Many of these commenters opposed the general personnel qualifications which allowed a dietitian to be qualified on the basis of education, training, or experience. They opposed this provision for the following reasons:

- Nonspecific requirements could lead to qualifying individuals without required preparation.
- There is a correlation within certain States between the levels of dietary deficiency among residents and the State's dietitian qualifications requirements.
- Dietitians are educated in the fields of physiology and disease processes, thus they are able to make appropriate recommendations relative to diet to physicians as needed.
- A general definition of dietitian opens the way for health care providers to utilize individuals who may have marginally related educational background such as certification as dietary managers or dietary technicians with inadequate skills in identifying nutrition care problems and appropriate nutrition care intervention.

Response: We recognize that section 4801(d) of OBRA '90 provides, in part, that any regulation promulgated by the Secretary after OBRA '87 with respect to dietary services shall include requirements that are at least as stringent as the requirements in effect prior to the enactment of OBRA '87. We believe, however, that the new rules are at least as stringent as those in effect prior to OBRA '87. In fact, the United States District Court for the District of Columbia specifically concluded that the standards appearing in the final rule are at least as stringent as those in existence prior to the enactment of OBRA '87. See *Gray Panthers Advocacy Committee, et al.* v. *Sullivan,* Civil Action No. 89–0605–NHJ (D.D.C. Sept. 17, 1990). Our objective in these rules is to focus on outcome as recommended by the IoM report. With the previous regulation, there was no assurance that each resident was receiving nutritious or quality meals. Under these rules, since high quality services are the standard, this weakness has been alleviated.

Accordingly, current regulations at 42 CFR 405.1101 allow individuals other than a qualified dietitian to manage or direct the dietary services whereas the final rule at § 483.35(a) requires the facility to employ a qualified dietitian either full-time, part-time, or on a consultant basis. We have retained the language which permits an individual to qualify as a dietitian either through registration by the Commission on Dietetic Registration of the American Dietetic Association (ADA) or on the basis of education, training, or experience in identification of dietary needs, planning, and implementation of dietary programs because we believe that there are some individuals not registered by the ADA who are appropriate for employment as dietitians. However, the survey guidelines contain a list of the specific experience requirements that persons not registered by the ADA must meet, a number of which are specific to the needs of geriatric and physically impaired persons and to health care institutional settings. Additionally, the objective of the final rule is to require that the dietetic services assure that the meals meet the nutritional and special dietary needs of each resident and that services meet "professional standards of quality." This is in keeping with the emphasis of the final rule which focuses on outcome, not process, thus avoiding undue reliance on staff qualifications. Also, we have added requirements to the regulation within the resident assessment section at § 483.20(b)(2)(v)

to assure that dietary issues are considered.

Comment: A number of commenters noted that based upon the requirement at § 483.75(i)(2) (now § 483.75(g)), "professional staff must be licensed, certified, or registered in accordance with applicable State laws." The general dietitian definition published in the Federal Register would not meet this requirement.

Response: The statement, "on the basis of education, training, or experience," does not relieve the facility from adhering to State and local laws as stated at § 483.75(b) which requires compliance with Federal, State and local laws, regulations and codes, and with accepted professional standards and principles that apply to professionals providing services in such a facility. If State licensure law requires higher personnel qualifications for dietitians than are established in this regulation, those qualifications must be met.

Comment: Commenters recommended modifying § 483.35(a)(2) to create a new dietary position in the regulations. This individual would be a dietary service supervisor, who is:

- A dietitian as identified in § 483.35 (a)(1) or (a)(2); or
- A dietitian technician registered or eligible for registration with the Commission on Dietetic Registration of the American Dietetic Association; or
- A certified dietary manager or one who is eligible with the Certifying Board for Dietary managers; or
- A graduate of a Dietary Managers Association approved dietary manager training program; or
- A graduate of a State approved course that provided 90 or more hours classroom instruction.

Response: In keeping with our emphasis on proper outcomes, we decided not to include specific qualifications for dietetic service supervisor where that individual is other than a dietitian. As noted below, however, we have strengthened the requirement for consultation where the dietetic service supervisor is not a dietitian.

Comment: Commenters recommended that we also define a qualified as one who has a baccalaureate degree with major studies in food and nutrition, dietetics, or food service management and has one year of supervisory experience in the dietetic services of a health care institution and participates annually in continuing dietetic education.

Response: We do not believe this definition for dietitian should be added since the current definition provides sufficient latitude for such individuals to be employed as dietitians if they have sufficient experience.

Comment: Section 483.35(a)(1) requires that "if a dietitian is not employed full-time, the facility must designate a person to serve as the director of food service." Several commenters opposed the deletion of the requirement that the director of food services be a qualified dietitian and, if not, receive frequent consultation from one so qualified. One commenter recommended the establishment of qualifications for the director of food service to be at a minimum of a 90-hour training course.

Response: Inasmuch as we have required every facility to retain a qualified dietitian on a part-time, full-time, or consultant basis, we do not believe it would impose an additional burden on the facility to require that when the facility designates an individual (who is not a qualified dietitian) to serve as director of food service he or she receives consultation from a qualified dietitian. Thus, we revised § 483.35(a)(1) to read: "If a qualified dietitian is not employed full-time, the facility must designate a person to serve as the director of food service who receives frequent consultation from a qualified dietitian." We do not believe it is necessary to specify completion of a 90-hour training course or other specific requirements.

Comment: One commenter recommended we modify § 483.35(b) to state: "There should be sufficient dietary staff on duty for 12 hours per day."

Response: The fundamental basis for having dietary staff on duty 12 hours per day was to prevent a facility from hiring dietary staff for only one eight-hour shift and compressing all three meals into that shift. We have chosen not to continue this requirement because dietary staff coverage over a 12-hour period does not necessarily equate with a meal span (from breakfast to dinner) of 12 hours. Because time is necessary for preparation and clean-up, 12-hour coverage by dietary staff could equate to a meal span (from breakfast to dinner) of substantially less than 12 hours. Instead, we have relied on a standard at § 483.35(f) which limits the period of time between an evening meal and breakfast to 14 hours. Thus, a 10-hour meal span from breakfast to dinner is required. We believe this standard is consistent with the regulation's emphasis on quality of care, rather than on the mere capacity to provide such care. By limiting the period of time between meals, a facility is required to provide meals at appropriate times throughout the day. Such a requirement is in keeping with the objective of the final rule, which is to look at the care actually received by each resident, and thus to prevent any undue reliance on staff qualifications as an assurance that high quality care is in fact rendered to nursing home patients.

Comment: One commenter asked us to specify the number of choices that must be offered to residents in response to the requirement that each resident receives and the facility provides substitutes offered of similar nutritive value to residents who refuse food served.

Response: We believe the commenter's recommendation is unduly restrictive. We chose not to enumerate the number of choices the facility should provide but expect that a reasonable effort should be made to accommodate the residents.

Comment: One commenter suggested that we substitute at § 483.35(f)(3) "snack will be available" in lieu of "must offer" in the requirement that provides that "the facility must offer snacks at bedtime daily." Another recommended adding at the end of the statement, "unless medically contraindicated."

Response: The availability of snacks is not sufficient since the condition of the residents may not allow them to obtain the snacks. However, offering the snacks provides an opportunity for the residents to exercise choice by accepting or declining them. The resident's plan of care would provide the necessary constraints, thus adding "unless medically contraindicated" would be unnecessary. Because we want to assure that care planners recognize the need to deal with these issues, we have added a sentence to § 483.20(d)(1) that makes this point.

Comment: Section 483.35(f)(2) provides that there must be no more than 14 hours between a substantial evening meal and breakfast the following day except as provided in § 483.35(f)(4) that specifies: When a nourishing snack is provided at bedtime, up to 16 hours may elapse between a substantial evening meal and breakfast the following day if a resident group agrees to this meal span. A commenter opposed allowing the 16 hour time span.

Response: We did not accept this comment because the regulation only allows a 16 hour time span when a nourishing snack is served and when the resident group agrees. Thus, the flexibility here is only at the discretion of the residents.

Summary of Changes to § 483.35

As a result of our evaluation of comments we are adding a requirement

to § 483.35(a)(1). We now require if a qualified dietitian is not employed full time the person designated to serve as director of food service must receive frequently scheduled consultation from a qualified dietitian.

Section 483.4 Physician Services

Summary of Provisions

Section 483.40 specifies that a physician must personally approve in writing a recommendation that an individual be admitted to a facility, and that each resident must remain under the care of a physician, and if possible, designate a personal physician.

Section 483.40(a) specifies that the facility must ensure medical supervision of each resident by a physician.

Section 483.40(b) specifies that the physician must review the resident's total program of care at each visit; write, sign and date progress notes; and sign all orders.

Section 483.40(c) specifies that the physician must see the resident at least every 30 days for the first 90 days after admission and at least once every 60 days thereafter.

Section 483.40(e) specifies when a physician may delegate tasks to a physician assistant, clinical nurse specialist, or nurse practitioner.

Comments and Responses

Comment: We received a number of general comments regarding the physician services portion of the regulations. Some indicated that the regulations appear to restrict the physician's professional judgment, resulting in a general decrease in physician control of the resident's medical regimen. Another suggested that HCFA convene an emergency conference with providers, consumers, and leading specialists in geriatrics on ways to increase the quantity and quality of physician involvement in nursing homes. Others asserted that the nursing facility should not be held accountable for lack of compliance with the regulations by the physician, over whom the facility has no control. One commenter suggested that the introductory statement, which requires that a physician "personally approve" an admission recommendation, be clarified to indicate that this merely requires the physician's written approval, not the physician's physical presence at the time the individual is admitted.

Response: The commenters who felt that the regulations diminish physician control of the resident's medical regimen did not offer any specific examples to support their contention. Such a result was not the intent of the physician services requirements, and we do not believe that the regulations will have this effect in practice. Regarding the suggestion for an emergency conference on physician services in nursing homes, we appreciate the need to encourage the increased involvement of physicians in this setting, an aim which was reflected in the Institute of Medicine report on nursing home regulation. With this in mind, we have attempted, where possible, to develop requirements that would facilitate physician involvement by being less burdensome (e.g., allowing a variance of several days in the required visit schedule) and more flexible (e.g., permitting increased delegation of tasks to physician extenders) than the requirements that they replaced. While convening such a conference may prove useful after the regulations have been fully implemented, we believe that there should first be time to assess the impact of these new requirements on physician activity in the nursing home setting. With regard to the issue of holding the facility accountable for the compliance of the physician, we reiterate the point made in the preamble to the February 2 final rule (54 FR 5340): the nature of the current survey and certification process is such that our enforcement mechanism is primarily through the facility itself rather than through the individual practitioners that serve the facility's residents. We would welcome suggestions on ways to ensure greater direct accountability by individual practitioners, consistent with the need to encourage greater involvement by physicians in the nursing home setting. Finally, we are accepting the comment which requested that the introductory statement be clarified, and are revising the statement to require that the physician "personally approve in writing" a recommendation to admit an individual.

Comment: One commenter expressed general support for the provision in § 483.40(a) that the facility ensure medical supervision of every resident. Two others asked that we restore the previous SNF requirement for a medical evaluation/physicial examination within 48 hours of admission, unless performed no more than 5 days prior to admission.

Response: We believe that the requirement in the regulations (§ 483.20) for a comprehensive resident assessment will subsume the function of the previous SNF requirement, i.e., the compilation of relevant information on the residents medical status within a relatively short time after admission occurs.

Comment: One commenter agreed with the provisions of § 483.40(b) regarding physician visits as proposed. Two commenters interpreted the provision as requiring the physician himself or herself to review the care plan, write progress notes, and sign orders at each visit, which would conflict with regulations at § 483.40 (c)(4) and (e)(2) by not allowing a physician extender to perform these functions under delegation from the physician. Another commenter suggested that the regulations add a requirement for the facility to provide adequate, comfortable, and private space for examinations and treatment. One commenter suggested that § 483.40(b)(3) be revised to require the physician to date as well as sign all orders, and another indicated that the regulations should require a mandatory reassessment any time a physician orders a physical or chemical restraint.

Response: The commenters who believe that this provision precludes the physician from delegating these functions misunderstand the provision at § 483.40(e)(2). In prohibiting the delegation of any tasks which the regulations specify must be performed personally, § 483.40(e)(2) refers only to those provisions in the regulations text that actually use the word "personally." Since the text of § 483.40(b) does not say that the physician must "personally" review care plans, write progress notes, or sign orders, these functions can be delegated under § 483.40(e). As for the need to provide adequate and private space for examinations and treatment, the regulations already address this. Section 483.10(e)(1) requires personal privacy in several areas, including medical treatment, and § 483.70(c)(1) requires the facility to have sufficient space to provide residents with needed health services. We are accepting the suggestion to revise § 483.40(b)(3) to require that the physician sign and date all orders. With regard to mandatory reassessment of orders for physical and chemical restraints, we are currently developing a separate proposed rule that will consider this issue.

Comment: One commenter was not sure whether § 483.40(c) concerning frequency of physician visits requires the physician to make an actual face-to-face visit to the resident or merely review the resident's chart on site; however, another commenter correctly interpreted the wording that the resident "must be seen" by the physician as requiring an actual, face-to-face visit, and expressed support for this requirement. One commenter suggested the regulation should specify that a

resident must be seen by the physician at the time of admission.

Response: As indicated in the preamble to the February 2, 1989 final rule (54 FR 5341), the wording of the regulation, which states that the resident "must be seen" by the physician, requires an actual, face-to-face contact. However, we are not requiring that the resident be seen by the physician at the time of admission since the decision to admit an individual to a nursing facility (whether from a hospital or from the individual's own residence) generally involves physician contact during the period immediately preceding the admission. Further, we would note that the resident assessment requirement at § 483.20(a) does require the facility to have, at the time of admission, physician orders for the resident's immediate care.

Comment: Several commenters expressed support for the added flexibility introduced by allowing the 10-day variance in the required physician visit schedule (although some expressed a continued preference for wording the schedule in terms of months rather than days). Two commenters suggested that the maximum allowable variance should be reduced from 10 to 5 days. One commenter objected to allowing the variance in NFs, where 90-day visit intervals apply.

Response: We believe that the variance provides needed flexibility in implementing the required physician visit schedule, and that it is appropriate in the NF setting as well as in SNFs. We also believe that it would be less feasible, in attempting to provide this flexibility, to word the visit schedule requirement in terms of months rather than days. For example, requiring a visit "every 2 months" rather than "every 60 days" could result in significantly more than 60 days elapsing between visits. In choosing 10 days as the maximum length of the variance, we modeled this provision after section 1903(g)(6)(C) of the Act, which allows a similar 10-day variance for the completion of required physician certifications and recertifications.

Comment: Several commenters supported the provision allowing alternate visits to be delegated to physician extenders (PEs), while one commenter opposed it. One commenter indicated that PEs should be allowed to perform this function independently of the physician, while another expressed concern that there should be adequate physician supervision of any delegated tasks.

Response: As indicated at 54 FR 5342 of the preamble to the February 2, 1989 final rule, we believe that to the extent possible, the regulations should allow for the effective utilization of PEs in the nursing home setting. However, we also believe that the physician continues to exercise supervision in this area, in keeping with the statutory requirement (at section 1819(b)(6)(A) of the Act) for the medical care of every SNF resident to be provided under the supervision of a physician. Therefore, we are leaving this provision unchanged for SNFs. However, we are revising the provisions that govern the delegation of physician tasks in NFs, to reflect the recent amendment of section 1919(b)(6)(A) of the Act, as discussed below.

Comment: Some commenters indicated that requiring physician visits every 90 days in NFs is too frequent, and will increase the burden on rural physicians. Another indicated that 90-day intervals are too infrequent, and recommended restoring the previous 60-day requirement, with an exception when the physician documents that this frequency is not necessary. Another commenter supported the 90-day visit interval. Two commenters suggested that, in keeping with the OBRA '87 emphasis on uniform requirements for Medicare and Medicaid facilities, the physician visit schedule should be made the same for SNFs and for ICFs/NFs; they noted that under the final rule, the visit schedules for SNFs and for ICFs/NFs diverge after the first 90 days. Two other commenters suggested that the frequency of the visit schedule be based on the status of the resident (e.g., SNF-level vs. ICF-level) rather than that of the facility. Another indicated that the regulations should require a physician to visit more frequently than the prescribed intervals when a resident's condition warrants it.

Response: We note that under OBRA '87, the distinction between SNFs and ICFs under the Medicaid program cease, effective October 1, 1990, and all such facilities will be categorized as NFs. Therefore, we do not believe that distinctions between the SNF- and ICF-level status of residents should serve as the basis for determining the applicable physician visit schedule. Further, we believe that the creation of a single facility category under Medicaid, which will include many facilities that have been participating in the Medicaid program as SNFs, supports the view of the commenters who advocate a uniform-physician visit schedule for both Medicare SNFs and Medicaid NFs. We believe that this change, plus the generally increasing acuity of nursing home residents, argues in favor of using the more stringent SNF visit schedule uniformly in Medicaid NFs as well as Medicare SNFs, and we are revising § 483.40(c) of the regulations to accomplish this. With regard to requiring a physician to visit more frequently when a resident's condition warrants it, we note that the regulations require that residents be seen by a physician "at least" at the prescribed intervals. The intent of this wording is that the physician should make visits in excess of the prescribed minimum when warranted by the resident's medical needs, and we would expect that surveyors will ascertain whether such additional visits are, in fact, made when these circumstances apply.

Comment: Two commenters expressed general support for the idea of allowing physician delegation of tasks to PEs, while one opposed it. Several commenters urged the addition of clinical nurse specialists (CNSs) to the categories of personnel to whom tasks can be delegated, citing section 4218 of OBRA '87, which allows CNSs to perform the required certifications and recertifications for Medicaid nursing home patients. One commenter, though supporting the general idea of physician delegation of tasks to PEs, opposed the provision in the regulations which would permit a facility to set its own policy on delegation that is more restrictive than Federal or State policies.

Response: With regard to SNFs, we are revising § 483.40(c) and (e) to extend the applicability of the physician delegation provision to individuals who are licensed by the State as CNSs, subject to the same requirements that apply to the other categories of personnel included in this provision. We are leaving unchanged the provision allowing a facility to set its own policies regarding physician delegation. We believe it is appropriate to allow the facility some measure of discretion in this area. We would also note that this provision appeared verbatim in the proposed rule that was published on October 16, 1987, and no objections to it were expressed in the large volume of comments that we received on that proposed rule.

The requirements for physician services in NFs are affected by a recent amendment to section 1919(b)(6)(A) of the Act, which serves as the statutory basis for these requirements. Prior to its amendment, this section of the Act was identical to section 1819(b)(6)(A) (for SNFs) in requiring that each resident's care be provided under the supervision of a physician. However, section 4801(d) of OBRA '90 has created an alternative to physician supervision in NFs, by giving States the option of permitting supervision by "* * * a nurse practitioner, clinical nurse specialist, or physician assistant who is not an

employee of the facility but who is working in collaboration with a physician * * *." This means that the statutory requirement for physician supervision in NFs, as well as the full range of regulatory requirements on physician services in NFs that flows from this statutory requirement, can now be satisfied when performed by the types of physician extenders specified in the law, if a State so elects. Therefore, we are adding a new paragraph (f) "Performance of physician tasks in NFs," to this section to indicate that, at State discretion, any physician requirement in a NF (including tasks which the regulations specify must be performed personally by the physician, such as physician visits and admission recommendations) may also be satisfied when performed by the types of physician extenders specified in the law, working in collaboration with a physician. (In this context, we intend to use the definition of "collaboration" contained in section 1861(aa) (4) of the Act, which will be implemented in a separate set of regulations. When those regulations are published, we will insert a cross-reference to them in § 483.40(f).)

In view of our broad objective of making requirements for SNFs and NFs as similar as possible, it may be asked whether these new provisions should be extended to SNFs as well as NFs. Congress, however, in amending the NF provision at section 1919(b)(6)(A) of the Act, declined to make a similar amendment to the corresponding SNF provision at section 1819(b)(6)(A), thus leaving unchanged the existing requirement for physician supervision in SNFs. Therefore, we are leaving intact the existing provisions on physician delegation of tasks contained in paragraph (e) of this section, but we are revising that paragraph to clarify that it now applies only to Medicare SNFs. This means that the extent to which physician services are delegated to physician extenders in SNFs will continue to be determined by the provisions of § 483.40(e), while the extent to which these services are performed by physician extenders in NFs will be determined by the individual States under new § 483.40(f).

Summary of Changes to § 483.40

As a result of our evaluation of comments, we are making the following changes in addition to minor technical or editorial versions:

- In the introductory material in § 483.40, we clarify that the physician's approval of a recommendation to admit a person must be in writing.
- In § 483.40(b)(3), we add the requirement that the physician must date all orders.
- In § 483.40(c), we eliminate the frequency of visit interval applicable to Medicaid NFs and apply the requirements, formerly applicable to SNF residents, to all long term care facilities.
- In § 483.40 (c) and (e), we add clinical nurse specialist as an individual to whom a physician may delegate tasks. We also clarify that paragraph (e) applies only to physician services in SNFs.
- In § 483.40(f), we are adding a provision which deals with performance of physician services in NFs.

Section 483.45 Specialized Rehabilitative Services

Summary of Provisions

Section 483.45 specifies that facilities that provide rehabilitative services must either furnish them directly or arrange to obtain them from a provider of rehabilitative services. The rule indicates in the introductory statement that a facility must provide rehabilitative services to every resident it admits and includes examples of rehabilitative services. Section 483.45 also includes requirements dealing with provision of services and qualifications.

Comments and Responses

Comment: Many commenters objected to requiring that facilities provide rehabilitative services to all residents and recommended that these services be provided only to patients who need them.

Response: We agree that these services should be provided only to patients who need them, and we indicated in § 483.45(a) of the February 2 rule that these services are to be provided when they are required in a resident's comprehensive plan of care. To remove ambiguity, we have removed the introductory statement that appeared to conflict with § 483.45(a) and incorporated the examples into § 483.45(a).

Comment: A number of commenters suggested that the section on specialized rehabilitative services be expanded to include mental health services. Some of them suggested that the term "psychiatric rehabilitation" be used in this section to describe the services to be provided.

Response: We agree with the commenters that these services are required under sections 1819(b)(4) and 1919(b)(4) of the law and, in the February 2 rule we included them under the quality of care section. We also agree that the specialized rehabilitative services section should be revised to reflect these services. The OBRA '90 amendments to these sections confirm our view. Therefore, we have added the words rehabilitative services for mental illness and mental retardation to the list of services in this section.

Comment: A few commenters stated that HCFA should only require specialized rehabilitative services to the extent that the services are otherwise covered in the State plan.

Response: Specialized rehabilitative services are considered a nursing facility service and, thus, are included within the scope of facility services. They must be provided to facility patients who need them even when the services are not specifically enumerated in the State plan. That is, such services are covered NF services and eligible for Federal Financial Participation when provided to Medicaid residents of an NF. Therefore, no change has been made in response to these comments.

Comment: A few commenters asked that we clarify whether a fee can be charged for rehabilitative services in order to insure adequate reimbursement to the facility.

Response: No fee can be charged to a Medicaid recipient for specialized rehabilitative services because they are covered facility services.

Comment: Two commenters indicated that HCFA should require that rehabilitative services be provided to every patient.

Response: We do not believe that these services should be provided to any patient who does not need them, and we believe the deletion of the introductory statement referred to earlier clarified the rule to reflect this policy.

Comment: One commenter stated that HCFA should not require that every facility provide specialized rehabilitative services.

Response: A facility does not have to provide rehabilitative services if it does not have residents who require these services. If a resident develops a need for these services after admission, the facility must either arrange to provide the services, or, where appropriate, arrange to transfer the patient to a facility that can provide the services.

Comment: One commenter suggested that we include a reference to the transfer requirements under § 483.12 for facilities that are unable to meet a resident's rehabilitative service needs.

Response: This is the appropriate reference for facilities that must transfer patients to obtain needed services. We have not added a cross-reference in this section because we do not believe that it

is necessary; facilities should have an awareness of the transfer requirements which may need to be met in a number of situations.

Comment: One commenter suggested that we add respiratory care as an example of rehabilitative services, an another suggested that we add audiology as an example.

Response: We have not added these examples because we believe that the examples already included are sufficient; this group of examples is not intended to be an inclusive list of services.

Comment: One commenter suggested that we delete the term "specialized" since it seems unnecessary.

Response: We have not deleted this term. It serves to differentiate these services from general rehabilitative services provided by nurses.

Comment: One commenter suggested that we require under § 483.45(b) that qualified personnel be certified or licensed.

Response: All professional staff must be licensed, certified, or registered in accordance with applicable State laws as required under § 483.75(g)(2).

Comment: One commenter requested that we link rehabilitative services to the multidisciplinary assessment and the quality of care and quality of life requirements. This commenter also suggested that we require adequate staff to support professional rehabilitative service providers. Finally, it was suggested we retain our current requirements for a safe and adequate space to provide these services.

Response: All services are to be considered in the quality of care and quality of life requirements; we do not believe it is necessary to cross refer every service to these requirements. We have not added specific requirements relating to space because we believe that the requirement at § 483.70(c)(1) already requires sufficient space for health services. As for support personnel we believe that under an outcome approach to regulation it is preferable to allow facilities maximum flexibility in these matters.

Comment: Two commenters requested that we reinstate previous requirements relating to progress notes and personnel qualifications.

Response: We do not believe that requirements concerning progress notes are appropriate in an outcome-oriented regulation. The personnel qualifications requirements are now in § 483.75(g)(2).

Summary of Changes to § 483.45

As a result of our evaluation of comments we are making the following changes:

- We are deleting the introductory material of § 483.45 and adding corresponding material to paragraph (a). We also list rehabilitative services for mental illness and mental retardation in the list of examples of specialized services.

Section 483.55 Dental Services

Summary of Provision

Section 483.55 requires that facilities assist residents in obtaining routine and emergency dental care, and ensure that a dentist is available, and if necessary, assist residents in making appointments and in arranging for transportation to and from the dentist's office.

We received comments expressing a variety of concerns about the provisions of the final regulations contained in § 483.55 (a), advisory dentist, and (b), outside services. These paragraphs were to be in effect only during the period prior to October 1, 1990. Since Congress has now imposed a moratorium on implementing any portion of the final regulations prior to October 1, 1990, the concerns expressed about these provisions have been rendered moot, and we are deleting § 483.55 (a) and (b) from the regulations. We also received comments regarding the possible prospective application, as of October 1, 1990, of individual provisions contained in these two sections, as discussed below.

Section 483.55(c) (redesignated to § 483.55(a) in this final rule) specifies that an SNF must provide or obtain from an outside resource routine and emergency service to meet the needs of each resident, and may charge an additional amount for the services.

Section 483.55(d) (redesignated to § 483.55(b) in this final rule) specifies that an NF must provide or obtain from an outside resource, routine dental services (to the extent covered under the State plan) and emergency dental services for each resident.

Comments and Responses

Comment: Several commenters asked why the requirement for an advisory dentist (in regulations at § 405.1129(a) only through September 30, 1990) is discontinued and suggested retaining the requirement beyond that date.

Response: The elimination of the advisory dentist requirement, effective October 1, 1990, is part of the dental services regulations overall shift in emphasis effective on that date. Prior to October 1, 1990, under the SNF regulations a facility must assist its residents in obtaining dental services on their own; thus, making it necessary to specify the involvement of an advisory dentist in order to ensure that facility staff receive appropriate advice and consultation on dental issues. Effective October 1, 1990, however, facilities are directly responsible for the dental care needs of their residents, as specified in OBRA '87. (In addition, § 483.20(b)(2)(ix) specifies a resident's dental condition as one of the required elements of the comprehensive resident assessment.) Effective October 1, 1990, when the facility assumes direct responsibility for the dental care needs of its residents, it is responsible as well for seeing that such services are furnished in accordance with accepted professional standards and principles (see § 483.75(b)). Therefore, we believe that a separate, prescriptive requirement for obtaining professional consultation and advice on dental matters is no longer necessary after October 1, 1990.

Comment: Some commenters noted that the provisions of § 483.55(b) (1) through (4) state that they are in effect only after October 1, 1990. They inquired whether these service requirements and those listed in § 405.1129(b) of the SNF regulations (assistance with arranging appointments and transportation), which also are not in effect as of October 1, 1990, will be required after October 1, 1990.

Response: Based on the original effective date of October 1, 1989, contained in the February 2, 1989 rules, these requirements were intended to clarify what service requirements apply during the interval October 1, 1989 to October 1, 1990. We did not intend to discontinue the requirements concerning assistance in making appointments, arranging for transportation and referring patients with lost or damaged dentures. These requirements were intended to remain in effect after October 1, 1990, and we are revising the dental services regulations that become effective on October 1, 1990, to include an explicit reference to them.

Comment: One commenter expressed support for the introductory statement's requirement that the facility assist residents in obtaining routine and 24-hour emergency dental care. Several commenters noted that the wording of § 483.55(c)(2), which permits SNFs to charge an additional amount only for emergency dental services, does not appear consistent with the text at the end of section 1819(b)(4)(A) of the Act, which refers to routine as well as emergency dental services. Others suggested that the wording should be made more similar to that of the law by stating that the SNF "is not required to provide or arrange for" these services without additional charge.

Response: We agree with the commenter that the wording is not consistent with the corresponding portion of section 1819 of the Act, and we are revising it to conform to that provision. Due to removal of outdated material, the change appears at new § 483.55(a)(2).

Comment: Some commenters expressed concern with § 483.55(d)(1) (redesignated to § 483.55(b)(1) in this final rule) which requires Medicaid NFs, effective October 1, 1990, to furnish routine dental services, but only to the extent that such services are covered under the Medicaid State plan. Several commenters requested clarification regarding the facility's financial responsibility for dental services generally, and specifically with regard to routine dental services that are not covered in the State plan. Another commenter suggested that the regulations be revised to include the qualification contained in the law, that services are only required to the extent that they are needed to fulfill the resident's plan of care.

Response: We believe that section 1919(b)(4)A)(vi) of the Act clearly specifies that NFs are responsible for providing or arranging for routine dental services only to the extent that such services are covered under the Medicaid State plan, and that the wording of the new § 483.55(b) reflects this. Similarly, the wording of the new § 483.55(a), as we are revising it, will make clear that Medicare SNFs will be allowed to impose an additional charge for furnishing routine and emergency dental services. With regard to the comment on the plan of care, we agree that sections 1819(b)(4)(A)(vi) and 1919(b)(4)(A)(vi) of the Act make the facility responsible for providing dental services only to the extent that they are needed to fulfill the resident's plan of care. However, as described in sections 1819(b)(2) and 1919(b)(2), the objective of the plan of care is to "attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident * * *" Further, the operative wording in the dental services clause in the law itself refers to the provision of dental services "to meet the needs of each resident", which we believe is consistent with the stated objective of the plan of care. Consistent with the statute, this wording is already reflected in the regulations describing dental services requirements for NFs, and we are adding it to the regulations for SNFs.

Summary of Changes to § 483.55

We are deleting material that is out-of-date and pertains to services prior to October 1, 1990. This required editorial revisions and redesignation of paragraphs.

As a result of our evaluation of comments we are making the following changes:

- In § 483.55(a)(2) (redesignated from § 483.55(c)(2)), we are conforming the requirement concerning allowable charges to the patient for dental services to the wording in section 1819(b)(4)(A) of the Act.
- We are revising § 483.55(a)(3), (a)(4), and (b) to reflect changes made as a result of OBRA '87 provisions.

Section 483.60 Pharmacy Services

Summary of Provisions

Section 483.60 requires a facility to provide routine and emergency drugs and biologicals to its residents.

Section 483.60(a) concerning methods and procedures and § 483.60(c) concerning pharmaceutical services committee are deleted since they were only intended to be in effect until October 1, 1990. Section 483.60(b) has been redesignated as § 483.60(a), and paragraphs (d) through (g) have been redesignated as (b) through (e), respectively.

Section 483.60(e), redesignated as § 483.60(c) requires a pharmacist to conduct a monthly drug regimen review and report any irregularities to the attending physician and director of nursing.

Section 483.60(f), redesignated as § 483.60(d), requires the facility to label drugs and biologicals in accordance with accepted professional principles.

Comments and Responses

Comment: Eight commenters were concerned about a requirement of the pharmacist-conducted drug regimen review. It stated that reports must be sent to the attending physician or the director of nursing or both. Commenters objected, saying that all reports should go to both.

Response: Commenters have convinced us that what is important to the physician is always important to the director of nursing and vice-versa. Therefore, we have modified the regulation to require that drug regimen review reports go to both the attending physician and the director of nursing.

Comment: Five commenters were concerned because this requirement stated that facilities are responsible for labeling drugs. The commenters thought that the regulations should state that the pharmacies are responsible for this task.

Response: Ultimately, a facility is responsible for the quality and timeliness of all the services received by its residents (see § 483.75(h)), but the commenters are correct that it is also a pharmacy responsibility to label drug containers accurately. We have therefore modified redesignated § 483.60(d) to state, "Drugs and biologicals used in a facility must be labeled in accordance with currently accepted professional principles." This will impose currently accepted labeling requirements on facilities even though the pharmacies will be immediately responsible for accomplishing the task.

Comment: Six commenters expressed concern about the requirement that all drug labels contain an expiration date. Their concern stems from the fact that at least one State Board of Pharmacy does not require expiration dates on drug labels if it is anticipated that a drug will be consumed within a short period of time (e.g., 7 days).

Response: Formerly, the regulations required expiration dates "when applicable". We deleted "when applicable" from the February 2 final rule because the vast majority of drugs approved by the Food and Drug Administration must have expiration dates on the manufacturer's container (see 21 CFR 211.137). We do not wish to supersede State Law in matters of drug labeling. Therefore, we are adding to redesignated § 483.60(d) the term "when applicable", which will mean that expiration dates must be on the labels of drugs used in long-term care facilities unless State law stipulates otherwise.

Summary of Changes to § 483.60

We are deleting material that is out-of-date and pertains to services prior to October 1, 1990.

As a result of our evaluation of comments we are making the following changes:

- In redesignated § 483.60(c) we add the requirement that drug regimen review reports go to both the attending physician and the director of nursing.
- We are clarifying redesignated § 483.60(d) to state, "Drugs and biologicals used in a facility must be labeled in accordance with currently accepted professional principles." We are also adding to § 483.60(d) the term "when applicable".

Section 483.65 Infection Control

Summary of Provisions to § 483.65

Section 483.65 requires that the facility provide a sanitary environment.

Section 483.65(a) requires a facility to establish an infection control program, under which it investigates, controls, and prevents infections, decides on isolation procedures, and maintains a

record of incidents and corrective actions related to infections.

Comments and Responses

Comment: A number of commenters suggested that the requirement that the facility have an infection control program that prevents infections is unreasonable since total prevention of infections is not possible in all circumstances.

Response: We have not accepted these comments. The word "prevents" does not absolutely mean that residents will never experience infections. We therefore feel that a change in the wording would not change the intent or enforceability of the regulation.

Summary of Changes to § 483.65

Except for minor editorial revisions, the rule is unchanged.

Section 483.70 Physical Environment

Summary of Provisions

Section 483.70 requires that the facility must be constructed, equipped and maintained to protect the health and ensure the safety of residents, personnel and the public.

Section 483.70(d) requires that resident rooms must be designed and equipped for adequate nursing care, comfort, and privacy of residents.

Comments and Responses

Comment: Several commenters felt that the requirement at § 483.70(d)(1)(v) for facilities certified after August 1, 1989 to have "ceiling suspended curtains which extend around the bed to provide total visual privacy in combination with adjacent walls and curtains" should be waived in private rooms where full visual privacy may be assured by closing the door.

Response: We have accepted these comments and have changed the final rule to state an exception for private rooms. We also change the certification date to March 31, 1991, since our intention was that this provision apply to facilities certified when these regulations are effective.

Comment: The requirement at § 483.70(d)(3)(i) allows the survey agency to permit variations in requirements relating to the number of residents in the room and the size of the rooms when the facility demonstrates that the variations are required by the special needs of the residents and will not adversely affect their health and safety. The commenter stated the wording of this requirement is more stringent than that which was previously stated at 42 CFR 405.1134(e).

Response: It was not our intent to make this requirement more stringent than what was previously written. Thus, we are revising this requirement to reflect the previous wording of the regulation to state: "That such variations are in accordance with the special needs of the residents * * *"

Summary of Changes to § 483.70

We are making minor editorial changes, cross reference conforming changes, and deleting outdated material.

- In § 483.70(d)(1)(iii) we are clarifying the language to reflect the Life Safety Code requirement that specifies a resident's room must have direct access to a corridor that leads to an exit from the building.
- In § 483.70(d)(1)(v) we have added an exception for private rooms.
- In § 483.70(d)(3)(i) we are revising the requirement to reflect previous wording of the regulations that permits variations in accordance with the special needs of the residents.

Section 483.75 Administration

Summary of Provisions

Section 483.75 specifies the 22 requirements required by the Act that a facility must follow to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

Section 483.75(e) (redesignated to § 483.75(d) in this final rule) specifies that a facility must have a governing body or designated person functioning as a governing body that is legally responsible for establishing, implementing and making available to residents and the public written policies regarding management and operation of the facility.

Section 483.75(g) (redesignated to § 483.75(e) in this final rule) specifies certain requirements for the training and competency evaluation of nurse aides.

Section 483.75(l) (redesignated to § 483.75(j) in this final rule) specifies that SNFs must provide or obtain clinical laboratory services to meet the needs of their residents.

Section 483.75(m) (redesignated to § 483.75(k) in this final rule) specifies that a facility must provide or obtain radiology and other diagnostic services to meet the needs of the residents.

Section 483.75(n) (redesignated to § 463.75(l) in this final rule) specifies that the facility maintain clinical records on each resident with accepted professional standards and practices.

Section 483.75(o) (redesignated to § 483.75(m) in this final rule) specifies that the facility must have detailed written plans and procedures to meet all potential emergencies and train employees in emergency procedures.

Section 483.75(p) (redesignated to § 483.75(n) in this final rule) specifies transfer agreement requirements.

Section 483.75(r) (redesignated to § 483.75(o) in this final rule) specifies that a facility must maintain a quality assessment and assurance committee, composition of the committee, and committee responsibility.

Comments and Responses

Comments: Section 483.75(e)(2)(i) (redesignated to § 483.75(d)(2)(i) in this final rule) provides that the governing body appoints the administrator who is licensed by the State. Commenters from hospital-based skilled nursing facilities (SNFs) objected to this requirement since hospital administrators of such units traditionally have not been required to obtain additional licensure as nursing home administrators, and this provision would have had that effect.

Response: With regard to administrator of hospital-based SNFs, we do not intend in this requirement to impose a more stringent standard for licensure than existed previously. We note that section 1908 of the Act contains a longstanding requirement for licensure of every nursing home administrator in a manner provided for by each State. The regulations (42 CFR 431.700ff.) issued on March 29, 1972 (37 FR 6450) to implement this provision specifically exempt the administrator of a distinct part of a hospital from the requirement for licensure as a nursing home administrator when the distinct part itself is not licensed separately under State law from the surrounding hospital. As the Preamble to those regulations notes,

> * * * the hospital administrator who has basic responsibility for the entire institution has qualifications of education and experience that assure competent administration of the whole institution, including the "distinct part."

Thus, in review of the longstanding policy of following the provisions of State licensure laws in this area, we are modifying redesignated § 483.75(d)(2)(i) to mandate licensure as a nursing home administrator only when so required by the State.

Comment: One commenter pointed out that the requirement for facilities to file in the clinical record signed and dated reports of clinical laboratory services would be difficult if not impossible to implement due to the many laboratories that produces computer generated laboratory reports.

Response: We do not want to discourage the use of computerized records and reports in any way. We therefore have accepted this comment

and have changed the regulation at § 483.75(1)(2)(iv) (redesignated to § 483.75(j)(2)(iv) in this final rule) to read, "File in the resident's clinical record laboratory reports that are dated and contain the name and address of the issuing laboratory."

Comment: A number of comments suggested that the requirement holding the facility responsible for the quality and timeliness of the services obtained from outside laboratories is unfair.

Response: We have not accepted these comments. A facility that obtains outside clinical laboratory services should obtain such services from a laboratory that meets the criteria for quality and timeliness of services. If the laboratory providing the services does not meet these criteria, the facility should make arrangements to obtain services from a laboratory that does meet these criteria. Further, we note that once the forthcoming final regulations implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) become effective, a laboratory's certification under the CLIA '88 standards will in itself represent satisfactory assurance that it does, in fact, meet these criteria.

We are, however, amending the regulations at § 483.75(j)(1)(iv), which discuss facilities that do not provide lab service onsite, by adding physician office labs (POLs) to the description of acceptable offsite settings for obtaining lab services. As a result of the longstanding reference to POLs contained in the previous Medicare SNF conditions of participation at 42 CFR 405.1128(a), it has become a common practice for SNFs to obtain offsite lab services from these entities. When the interim final regulations were published on February 2, 1989, we deleted the existing reference to POLs without fully realizing the effect this action could have on the many SNFs and NFs which have well-established relationships with POLs. It was not our intent, however, to disrupt the prevailing practice of utilizing this setting as a source of offsite lab services. Further, the use of POLs is addressed in forthcoming final regulations that will establish specific standards for them in connection with implementation of CLIA '88. Therefore, we are restoring a reference to POLs to these final regulations. Of course, as with any service that it obtains from an outside source, when a facility chooses to obtain lab services from a physician's office, the facility remains responsible for the quality and timeliness of the service (see § 483.75(h)(2)).

Comment: Commenters were concerned that we did not require staffing of the clinical records service by qualified professionals.

Response: As discussed in the preamble to the February 2 final regulation, commenters convinced us that we should defer to State law concerning professional qualifications. The IoM also concluded that it is inappropriate to prescribe detailed staffing standards. We, therefore, are not specifying qualifications for medical records personnel. The medical records department and the other departments in the facility must, in accordance with § 483.75(i) (redesignated to § 483.75(g) in this final rule), employ professionals necessary to carry out the provisions in the regulations and these professionals must be licensed, certified, or registered in accordance with applicable State laws.

Comment: Several commenters felt that the requirements to train all employees to carry out staff drills using emergency procedures should include the requirement for unannounced drills on all shifts.

Response: The purpose of a staff drill is to test the efficiency, knowledge, and response of institutional personnel in the event of an emergency. We agree with commenters that unannounced staff drills can be effective, although care must be exercised not to disturb or excite patients. We have revised the regulations at § 483.75(o)(2) (redesignated in this final rule as § 483.75(m)(2)) to require unannounced staff drills. As indicated above, these drills are directed at the facility's staff, and need not affect or involve its residents.

Response: We are prepared to accept these comments and add a statement to § 483.75(r)(3) (redesignated in this final rule as § 483.75(o)(3)) to read, "Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions." However, section 4008(h)(2)(B) of OBRA '90 specifically prohibits the State or the Secretary from requiring disclosure of records of the quality assessment or assurance committee except in so far as such disclosure is related to compliance of such committee with the requirements of the statute. Therefore, we are revising § 483.75(a)(3) to incorporate the statutory language.

Summary of Changes to § 483.75

We are deleting material that is out-of-date and pertains to services prior to October 1, 1990. This required editorial revisions and redesignations of paragraphs.

As a result of our evaluation of comments and editorial revisions we are making the following changes:

- We are deleting § 483.75(a)(1)(ii), which provided an option for a facility to be "approved" (rather than actually licensed) by the State or local licensing authority. OBRA '87 has now eliminated this option from the law, effective October 1, 1990.
- In redesignated § 483.75(e) we are changing the effective date of when facilities must comply with the nurse aide training provisions of this section from January 1, 1990 to October 1, 1990. This change is mandated by section 6901(b)(1) of OBRA '89. We have also added several requirements mandated by OBRA '90. The nurse aide training and competency evaluation requirements in this final rule are intended to state statutory requirements for facilities. Complete requirements for nurse aide training and competency evaluation are addressed in a separate regulations. Requirements enunciated in those regulations supersede the requirements in this rule.
- We are revising redesignated § 483.75(j)(2)(iv) to require a facility to file in the resident's clinical record laboratory reports that are dated and contain the name and address of the issuing laboratory.
- In redesignated § 483.75(k) we are revising the provision to require that both nursing facilities and skilled nursing facilities must provide or obtain radiology and other diagnostic services to meet the needs of their residents. We are making this change to reflect the provisions of OBRA '87 and the definition of facility in the regulation at § 483.5. Through technical error, we omitted nursing facilities in the February 2 rule.
- In redesignated § 483.75(l) we are deleting provisions relating to inspection and copying of records to avoid redundancy. Upon review of this section we found that a duplicate requirement is in paragraph (b) (i) and (ii) of § 483.10, Resident's rights.
- We are revising redesignated § 483.75(m)(2) to require the facility to have unannounced staff drills.
- We are revising designated § 483.75(n) to reflect the provisions of the paragraph following section 1919(a)(3) of the Act. This paragraph specifies that the requirement for a facility to have in effect a transfer agreement with a hospital does not apply to a nursing facility which is located in a State on an Indian reservation.
- We are deleting paragraph (q) concerning utilization review which does not apply after September 30, 1990.
- We are adding to redesignated

§ 483.75(o) a new paragraph (3) that is based on amendments to the Act mandated by OBRA '90 which states that a State or the Secretary may not require disclosure of the records of such committee except where disclosure is related to the compliance of such committee with the requirements of this section.

• We are deleting paragraph (t) concerning independent medical review and audit which does not apply after September 30, 1990.

Comments on Part 442, Standards for Payment for Skilled Nursing and Intermediate Care Facility Services

There were no public comments on part 442. Nonetheless, some technical corrections are needed to conform our regulations with changes made by OBRA '87, essentially eliminating the distinction between Medicaid SNFs and ICFs. We are renaming part 442 as "Conditions for Payment for Nursing Facility and Intermediate Care Facility Services for the Mentally Retarded" to reflect current nomenclature.

Where necessary, we delete references to "SNFs" and "ICFs" and replace them with "NF" or "facility." Provisions, formerly applicable to all intermediate care facilities, are specifically applied to ICFs for the mentally retarded (ICFs/MR) now. These conforming changes, and updates of cross references, have resulted in changes to §§ 442.1, 442.2, 442.12(a), 442.13(c), 442.30, 442.40 (b) and (c), 442.42(a); 442.101, 442.105, 442.110(a), 442.117, and 442.118.

In addition, we are making the following technical revisions to part 442. In § 442.13(b), which concerns the effective date of a provider agreement, we are adding a statement that the provider must meet any other requirements imposed by the Medicaid agency. Previous wording may have incorrectly implied that an agreement would be effective on the date Federal requirements are met even if additional or more stringent State requirements were not. In § 442.105 we revise the heading to, "Certification with standard level deficiencies: General provisions." Previous wording may have incorrectly implied that a facility would be certified even if it was out of compliance with a statutory condition of participation or coverage.

Comments on Part 447, Payments for Services

Section 447.253 Other Requirements

Summary of Provisions

Section 447.253 specifies that the Medicaid State Agency must comply with all other requirements of subpart C in order to receive HCFA approval of a State plan change. In the February 2 regulations we added a new paragraph (b)(1)(iii) to require that the method and standards used by the Medicaid agency to establish payment for NF services take into account certain requirements of part 483.

Comments and Responses

Comment: One commenter expressed concern that the methodologies being employed by States are, in many instances, inadequate based on preliminary information relative to the individual State Medicaid agencies' attempts at costing out the various provisions of OBRA. Commenters stated that unless very specific guidance is provided by HCFA, litigation will be undertaken in many States to assure adequate reimbursement. The commenter recommended that HCFA spell out in detail how costs of compliance with OBRA's provisions must be "taken into account" by each State since the commenter believes this approach is very inefficient as well as expensive for all concerned.

Response: In March 1990, we revised part 6 of the State Medicaid Manual by adding a new section 6002.3. This section provided instructions and guidance to States regarding what was required to demonstrate that payment rates to nursing facilities, as of October 1, 1990, account for the additional costs incurred by facilities in complying with each of the specific requirements described in sections 1919(b) (other than paragraph (3)(F) thereof), 1919(c), and 1919(d) of the Act. These instructions were included in the State Medicaid Manual because we believe this is the appropriate vehicle for this information.

Comment: One commenter recommended that the language in § 447.253(b)(1) that requires the method and standards used by the Medicaid agency to establish payment for nursing facility services take into account not only "the cost" but "the specific, and actual reasonable costs" of complying with the requirements of part 483 of subpart B.

Response: Current regulations at 42 CFR 447.253(b)(1) require that payment rates are reasonable and adequate to meet the costs that must be incurred by efficiently and economically operated providers to provide services in conformity with applicable State and Federal laws, regulations and quality and safety standards. The basis for this requirement is found in section 1902(a)(13)(A) of the Act. In this respect, we do not believe it necessary or appropriate to add the commenter's suggested additional qualifiers.

Comment: One commenter requested that the following language be substituted in § 447.253(b)(1): "With respect to long-term care facility services, the methods and standards used to determine payment rates must assure that the specific, actual and reasonable costs of complying with all requirements of subsections (b) (other than paragraph 3F thereof), (c), and (d) of section 1919 of the Act are met by including, on a prospective per-patient day basis, an immediate increase above the existing payment rate which will cover in full the costs as incurred in complying with said requirements. The State must include all relevant factors in making the rate determination including studies which assure that the rate will allow the facility to be in full compliance with the requirements of the Act. The separately identified costs must be in addition to, or as an add-on to, the rate which is otherwise determined by the State plan and not affected by any limitations described in the State plan."

Response: We do not believe there is any need to change the current language of § 447.253(b)(1)(iii)(A). Section 6002.3 of the State Medicaid Manual transmittal, issued in March 1990, addresses the concerns indicated in the above comment. We also do not believe that OBRA related costs should be treated any differently than other facility costs. Rates proposed in State plan amendments must, as of October 1, 1990, account for these additional costs.

Comment: One commenter was concerned that the OBRA '87 requirement for States to assure that payment rates to nursing facilities take into account the costs of compliance with the law (other than the costs of active treatment) has not been provided to appropriate State agencies. The commenter recommended that a State Operations Manual Issuance pertaining to this assurance, including the timing requirements for State plan amendments and availability of methodology for establishing payment rates, should be published to better assure adequate facility payment for all of the new requirements established by this regulation.

Response: As indicated above, section 6002.3 of the State Medicaid Manual as revised in March 1990, provides instructions and guidance to States regarding what is required in order to ensure compliance with the new requirements.

Comment: One commenter recommended that § 447.272 be amended to exclude ICFs/MR from the

provisions regarding Medicare upper payment limits.

Response: We disagree. The upper payment limits are based upon costs that would have been paid under Medicare payments principles. The fact that Medicare has no program similar to the Medicaid ICF/MR program is immaterial. Medicare payment principles need to be applied.

Summary of Changes to Part 447

We are revising part 447 to replace the terms SNF and ICF with NF or otherwise delete the SNF and ICF terminology when no longer applicable. We also update cross references and delete outdated material. Revisions occur in §§ 447.251, 447.253, 447.255 and 447.272.

Comments on Part 488, Survey and Certification Procedures

There were no public comments on part 488. Nonetheless, some technical corrections are needed to conform our regulation with changes made by OBRA '87, essentially eliminating the distinction between Medicaid SNF and ICFs. We also update terminology and cross-references.

Corrections are being made to the authority citation and the following: §§ 488.1, 488.3, 488.10(a)(1), 488.11, 488.18 (a) and (b), 488.20 (a) and (c), 488.24 (a) and (b), 488.26(a), 488.28 (a) and (b), 488.50(a), and 488.56 (a) and (b).

Comments on Part 498, Appeals Procedures for Determinations That Affect Participation in the Medicare Program

There were no public comments on part 498. Nonetheless, we are making a technical correction to substitute "NFs" for "ICFs" in § 498.3 to reflect the nomenclature change required by OBRA '87.

III. Regulatory Impact Analysis

A. Introduction

Executive Order (E.O.) 12291 requires us to prepare and publish a final regulatory impact analysis for any proposed regulation that meets one of the E.O. criteria for a "major rule"; that is, that will be likely to result in—

- An annual effect on the economy of $100 million or more;
- A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or,
- Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

In addition, we generally prepare a final regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), unless the Secretary certifies that a final regulation will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we consider all Medicare and Medicaid long term care providers as small entities. Individuals and states are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis for any final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of Section 1102(b) of the Act, we define a small rural hospital as a hospital which is located outside a Metropolitan Statistical Area and has fewer than 50 beds.

When we published both the proposed (October 16, 1987) and final (February 2, 1989) rules, we prepared an analysis intended to conform to the objectives of E.O. 12291 and the RFA. In these analyses, we made the same general point regarding the cost of implementing the nursing home reform provisions that was made by the Institute of Medicine in its report. In fact, we quoted it as follows:

> The effects of the recommendations on the costs of regulation and on the costs of providing care to residents are not easily calculated for two reasons: (1) The quantitative and qualitative changes to behavior of the various actors in the system, and the effects on efficiency of the regulatory agencies and nursing homes, cannot be predicted on the basis of current data; (2) current data about staffing and costs in nursing homes and in state regulatory agencies are not available in sufficient detail; and (3) some immediate costs are likely to produce long-term savings that cannot be estimated. Given these uncertainties, any estimates made—even with the assistance of a very elaborate cost model—would have to present a wide range of costs to account for interactions of varying assumptions. (Page 214)

We also discussed in the case of the NPRM our estimate of the cost of increased nurse staffing, which was approximately $100 million a year. In the case of the final regulation, we noted that the changes made since publication of the NPRM were virtually all explicitly required by OBRA '87. We noted one exception (privacy curtains) and explained that the requirement would apply only to new NFs, thus minimizing the cost.

This final rule revises the February 2, 1989, final rule with comment period based on comments submitted by the public. Charges made as a result of comments received are summarized in section II of this preamble. We do not believe that any of the changes incorporated into this final rule as a result of the comments would have any significant impact and we are therefore not preparing an analysis with respect to them.

Although we do not believe that the changes in this document would have a significant impact, we do have additional information about the potential cost of the changes contained in OBRA '87, as reflected by the February 2, 1989 final regulation and other OBRA '87 requirements that have been implemented on the basis of the statute or instructions pending the completion of rulemaking.

Our information flows from the data submitted by States pursuant to the OBRA '87 requirement that they revise their State Medicaid plans to include additional costs to be incurred by NFs as a result of the OBRA '87 provisions. We have received 49 amendments, of which 36 have been approved, 5 disapproved, and 8 are pending further action. Of the plans that have been submitted and approved, the rate increases average $1.44 per day. These 36 States anticipate spending an additional $338.8 million for NF care in FY 1991. The increases in spending vary sufficiently from State to State so that it is not possible to anticipate, based on the plans approved to date, the increases of the remaining States or to estimate the total with accuracy. Nonetheless, it is clear from the information available to date that the OBRA '87 provisions have resulted in anticipated State payments high enough to constitute the February 2, 1989 final regulation as a major rule within the meaning of the Executive order.

B. Reporting Requirements

Sections 483.13(c), 483.60(b)(2), 483.65(a)(3), 483.75(h), 483.75(j)(1)(iv), 483.75(j)(2)(iv), 483.75(k)(1)(ii), 483.75(k)(2)(iv), 483.75(m), and 483.75(n) of this final rule contain information collections that are subject to Office of Management and Budget (OMB) approval under the Paperwork Reduction Act of 1980. Long-term care facilities must provide documentation to assure compliance with the requirements in order to receive Federal funds for Medicare and Medicaid. Public reporting burden for this collection of information is estimated to be 1,167,500 hours for approximately 15,500 facilities. (Comparable reporting burden for information collection requirements in

existing regulations is 2,585,317 hours annually.) A notice will be published in the **Federal Register** when approval for the reduced burden is obtained.

List of Subjects

42 CFR Part 442

Grant programs-health, Health facilities, Health professions, Health records, Medicaid, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 447

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

42 CFR Part 483

Grant programs-health, Health facilities, Health professions, Health records, Medicaid, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 488

Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

Chapter IV—Health Care Financing Administration, Department of Health and Human Services

42 CFR chapter IV is amended as follows:

PART 442—CONDITIONS FOR PAYMENT FOR NURSING FACILITY AND INTERMEDIATE CARE FACILITY SERVICES FOR THE MENTALLY RETARDED

A. Part 442 is amended as follows:

1. The authority citation for part 442 continues to read as follows:

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

2–3. In subpart A, § 442.1, paragraph (a) is revised to read as follows:

Subpart A—General Provisions

§ 442.1 Basis and purpose.

(a) This part states requirements for provider agreements and facility certification relating to the provision of services furnished by nursing facilities and intermediate care facilities for the mentally retarded. This part is based on the following sections of the Act:

Section 1902(a)(4), administrative methods for proper and efficient operation of the State plan;
Section 1902(a)(27), provider agreements;
Section 1902(a)(28), skilled nursing facility standards;
Section 1902(a)(33)(B), State survey agency functions;
Section 1902(i), circumstances and procedures for denial of payment and termination of provider agreements in certain cases;
Section 1905 (c) and (d), definition of intermediate care facility services;
Section 1905 (f) and (i), definition of skilled nursing facility services;
Section 1910, certification and approval of SNFs and of RHCs;
Section 1913, hospital providers of skilled nursing and intermediate care services, and
Section 1922, correction and reduction plans for intermediate care facilities for the mentally retarded.

* * * * *

4. In subpart A, § 442.2 the definition of "Facility", is revised as follows;

§ 442.2 Terms.

In this part—

Facility refers to a nursing facility, and an intermediate care facility for the mentally retarded or persons with related conditions (ICF/MR).

* * * * *

5. In subpart B, § 442.12(a) is revised to read as follows:

§ 442.12 Provider agreement: General requirements.

(a) *Certification and recertification.* Except as provided in paragraph (b) of this section, a Medicaid agency may not execute a provider agreement with a facility for nursing facility services nor make Medicaid payments to a facility for those services unless the Secretary or the State survey agency has certified the facility under this part to provide those services. (See § 442.101 for certification by the Secretary or by the State survey agency).

6. Section 442.13 (b) and (c)(2) are revised to read as follows:

§ 442.13 Effective date of agreement.

* * * * *

(b) *All Federal requirements are met on the date of the survey.* The agreement must be effective on the date the onsite survey is completed (or on the day following the expiration of a current agreement) if, on the date of the survey the provider meets all Federal requirements and any other requirements imposed by the Medicaid agency.

(c) * * *

(2) The date on which a NF or an ICF/MR is found to meet all conditions of participation, and the facility submits an acceptable correction plan for lower level deficiencies, or an approvable waiver request, or both.

* * * * *

§ 442.20 [Removed]

6a. Section 442.20 is removed.

7. In subpart B, § 442.30(a) introductory text and paragraph (a)(1) are revised to read as follows:

§ 442.30 Agreement as evidence of certification.

(a) Under §§ 440.40(a) and 440.150 of this chapter, FFP is available in expenditures for NF and ICF/MR services only if the facility has been certified as meeting the requirements for Medicaid participation, as evidenced by a provider agreement executed under this part. An agreement is not valid evidence that a facility has met those requirements if HCFA determines that—

(1) The survey agency failed to apply the applicable requirements under part 483 for NFs or subpart D of part 483 of this chapter, which sets forth the conditions of participation for ICFs/MR.

* * * * *

8. Section 442.40 (b) and (c) are revised to read as follows:

§ 442.40 Availability of FFP during appeals.

* * * * *

(b) *Scope, applicability, and effective date*—(1) *Scope.* This section sets forth the extent of FFP in State Medicaid payments to a NF or an ICF/MR after its provider agreement has been terminated or has expired and not be renewed.

(2) *Applicability.* (i) This section and § 442.42 apply only when the Medicaid agency, of its own volition, terminates o does not a renew a provider agreement, and only when the survey agency certifies that there is no jeopardy to recipient health and safety. When the survey agency certifies that there is jeopardy to recipient health and safety, or when it fails to certify that there is no jeopardy, FFP ends on the effective date of termination or expiration.

(ii) When the State acts under instructions from HCFA, FFP ends on the date specified by HCFA (HCFA instructs the State to terminate the Medicaid provider agreement when HCFA in validating a State survey agency certification, determines that a NF or an ICF/MR does not meet the requirements for participation.)

(3) *Effective date.* This section and § 442.42 apply to terminations or expirations that are effective on or after September 28, 1987. For terminations or nonrenewals that were effective before that date, FFP may continue for up to 120 days from September 28, 1987, or 12 months from the effective date of termination or nonrenewal, whichever is earlier.

(c) *Basic rules.* (1) Except as provided in paragraphs (d) and (e) of this section, FFP in payments to a NF or an ICF/MR ends on the effective date of termination of the facility's provider agreement, or if the agreement is not terminated, on the effective date of expiration.

(2) If State law, or a Federal or State court order or injunction, requires the agency to extend the provider agreement or continue payments to a facility after the dates specified in paragraph (d) of this section, FFP is not available in those payments.

§ 442.42 [Amended]

9. In § 442.42(a), the phrase "a NF or an ICF/MR" is substituted for the phrase "a SNF or ICF".

10. The heading of subpart C is revised to read as follows:

Subpart C—Certification of NFs and ICFs/MR

11. In subpart C, § 442.101 is revised to read as follows:

§ 442.101 Obtaining certification.

(a) This section states the requirements for obtaining notice of an ICF/MR's certification before a Medicaid agency executes a provider agreement under § 442.12.

(b) The agency must obtain notice of certification from the Secretary for an ICF/MR located on an Indian reservation.

(c) The agency must obtain notice of certification from the survey agency for all other ICF/MR.

(d) The notice must indicate that one of the following provisions pertains to the ICF/MR:

(1) An ICF/MR meets the conditions of participation set forth in subpart D of part 483 of this chapter.

(2) The ICF/MR has been granted a waiver or variance by HCFA or the survey agency under subpart D.

(3) An ICF/MR has been certified with standard-level deficiencies and

(i) All conditions of participation are found met; and

(ii) The facility submits an acceptable plan of correction covering the remaining deficiencies, subject to other limitations specified in § 442.105.

(e) The failure to meet one or more of the applicable conditions of participation is cause for termination or non-renewal of the ICF/MR provider agreement.

12. Section 442.105 is revised to read as follows:

§ 442.105 Certification with deficiencies: General provisions.

If a survey agency finds a facility deficient in meeting the requirements for NFs or the standards (for ICFs/MR), as specified under Subparts B and D of Part 483 of this chapter, the agency may certify the facility for Medicaid purposes under the following conditions:

(a) The agency finds that the facility's deficiencies, individually or in combination, do not jeopardize the patient's health and safety, nor seriously limit the facility's capacity to give adequate care. The agency must maintain a written justification of these findings.

(b) The agency finds acceptable the facility's written plan for correcting the deficiencies.

(c) If a facility was previously certified with a deficiency and has a different deficiency at the time of the next survey, the agency documents that the facility—

(1) Was unable to stay in compliance with the standard (for ICFs/MR) or requirements (for NFs) for reasons beyond its control, or despite intensive efforts to comply; and

(2) Is making the best use of its resources to furnish adequate care.

(d) If a facility has the same deficiency it had under the prior certification, the agency documents that the facility—

(1) Did achieve compliance with the standard (for ICFs/MR) or requirements (for NFs) at some time during the prior certification period;

(2) Made a good faith effort, as judged by the survey agency, to stay in compliance; and

(3) Again became out of compliance for reasons beyond its control.

(e) If a NF or ICF/MR has a deficiency of the types specified in § 442.111 or § 442.112 that requires a plan of correction extending beyond 12 months, the agency documents that the conditions of those sections are met.

13. In § 442.110, the section heading and paragraph (a) are revised to read as follows:

§ 442.110 Certification period: Facilities with deficiencies.

(a) Facilities with deficiencies may be certified under § 442.105 for the period specified in either paragraph (b) or (c) of this section. However, NFs with deficiencies that may require more than 12 months to correct may be certified under § 442.112.

* * * * *

§ 442.111 [Removed]

13a. Section 442.111 is removed.

14. In § 442.117, the section heading and paragraph (a)(1) are revised to read as follows:

§ 442.117 Termination of certification for NFs and ICFs/MR whose deficiencies pose immediate jeopardy.

(a) * * *

(1) The facility no longer meets applicable requirements for NFs or conditions of participation for ICFs/MR as specified in subpart B or D of part 483 of this chapter.

* * * * *

15. In § 442.118, paragraphs (a), (b)(1) and (b)(3)(i) are revised to read as follows:

§ 442.118 Denial of payments for new admissions.

(a) *Basis for denial of payments.*

The Medicaid agency may deny payment for new admissions to a NF or an ICF/MR that no longer meets the applicable conditions of participation specified under subpart B or D of part 483 of this chapter.

(b) * * *

(1) Provide the facility up to 60 days to correct the cited deficiencies and comply with the requirements (for NFs) or conditions of participation (for ICFs/MR).

* * * * *

(3) * * *

(i) The opportunity for the facility to present, before a State Medicaid official who was not involved in making the initial determination, evidence or documentation, in writing or in person, to refute the decision that the facility is out of compliance with the applicable requirements (for NFs) or conditions of participation (for ICFs/MR).

* * * * *

PART 447—PAYMENTS FOR SERVICES

B. Part 447 is amended as follows:

1. The authority citation for part 447 continues to read as follows:

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

Subpart C—Payment for Inpatient Hospital and Long-Term Care Facility Services

Payment Rates

2. In Subpart C, § 447.251 is amended by revising the definition of "long term care facility services" as follows:

§ 447.251 Definitions.

* * * * *

Long-term care facility services means intermediate care facility services for the mentally retarded (ICF/MR) and nursing facility (NF) services.

* * * * *

3. Section 447.255 is amended by revising paragraph (a) to read as follows:

§ 447.255 Related information.

* * * * *

(a) The amount of the estimated average proposed payment rate for each type or provider (hospital, ICF/MR, or nursing facility), and the amount by which that estimated average rate increased or decreased relative to the average payment rate in effect for each type of provider for the immediately preceding rate period;

* * * * *

4. Section 447.272 is amended by revising paragraphs (a) and (b) to read as follows:

§ 447.272 Application of upper payment limits.

(a) *General rule.* Except as provided in paragraph (c) of this section, aggregate payments by an agency to each group of health care facilities (that is, hospitals, nursing facilities and ICFs for the mentally retarded (ICFs/MR), may not exceed the amount that can reasonably be estimated would have been paid for those services under Medicare payment principles.

(b) *State operated facilities.* In addition to meeting the requirement of paragraph (a) of this section, aggregate payments to each group of State-operated facilities (that is, hospitals, nursing facilities and ICFs/MR) may not exceed the amount that can reasonably be estimated would have been paid under Medicare payment principles.

* * * * *

SUBCHAPTER E—STANDARDS AND CERTIFICATION

C. Part 483 is amended as follows:

1. The authority citation for part 483 is revised to read as follows:

Authority: Sec. 1102, 1819 (a)–(d), 1861 (j) and (1), 1863, 1871, 1902(a)(28), 1905 (a) and (c), and 1919 (a)–(d) of the Social Security Act (42 U.S.C. 1302, 1395(i) (3)(a)–(d), 1395x (j) and (1), 1395hh, 1396(a)(a)(28), and 1396d(c) and 1396r (a)–(d)), unless otherwise noted.

PART 483—REQUIREMENTS FOR LONG TERM CARE FACILITIES

Subpart B—Requirements for Long Term Care Facilities

2–3. In subpart B, §§ 483.1, 483.5, 483.10, 483.12, 483.13, 483.15, 483.20, and 483.25 are revised as follows:

§ 483.1 Basis and scope.

(a) *Basis in legislation.* (1) Sections of the Act 1819 (a), (b), (c), and (d) provide that—

(i) Skilled nursing facilities participating in Medicare must meet certain specified requirements; and

(ii) The Secretary may impose additional requirements (see section 1819(d)(4)(B)) if they are necessary for the health and safety of individuals to whom services are furnished in the facilities.

(2) Sections 1919 (a), (b), (c), and (d) of the Act provide that nursing facilities participating in Medicaid must meet certain specific requirements.

(b) *Scope.* The provisions of this part contain the requirements that an institution must meet in order to qualify to participate as a SNF in the Medicare program, and as a nursing facility in the Medicaid program. They serve as the basis for survey activities for the purpose of determining whether a facility meets the requirements for participation in Medicare and Medicaid.

§ 483.5 Definitions.

For purposes of this subpart—

Facility means, a skilled nursing facility (SNF) or a nursing facility (NF) which meets the requirements of sections 1819 and 1919 (a), (b), (c), and (d) of the Act. "Facility" may include a distinct part of an institution specified in § 440.40 or § 440.150 of this chapter, but does not include an institution for the mentally retarded or persons with related conditions described in § 440.150(c) of this chapter. For Medicare and Medicaid purposes (including eligibility, coverage, certification, and payment), the "facility" is always the entity which participates in the program, whether that entity is comprised of all of, or a distinct part of a larger institution. For Medicare, a SNF (see section 1819(a)(1)), and for Medicaid, a NF (see section 1919(a)(1)) may not be an institution for mental diseases as defined in § 435.1009.

§ 483.10 Resident rights.

The resident has a right to a dignified existence, self-determination, and communication with and access to persons and services inside and outside the facility. A facility must protect and promote the rights of each resident, including each of the following rights:

(a) *Exercise of rights.*

(1) The resident has the right to exercise his or her rights as a resident of the facility and as a citizen or resident of the United States.

(2) The resident has the right to be free of interference, coercion, discrimination, and reprisal from the facility in exercising his or her rights.

(3) In the case of a resident adjudged incompetent under the laws of a State by a court of competent jurisdiction, the rights of the resident are exercised by the person appointed under State law to act on the resident's behalf.

(4) In the case of a resident who has not been adjudged incompetent by the State court, any legal-surrogate designated in accordance with State law may exercise the resident's rights to the extent provided by State law.

(b) *Notice of rights and services.*

(1) The facility must inform the resident both orally and in writing in a language that the resident understands of his or her rights and all rules and regulations governing resident conduct and responsibilities during the stay in the facility. The facility must also provide the resident with the notice (if any) of the State developed under section 1919(e)(6) of the Act. Such notification must be made prior to or upon admission and during the resident's stay. Receipt of such information, and any amendments to it, must be acknowledged in writing;

(2) The resident or his or her legal representative has the right—

(i) Upon an oral or written request, to access all records pertaining to himself or herself including clinical records within 24 hours; and

(ii) After receipt of his or her records for inspection, to purchase at a cost not to exceed the community standard photocopies of the records or any portions of them upon request and 2 working days advance notice to the facility.

(3) The resident has the right to be fully informed in language that he or she can understand of his or her total health status, including but not limited to, his or her medical condition;

(4) The resident has the right to refuse treatment, and to refuse to participate in experimental research; and

(5) The facility must—

(i) Inform each resident who is entitled to Medicaid benefits, in writing, at the time of admission to the nursing facility or, when the resident becomes eligible for Medicaid of—

(A) The items and services that are included in nursing facility services under the State plan and for which the resident may not be charged;

(B) Those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; and

(ii) Inform each resident when changes are made to the items and services specified in paragraphs (5)(i)(A) and (B) of this section.

(6) The facility must inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare or by the facility's per diem rate.

(7) The facility must furnish a written description of legal rights which includes—

(i) A description of the manner of protecting personal funds, under paragraph (c) of this section;

(ii) A description of the requirements and procedures for establishing eligibility for Medicaid, including the right to request an assessment under section 1924(c) which determines the extent of a couple's non-exempt resources at the time of institutionalization and attributes to the community spouse an equitable share of resources which cannot be considered available for payment toward the cost of the institutionalized spouse's medical care in his or her process of spending down to Medicaid eligibility levels;

(iii) A posting of names, addresses, and telephone numbers of all pertinent State client advocacy groups such as the State survey and certification agency, the State licensure office, the State ombudsman program, the protection and advocacy network, and the Medicaid fraud control unit; and

(iv) A statement that the resident may file a complaint with the State survey and certification agency concerning resident abuse, neglect, and misappropriation of resident property in the facility.

(8) The facility must inform each resident of the name, specialty, and way of contacting the physician responsible for his or her care.

(9) The facility must prominently display in the facility written information, and provide to residents and applicants for admission oral and written information about how to apply for and use Medicare and Medicaid benefits, and how to receive refunds for previous payments covered by such benefits.

(10) *Notification of changes.* (i) A facility must immediately inform the resident; consult with the resident's physician; and if known, notify the resident's legal representative or an interested family member when there is—

(A) An accident involving the resident which results in injury and has the potential for requiring physician intervention;

(B) A significant change in the resident's physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications);

(C) A need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or

(D) A decision to transfer or discharge the resident from the facility as specified in § 483.12(a).

(ii) The facility must also promptly notify the resident and, if known, the resident's legal representative or interested family member when there is—

(A) A change in room or roommate assignment as specified in § 483.15(e)(2); or

(B) A change in resident rights under Federal or State law or regulations as specified in paragraph (b)(1) of this section.

(iii) The facility must record and periodically update the address and phone number of the resident's legal representative or interested family member.

(c) *Protection of Resident Funds.* (1) The resident has the right to manage his or her financial affairs, and the facility may not require residents to deposit their personal funds with the facility.

(2) *Management of personal funds.* Upon written authorization of a resident, the facility must hold, safeguard, manage, and account for the personal funds of the resident deposited with the facility, as specified in paragraphs (c)(3)–(8) of this section.

(3) *Deposit of funds.* (i) *Funds in excess of $50.* The facility must deposit any residents' personal funds in excess of $50 in an interest bearing account (or accounts) that is separate from any of the facility's operating accounts, and that credits all interest earned on resident's funds to that account. (In pooled accounts, there must be a separate accounting for each resident's share.)

(ii) *Funds less than $50.* The facility must maintain a resident's personal funds that do not exceed $50 in a non-interest bearing account, interest-bearing account, or petty cash fund.

(4) *Accounting and records.* The facility must establish and maintain a system that assures a full and complete and separate accounting, according to generally accepted accounting principles, of each resident's personal funds entrusted to the facility on the resident's behalf.

(i) The system must preclude any commingling of resident funds with facility funds or with the funds of any person other than another resident.

(ii) The individual financial record must be available through quarterly statements on request to the resident or his or her legal representative.

(5) *Notice of certain balances.* The facility must notify each resident that receives Medicaid benefits—

(i) When the amount in the resident's account reaches $200 less than the SSI resource limit for one person, specified in section 1611(a)(3)(B) of the Act; and

(ii) That, if the amount in the account, in addition to the value of the resident's other nonexempt resources, reaches the SSI resource limit for one person, the resident may lose eligibility for Medicaid or SSI.

(6) *Conveyance upon death.* Upon the death of a resident with a personal fund deposited with the facility, the facility must convey within 30 days the resident's funds, and a final accounting of those funds, to the individual or probate jurisdiction administering the resident's estate.

(7) *Assurance of financial security.* The facility must purchase a surety bond, or otherwise provide assurance satisfactory to the Secretary, to assure the security of all personal funds of residents deposited with the facility.

(8) *Limitation on charges to personal funds.* The facility may not impose a charge against the personal funds of a resident for any item or service for which payment is made under Medicaid or Medicare.

(d) *Free choice.* The resident has the right to—

(1) Choose a personal attending physician;

(2) Be fully informed in advance about care and treatment and of any changes in that care or treatment that may affect the resident's well-being; and

(3) Unless adjudged incompetent or otherwise found to be incapacitated under the laws of the State, participate in planning care and treatment or changes in care and treatment.

(e) *Privacy and confidentiality.* The resident has the right to personal privacy and confidentiality of his or her personal and clinical records.

(1) Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide a private room for each resident;

(2) Except as provided in paragraph (e)(3) of this section, the resident may approve or refuse the release of personal and clinical records to any individual outside the facility;

(3) The resident's right to refuse release of personal and clinical records does not apply when—

(i) The resident is transferred to another health care institution; or

(ii) Record release is required by law.

(f) *Grievances.* A resident has the right to—

(1) Voice grievances without discrimination or reprisal. Such grievances include those with respect to treatment which has been furnished as well as that which has not been furnished; and

(2) Prompt efforts by the facility to resolve grievances the resident may have, including those with respect to the behavior of other residents.

(g) *Examination of survey results.* A resident has the right to—

(1) Examine the results of the most recent survey of the facility conducted by Federal or State surveyors and any plan of correction in effect with respect to the facility. The results must be made available for examination by the facility in a place readily accessible to residents; and

(2) Receive information from agencies acting as client advocates, and be afforded the opportunity to contract these agencies.

(h) *Work.* The resident has the right to—

(1) Refuse to perform services for the facility;

(2) Perform services for the facility, if he or she chooses, when—

(i) The facility has documented the need or desire for work in the plan of care;

(ii) The plan specifies the nature of the services performed and whether the services are voluntary or paid;

(iii) Compensation for paid services is at or above prevailing rates; and

(iv) The resident agrees to the work arrangement described in the plan of care.

(i) *Mail.* The resident has the right to privacy in written communications, including the right to—

(1) Send and promptly receive mail that is unopened; and

(2) Have access to stationery, postage, and writing implements at the resident's own expense.

(j) *Access and visitation rights.* (1) The resident has the right and the facility must provide immediate access to any resident by the following:

(i) Any representative of the Secretary;

(ii) Any representative of the State;

(iii) The resident's individual physician;

(iv) The Sate long term care ombudsman (established under section 307(a)(12) of the Older Americans Act of 1965);

(v) The agency responsible for the protection and advocacy system for developmentally disabled individuals (established under part C of the Developmental Disabilities Assistance and Bill of Rights Act);

(vi) The agency responsible for the protection and advocacy system for mentally ill individuals (established under the Protection and Advocacy for Mentally Ill Individuals Act);

(vii) Subject to the resident's right to deny or withdraw consent at any time, immediate family or other relatives of the resident; and

(viii) Subject to reasonable restrictions and the resident's right to deny or withdraw consent at any time, others who are visiting with the consent of the resident.

(2) The facility must provide reasonable access to any resident by any entity or individual that provides health, social, legal, or other services to the resident, subject to the resident's right to deny or withdraw consent at anytime.

(3) The facility must allow representatives of the State Ombudsman, described in paragraph (j)(1)(iv) of this section, to examine a resident's clinical records with the permission of the resident or the resident's legal representative, and consistent with State law.

(k) *Telephone.* The resident has the right to have reasonable access to the use of a telephone where calls can be made without being overheard.

(l) *Personal property.* The resident has the right to retain and use personal possessions, including some furnishings, and appropriate clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents.

(m) *Married couples.* The resident has the right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement

(n) *Self-Administration of Drugs.* An individual resident may self-administer drugs if the interdisciplinary team, as defined by § 483.20(d)(2)(ii), has determined that this practice is safe.

(o) *Refusal of certain transfers.* (1) An individual has the right to refuse a transfer to another room within the facility, if the purpose of the transfer is to relocate—

(i) A resident of a SNF from the distinct part of the facility that is a SNF to a part of the facility that is not a SNF, or

(ii) If a resident of a NF from the distinct part of the facility that is a NF to a distinct part of the facility that is a SNF.

(2) A resident's exercise of the right to refuse transfer under paragraph (o)(1) of this section does not affect the individual's eligibility or entitlement to Medicaid benefits.

§ 483.12 Admission, transfer and discharge rights.

(a) Transfer and discharge—

(1) *Definition:* Transfer and discharge includes movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility.

(2) *Transfer and discharge requirements.* The facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless—

(i) The transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility;

(ii) The transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility;

(iii) The safety of individuals in the facility is endangered;

(iv) The health of individuals in the facility would otherwise be endangered;

(v) The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility. For a resident who becomes eligible for Medicaid after admission to a facility, the facility may charge a resident only allowable charges under Medicaid; or

(vi) The facility ceases to operate.

(3) *Documentation.* When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs (a)(2)(i) through (v) of this section, the resident's clinical record must be documented. The documentation must be made by—

(i) The resident's physician when transfer or discharge is necessary under paragraph (a)(2)(i) or paragraph (a)(2)(ii) of this section; and

(ii) A physician when transfer or discharge is necessary under paragraph (a)(2)(iv) of this section.

(4) *Notice before transfer.* Before a facility transfers or discharges a resident, the facility must—

(i) Notify the resident and, if known, a family member or legal representative of the resident of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand.

(ii) Record the reasons in the resident's clinical record; and

(iii) Include in the notice the items described in paragraph (a)(6) of this section.

(5) *Timing of the notice.* (i) Except when specified in paragraph (a)(5)(ii) of this section, the notice of transfer or discharge required under paragraph (a)(4) of this section must be made by the facility at least 30 days before the resident is transferred or discharged.

(ii) Notice may be made as soon as practicable before transfer or discharge when—

(A) the safety of individuals in the facility would be endangered under paragraph (a)(2)(iii) of this section;

(B) The health of individuals in the facility would be endangered, under paragraph (a)(2)(iv) of this section;

(C) The resident's health improves sufficiently to allow a more immediate transfer or discharge, under paragraph (a)(2)(ii) of this section;

(D) An immediate transfer or discharge is required by the resident's urgent medical needs, under paragraph (a)(2)(ii) of this section; or

(E) A resident has not resided in the facility for 30 days.

(6) *Contents of the notice.* For nursing facilities, the written notice specified in paragraph (a)(4) of this section must include the following:

(i) The reason for transfer or discharge;

(ii) The effective date of transfer or discharge;

(iii) The location to which the resident is transferred or discharged;

(iv) A statement that the resident has the right to appeal the action to the State;

(v) The name, address and telephone number of the State long term care ombudsman;

(vi) For nursing facility residents with developmental disabilities, the mailing address and telephone number of the agency responsible for the protection and advocacy of developmentally disabled individuals established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act; and

(vii) For nursing facility residents who are mentally ill, the mailing address and telephone number of the agency responsible for the protection and advocacy of mentally ill individuals established under the Protection and Advocacy for Mentally Ill Individuals Act.

(7) *Orientation for transfer or discharge.* A facility must provide sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility.

(b) *Notice of bed-hold policy and readmission*—(1) *Notice before transfer.* Before a nursing facility transfers a resident to a hospital or allows a resident to go on therapeutic leave, the nursing facility must provide written information to the resident and a family member or legal representative that specifies—

(i) The duration of the bed-hold policy under the State plan, if any, during which the resident is permitted to return and resume residence in the nursing facility; and

(ii) The nursing facility's policies regarding bed-hold periods, which must be consistent with paragraph (b)(3) of this section, permitting a resident to return.

(2) *Bed-hold notice upon transfer.* At the time of transfer of a resident for hospitalization or therapeutic leave, a nursing facility must provide to the resident and a family member or legal representative written notice which specifies the duration of the bed-hold policy described in paragraph (b)(1) of this section.

(3) *Permitting resident to return to facility.* A nursing facility must establish and follow a written policy under which a resident, whose hospitalization or therapeutic leave exceeds the bed-hold period under the State plan, is readmitted to the facility immediately upon the first availability of a bed in a semi-private room if the resident—

(i) Requires the services provided by the facility; and

(ii) Is eligible for Medicaid nursing facility services.

(c) *Equal access to quality care.*

(1) A facility must establish and maintain identical policies and practices regarding transfer, discharge, and the provision of services under the State plan for all individuals regardless of source of payment;

(2) The facility may charge any amount for services furnished to non-Medicaid residents consistent with the notice requirement in § 483.10(b)(5)(i) and (b)(6) describing the charges; and

(3) The State is not required to offer additional services on behalf of a resident other than services provided in the State plan.

(d) *Admissions policy.*

(1) The facility must—

(i) Not require residents or potential residents to waive their rights to Medicare or Medicaid; and

(ii) Not require oral or written assurance that residents or potential residents are not eligible for, or will not apply for, Medicare benefits.

(2) The facility must not require a third party guarantee of payment to the facility as a condition of admission or expedited admission, or continued stay in the facility. However, the facility may require an individual who has legal access to a resident's income or resources available to pay for facility care to sign a contract, without incurring personal financial liability, to provide facility payment from the resident's income or resources.

(3) In the case of a person eligible for Medicaid, a nursing facility must not charge, solicit, accept, or receive, in addition to any amount otherwise required to be paid under the State plan, any gift, money, donation, or other consideration as a precondition of admission, expedited admission or continued stay in the facility. However,—

(i) A nursing facility may charge a resident who is eligible for Medicaid for items and services the resident has requested and received, and that are not specified in the State plan as included in the term "nursing facility services" so long as the facility gives proper notice of the availability and cost of these services to residents and does not condition the resident's admission or continued stay on the request for and receipt of such additional services; and

(ii) A nursing facility may solicit, accept, or receive a charitable, religious, or philanthropic contribution from an organization or from a person unrelated to a Medicaid eligible resident or potential resident, but only to the extent that the contribution is not a condition of admission, expedited admission, or continued stay in the facility for a Medicaid eligible resident.

(4) States or political subdivisions may apply stricter admissions standards under State or local laws than are specified in this section, to prohibit discrimination against individuals entitled to Medicaid.

§ 483.13 Resident behavior and facility practices.

(a) *Restraints.* The resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms.

(b) *Abuse.* The resident has the right to be free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion.

(c) *Staff treatment of residents.* The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property.

(1) The facility must—

(i) Not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion;

(ii) Not employ individuals who have been—

(A) Found guilty of abusing, neglecting, or mistreating individuals by a court of law; or

(B) Have had a finding entered into the State nurse aide registry concerning abuse, neglect, mistreatment of residents or misappropriation of their property; and

(iii) Report any knowledge it has of actions by a court of law against an employee, which would indicate unfitness for service as a nurse aide or other NF staff to the State nurse aide registry or licensing authorities.

(2) The facility must ensure that all alleged violations involving mistreatment, neglect, or abuse, including injuries of unknown source, and misappropriation of resident property are reported immediately to the administrator of the facility and to other officials in accordance with State law through established procedures (including to the State survey and certification agency).

(3) The facility must have evidence that all alleged violations are thoroughly investigated, and must prevent further potential abuse while the investigation is in progress.

(4) The results of all investigations must be reported to the administrator or his designated representative and to other officials in accordance with State law (including to the State survey and certification agency) within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken.

§ 483.15 Quality of life.

A facility must care for its residents in a manner and in an environment that promotes maintenance or enhancement of each resident's quality of life.

(a) *Dignity.* The facility must promote care for residents in a manner and in an environment that maintains or enhances each resident's dignity and respect in full recognition of his or her individuality.

(b) *Self-determination and participation.* The resident has the right to—

(1) Choose activities, schedules, and health care consistent with his or her interests, assessments, and plans of care;

(2) Interact with members of the community both inside and outside the facility; and

(3) Make choices about aspects of his or her life in the facility that are significant to the resident.

(c) *Participation in resident and family groups.*

(1) A resident has the right to organize and participate in resident groups in the facility;

(2) A resident's family has the right to meet in the facility with the families of other residents in the facility;

(3) The facility must provide a resident or family group, if one exists, with private space;

(4) Staff or visitors may attend meetings at the group's invitation;

(5) The facility must provide a designated staff person responsible for providing assistance and responding to written requests that result from group meetings;

(6) When a resident or family group exists, the facility must listen to the views and act upon the grievances and recommendations of residents and families concerning proposed policy and operational decisions affecting resident care and life in the facility.

(d) *Participation in other activities.* A resident has the right to participate in social, religious, and community activities that do not interfere with the rights of other residents in the facility.

(e) *Accommodation of needs.* A resident has the right to—

(1) Reside and receive services in the facility with reasonable accommodation of individual needs and preferences, except when the health or safety of the individual or other residents would be endangered; and

(2) Receive notice before the resident's room or roommate in the facility is changed.

(f) *Activities.*

(1) The facility must provide for an ongoing program of activities designed to meet, in accordance with the comprehensive assessment, the interests and the physical, mental, and psychosocial well-being of each resident.

(2) The activities program must be directed by a qualified professional who—

(i) Is a qualified therapeutic recreation specialist or an activities professional who is—

(A) Licensed or registered, if applicable, by the State in which practicing; and

(B) Eligible for certification as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body on October 1, 1990; or

(ii) Has 2 years of experience in a social or recreational program within the last 5 years, 1 of which was full-time in a patient activities program in a health care setting; or

(iii) Is a qualified occupational therapist or occupational therapy assistant; or

(iv) Has completed a training course approved by the State.

(g) *Social Services.* (1)—The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

(2) A facility with more than 120 beds must employ a qualified social worker on a full-time basis.

(3) *Qualifications of social worker.* A qualified social worker is an individual with—

(i) A bachelor's degree in social work or a bachelor's degree in a human services field including but not limited to sociology, special education, rehabilitation counseling, and psychology; and

(ii) One year of supervised social work experience in a health care setting working directly with individuals.

(h) *Environment.*

The facility must provide—

(1) A safe, clean, comfortable, and homelike environment, allowing the resident to use his or her personal belongings to the extent possible;

(2) Housekeeping and maintenance services necessary to maintain a sanitary, orderly, and comfortable interior;

(3) Clean bed and bath linens that are in good condition;

(4) Private closet space in each resident room, as specified in § 483.70(d)(2)(iv) of this Part;

(5) Adequate and comfortable lighting levels in all areas;

(6) Comfortable and safe temperature levels. Facilities initially certified after October 1, 1990 must maintain a temperature range of 71–81°F; and

(7) For the maintenance of comfortable sound levels.

§ 483.20 Resident assessment.

The facility must conduct initially and periodically a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity.

(a) *Admission orders.* At the time each resident is admitted, the facility must have physician orders for the resident's immediate care.

(b) *Comprehensive assessments.*

(1) The facility must make a comprehensive assessment of a resident's needs, which—

(i) Is based on a uniform data set specified by the Secretary and uses an instrument that is specified by the State and approved by the Secretary; and

(ii) Describes the resident's capability to perform daily life functions and significant impairments in functional capacity.

(2) The comprehensive assessment must include at least the following information:

(i) Medically defined conditions and prior medical history;

(ii) Medical status measurement;

(iii) Physical and mental functional status;

(iv) Sensory and physical impairments;

(v) Nutritional status and requirements;

(vi) Special treatments or procedures;

(vii) Mental and psychosocial status;

(viii) Discharge potential;

(ix) Dental condition;

(x) Activities potential;

(xi) Rehabilitation potential;

(xii) Cognitive status; and

(xiii) Drug therapy.

(3) [Reserved]

(4) *Frequency.* Assessments must be conducted—

(i) No later than 14 days after the date of admission;

(ii) For current NF residents not later than October 1, 1991;

(iii) For current SNF residents not later than January 1, 1991;

(iv) Promptly after a significant change in the resident's physical or mental condition; and

(v) In no case less often than once every 12 months.

(5) *Review of assessments.* The nursing facility must examine each resident no less than once every 3 months, and as appropriate, revise the resident's assessment to assure the continued accuracy of the assessment.

(6) *Use.* The results of the assessment are used to develop, review, and revise the resident's comprehensive plan of care, under paragraph (d) of this section.

(7) *Coordination.* The facility must coordinate assessments with any State-required preadmission screening program to the maximum extent practicable to avoid duplicative testing and effort.

(c) *Accuracy of assessments.* (1) *Coordination.* (i) Each assessment must be conducted or coordinated with the appropriate participation of health professionals.

(ii) Each assessment must be conducted or coordinated by a registered nurse who signs and certifies the completion of the assessment.

(2) *Certification.* Each individual who completes a portion of the assessment must sign and certify the accuracy of that portion of the assessment.

(3) *Penalty for Falsification.* An individual who willfully and knowingly certifies (or causes another individual to certify) a material and false statement in a resident assessment is subject to civil money penalties. The implementing regulations for this statutory authority are located in Part 1003 of this chapter.

(4) *Use of independent assessors.* If a State determines, under a survey or otherwise, that there has been a knowing and willful certification of false statements under paragraph (c)(3) of this section, the State may require (for a period specified by the State) that resident assessments under this paragraph be conducted and certified by individuals who are independent of the facility and who are approved by the State.

(d) *Comprehensive care plans.* (1) The facility must develop a comprehensive care plan for each resident that includes measurable objectives and timetables to meet a resident's medical, nursing, and mental and psychosocial needs that are identified in the comprehensive assessment.

The plan of care must deal with the relationship of items or services ordered to be provided (or withheld) to the facility's responsibility for fulfilling other requirements in these regulations.

(2) A comprehensive care plan must be—

(i) Developed within 7 days after completion of the comprehensive assessment;

(ii) Prepared by an interdisciplinary team, that includes the attending physician, a registered nurse with responsibility for the resident, and other appropriate staff in disciplines as determined by the resident's needs, and, to the extent practicable, the participation of the resident, the resident's family or the resident's legal representative; and

(iii) Periodically reviewed and revised by a team of qualified persons after each assessment.

(3) The services provided or arranged by the facility must—

(i) Meet professional standards of quality; and

(ii) Be provided by qualified persons in accordance with each resident's written plan of care.

(e) *Discharge summary.* When the facility anticipates discharges a resident must have a discharge summary that includes—

(1) A recapitulation of the resident's stay;

(2) A final summary of the resident's status to include items in paragraph (b)(2) of this section, at the time of the discharge that is available for release to authorized persons and agencies, with the consent of the resident or legal representative; and

(3) A post-discharge plan of care that is developed with the participation of the resident and his or her family, which will assist the resident to adjust to his or her new living environment.

(f) *Preadmission screening for mentally ill individuals and individuals with mental retardation.*

(1) A nursing facility must not admit, on or after January 1, 1989, any new resident with—

(i) Mental illness as defined in paragraph (f)(2)(i) of this section, unless the State mental health authority has determined, based on an independent physical and mental evaluation performed by a person or entity other than the State mental health authority, prior to admission,

(A) That, because of the physical and mental condition of the individual, the individual requires the level of services provided by a nursing facility; and

(B) If the individual requires such level of services, whether specialized services the individual requires active treatment for mental illness; or

(ii) Mental retardation, as defined in paragraph (f)(2)(ii) of this section, unless the State mental retardation or developmental disability authority has determined prior to admission—

(A) That, because of the physical and mental condition of the individual, the individual requires the level of services provided by a nursing facility; and

(B) If the individual requires such level of services, whether the individual requires active treatment for mental retardation.

(2) *Definition.* For purposes of this section—

(i) An individual is considered to have "mental illness" if the individual has a serious mental illness as defined in § 483.102(b)(1).

(ii) An individual is considered to be "mentally retarded" if the individual is mentally retarded as defined in § 483.102(b)(3) or is a person with a related condition as described in 42 CFR 435.1009.

§ 483.25 Quality of care.

Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

(a) *Activities of daily living.* Based on the comprehensive assessment of a resident, the facility must ensure that—

(1) A resident's abilities in activities of daily living do not diminish unless circumstances of the individual's clinical condition demonstrate that diminution was unavoidable. This includes the resident's ability to—

(i) Bathe, dress, and groom;

(ii) Transfer and ambulate;

(iii) Toilet;

(iv) Eat; and

(v) Use speech, language, or other functional communication systems.

(2) A resident is given the appropriate treatment and services to maintain or improve his or her abilities specified in paragraph (a)(1) of this section; and

(3) A resident who is unable to carry out activities of daily living receives the necessary services to maintain good nutrition, grooming, and personal and oral hygiene.

(b) *Vision and hearing.* To ensure that residents receive proper treatment and assistive devices to maintain vision and hearing abilities, the facility must, if necessary, assist the resident—

(1) In making appointments, and

(2) By arranging for transportation to and from the office of a practitioner specializing in the treatment of vision or hearing impairment or the office of a professional specializing in the provision of vision or hearing assistive devices.

(c) *Pressure sores.* Based on the comprehensive assessment of a resident, the facility must ensure that—

(1) A resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable; and

(2) A resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.

(d) *Urinary Incontinence.* Based on the resident's comprehensive assessment, the facility must ensure that—

(1) A resident who enters the facility without an indwelling catheter is not catheterized unless the resident's clinical condition demonstrates that catheterization was necessary; and

(2) A resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible.

(e) *Range of motion.* Based on the comprehensive assessment of a resident, the facility must ensure that—

(1) A resident who enters the facility without a limited range of motion does not experience reduction in range of motion unless the resident's clinical condition demonstrates that a reduction in range of motion is unavoidable; and

(2) A resident with a limited range of motion receives appropriate treatment and services to increase range of motion and/or to prevent further decrease in range of motion.

(f) *Mental and Psychosocial functioning.* Based on the comprehensive assessment of a resident, the facility must ensure that—

(1) A resident who displays mental or psychosocial adjustment difficulty, receives appropriate treatment and services to correct the assessed problem, and

(2) A resident whose assessment did not reveal a mental or psychosocial adjustment difficulty does not display a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors, unless the resident's clinical condition demonstrates that such a pattern was unavoidable.

(g) *Naso-gastric tubes.* Based on the comprehensive assessment of a resident, the facility must ensure that—

(1) A resident who has been able to eat enough alone or with assistance is not fed by naso-gastric tube unless the resident's clinical condition demonstrates that use of a naso-gastric tube was unavoidable; and

(2) A resident who is fed by a naso-gastric or gastrostomy tube receives the appropriate treatment and services to prevent aspiration pneumonia, diarrhea, vomiting, dehydration, metabolic abnormalities, and nasal-pharyngeal ulcers and to restore, if possible, normal feeding function.

(h) *Accidents.* The facility must ensure that—

(1) The resident environment remains as free of accident hazards as is possible; and

(2) Each resident receives adequate supervision and assistance devices to prevent accidents.

(i) *Nutrition.* Based on a resident's comprehensive assessment, the facility must ensure that a resident—

(1) Maintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible; and

(2) Receives a therapeutic diet when there is a nutritional problem.

(j) *Hydration.* The facility must provide each resident with sufficient fluid intake to maintain proper hydration and health.

(k) *Special needs.* The facility must ensure that residents receive proper treatment and care for the following special services:

(1) Injections;

(2) Parenteral and enteral fluids;

(3) Colostomy, ureterostomy, or ileostomy care;

(4) Tracheostomy care;

(5) Tracheal suctioning;

(6) Respiratory care;

(7) Foot care; and

(8) Prostheses.

(l) *Unnecessary drug*—(1) *General.* Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:

(i) In excessive dose (including duplicate drug therapy); or

(ii) For excessive duration; or

(iii) Without adequate monitoring; or

(iv) Without adequate indications for its use; or

(v) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or

(vi) Any combinations of the reasons above.

(2) *Antipsychotic Drugs.* Based on a comprehensive assessment of a resident, the facility must ensure that—

(i) Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and

(ii) Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.

(m) *Medication Errors*—The facility must ensure that—

(1) It is free of medication error rates of five percent or greater; and

(2) Residents are free of any significant medication errors.

§§ 483.28 and 483.29 [Removed]

4. Sections 483.28 and 483.29 are removed.

5. In Subpart B, §§ 483.30, 483.35, 483.40, 483.45, 483.55, 483.60, 483.65, 483.70 and 483.75 are revised as follows:

§ 483.30 Nursing services.

The facility must have sufficient nursing staff to provide nursing and related services to attain or maintain the highest practicable physical, mental,

and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care.

(a) *Sufficient staff.* (1) The facility must provide services by sufficient numbers of each of the following types of personnel on a 24-hour basis to provide nursing care to all residents in accordance with resident care plans:

(i) Except when waived under paragraph (c) of this section, licensed nurses; and

(ii) Other nursing personnel.

(2) Except when waived under paragraph (c) of this section, the facility must designate a licensed nurse to serve as a charge nurse on each tour of duty.

(b) *Registered nurse.* (1) Except when waived under paragraph (c) or (d) of this section, the facility must use the services of a registered nurse for at least 8 consecutive hours a day, 7 days a week.

(2) Except when waived under paragraph (c) or (d) of this section, the facility must designate a registered nurse to serve as the director of nursing on a full time basis.

(3) The director of nursing may serve as a charge nurse only when the facility has an average daily occupancy of 60 or fewer residents.

(c) *Nursing facilities: Waiver of requirement to provide licensed nurses on a 24-hour basis.* To the extent that a facility is unable to meet the requirements of paragraphs (a)(2) and (b)(1) of this section, a State may waive such requirements with respect to the facility if—

(1) The facility demonstrates to the satisfaction of the State that the facility has been unable, despite diligent efforts (including offering wages at the community prevailing rate for nursing facilities), to recruit appropriate personnel;

(2) The State determines that a waiver of the requirement will not endanger the health or safety of individuals staying in the facility;

(3) The State finds that, for any periods in which licensed nursing services are not available, a registered nurse or a physician is obligated to respond immediately to telephone calls from the facility;

(4) A waiver granted under the conditions listed in paragraph (c) of this section is subject to annual State review;

(5) In granting or renewing a waiver, a facility may be required by the State to use other qualified, licensed personnel;

(6) The State agency granting a waiver of such requirements provides notice of the waiver to the State long term care ombudsman (established under section 307(a)(12) of the Older Americans Act of 1965) and the protection and advocacy system in the State for the mentally ill and mentally retarded; and

(7) The nursing facility that is granted such a waiver by a State notifies residents of the facility (or, where appropriate, the guardians or legal representatives of such residents) and members of their immediate families of the waiver.

(d) *SNFs: Waiver of the requirement to provide services of a registered nurse for more than 40 hours a week.*

(1) The Secretary may waive the requirement that a SNF provide the services of a registered nurse for more than 40 hours a week, including a director of nursing specified in paragraph (b) of this section, if the Secretary finds that—

(i) The facility is located in a rural area and the supply of skilled nursing facility services in the area is not sufficient to meet the needs of individuals residing in the area;

(ii) The facility has one full-time registered nurse who is regularly on duty at the facility 40 hours a week; and

(iii) The facility either—

(A) Has only patients whose physicians have indicated (through physicians' orders or admission notes) that they do not require the services of a registered nurse or a physician for a 48-hours period, or

(B) Has made arrangements for a registered nurse or a physician to spend time at the facility, as determined necessary by the physician, to provide necessary skilled nursing services on days when the regular full-time registered nurse is not on duty;

(iv) The Secretary provides notice of the waiver to the State long term care ombudsman (established under section 307(a)(12) of the Older American Act of 1965) and the protection and advocacy system in the State for the mentally ill and mentally retarded; and

(v) The facility that is granted such a waiver notifies residents of the facility (or, where appropriate, the guardians or legal representatives of such residents) and members of their immediate families of the waiver.

(2) A waiver of the registered nurse requirement under paragraph (d)(1) of this section is subject to annual renewal by the Secretary.

§ 483.35 Dietary services.

The facility must provide each resident with a nourishing, palatable, well-balanced diet that meets the daily nutritional and special dietary needs of each resident.

(a) *Staffing.* The facility must employ a qualified dietitian either full-time, part-time, or on a consultant basis.

(1) If a qualified dietitian is not employed full-time, the facility must designate a person to serve as the director of food service who receives frequently scheduled consultation from a qualified dietitian.

(2) A qualified dietitian is one who is qualified based upon either registration by the Commission on Dietetic Registration of the American Dietetic Association, or on the basis of education, training, or experience in identification of dietary needs, planning, and implementation of dietary programs.

(b) *Sufficient staff.* The facility must employ sufficient support personnel competent to carry out the functions of the dietary service.

(c) *Menus and nutritional adequacy.* Menus must—

(1) Meet the nutritional needs of residents in accordance with the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences;

(2) Be prepared in advance; and

(3) Be followed.

(d) *Food.* Each resident receives and the facility provides—

(1) Food prepared by methods that conserve nutritive value, flavor, and appearance;

(2) Food that is palatable, attractive, and at the proper temperature;

(3) Food prepared in a form designed to meet individual needs; and

(4) Substitutes offered of similar nutritive value to residents who refuse food served.

(e) *Therapeutic diets.* Therapeutic diets must be prescribed by the attending physician.

(f) *Frequency of meals.* (1) Each resident receives and the facility provides at least three meals daily, at regular times comparable to normal mealtimes in the community.

(2) There must be no more than 14 hours between a substantial evening meal and breakfast the following day, except as provided in (4) below.

(3) The facility must offer snacks at bedtime daily.

(4) When a nourishing snack is provided at bedtime, up to 16 hours may elapse between a substantial evening meal and breakfast the following day if a resident group agrees to this meal span, and a nourishing snack is served.

(g) *Assistive devices.* The facility must provide special eating equipment and utensils for residents who need them.

(h) *Sanitary conditions.* The facility must—

(1) Procure food from sources approved or considered satisfactory by Federal, State, or local authorities;

(2) Store, prepare, distribute, and serve food under sanitary conditions; and

(3) Dispose of garbage and refuse properly.

§ 483.40 Physician services.

A physician must personally approve in writing a recommendation that an individual be admitted to a facility. Each resident must remain under the care of a physician.

(a) *Physician supervision.* The facility must ensure that—

(1) The medical care of each resident is supervised by a physician; and

(2) Another physician supervises the medical care of residents when their attending physician is unavailable.

(b) *Physician visits.* The physician must—

(1) Review the resident's total program of care, including medications and treatments, at each visit required by paragraph (c) of this section;

(2) Write, sign, and date progress notes at each visit; and

(3) Sign and date all orders.

(c) *Frequency of physician visits.*

(1) The resident must be seen by a physician at least once every 30 days for the first 90 days after admission, and at least once every 60 days thereafter.

(2) A physician visit is considered timely if it occurs not later than 10 days after the date the visit was required.

(3) Except as provided in paragraphs (c)(4) and (f) of this section, all required physician visits must be made by the physician personally.

(4) At the option of the physician, required visits in SNFs after the initial visit may alternate between personal visits by the physician and visits by a physician assistant, nurse practitioner, or clinical nurse specialist in accordance with paragraph (e) of this section.

(d) *Availability of physicians for emergency care.* The facility must provide or arrange for the provision of physician services 24 hours a day, in case of an emergency.

(e) *Physician delegation of tasks in SNFs.* (1) Except as specified in paragraph (e)(2) of this section, a physician may delegate tasks to a physician assistant, nurse practitioner, or clinical nurse specialist who—

(i) Meets the applicable definition in § 491.2 of this chapter or, in the case of a clinical nurse specialist, is licensed as such by the State;

(ii) Is acting within the scope of practice as defined by State law; and

(iii) Is under the supervision of the physician.

(2) A physician may not delegate a task when the regulations specify that the physician must perform it personally, or when the delegation is prohibited under State law or by the facility's own policies.

(f) *Performance of physician tasks in NFs.* At the option of the State, any required physician task in a NF (including tasks which the regulations specify must be performed personally by the physician) may also be satisfied when performed by a nurse practitioner, clinical nurse specialist, or physician assistant who is not an employee of the facility but who is working in collaboration with a physician.

§ 483.45 Specialized rehabilitative services.

(a) *Provision of services.* If specialized rehabilitative services such as but not limited to physical therapy, speech-language pathology, occupational therapy, and health rehabilitative services for mental illness and mental retardation, are required in the resident's comprehensive plan of care, the facility must—

(1) Provide the required services; or

(2) Obtain the required services from an outside resource (in accordance with § 483.75(j) of this part) from a provider of specialized rehabilitative services.

(b) *Qualifications.* Specialized rehabilitative services must be provided under the written order of a physician by qualified personnel.

§ 483.55 Dental services.

The facility must assist residents in obtaining routine and 24-hour emergency dental care.

(a) *Skilled nursing facilities.* A facility (1) Must provide or obtain from an outside resource, in accordance with § 483.75(h) of this part, routine and emergency dental services to meet the needs of each resident;

(2) May charge a Medicare resident an additional amount for routine and emergency dental services;

(3) Must if necessary, assist the resident—

(i) In making appointments; and

(ii) By arranging for transportation to and from the dentist's office; and

(4) Promptly refer residents with lost or damaged dentures to a dentist.

(b) *Nursing facilities.* The facility (1) Must provide or obtain from an outside resource, in accordance with § 483.75(h) of this part, the following dental services to meet the needs of each resident:

(i) Routine dental services (to the extent covered under the State plan); and

(ii) Emergency dental services;

(2) Must, if necessary, assist the resident—

(i) In making appointments; and

(ii) By arranging for transportation to and from the dentist's office; and

(3) Must promptly refer residents with lost or damaged dentures to a dentist.

§ 483.60 Pharmacy services.

The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in § 483.75(h) of this part. The facility may permit unlicensed personnel to administer drugs if State law permits, but only under the general supervision of a licensed nurse.

(a) *Procedures.* A facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.

(b) *Service consultation.* The facility must employ or obtain the services of a licensed pharmacist who—

(1) Provides consultation on all aspects of the provision of pharmacy services in the facility;

(2) Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and

(3) Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

(c) *Drug regimen review.* (1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.

(2) The pharmacist must report any irregularities to the attending physician and the director of nursing, and these reports must be acted upon.

(d) *Labeling of drugs and biologicals.* Drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and including the appropriate accessory and cautionary instructions, and the expiration date when applicable.

(e) *Storage of drugs and biologicals.*

(1) In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys.

(2) The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs

subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.

§ 483.65 Infection control.

The facility must establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of disease and infection.

(a) *Infection control program.* The facility must establish an infection control program under which it—

(1) Investigates, controls, and prevents infections in the facility;

(2) Decides what procedures, such as isolation, should be applied to an individual resident; and

(3) Maintains a record of incidents and corrective actions related to infections.

(b) *Preventing spread of infection.* (1) When the infection control program determines that a resident needs isolation to prevent the spread of infection, the facility must isolate the resident.

(2) The facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease.

(3) The facility must require staff to wash their hands after each direct resident contact for which handwashing is indicated by accepted professional practice.

(c) *Linens.* Personnel must handle, store, process, and transport linens so as to prevent the spread of infection

§ 483.70 Physical environment.

The facility must be designed, constructed, equipped, and maintained to protect the health and safety of residents, personnel and the public.

(a) *Life safety from fire.* Except as provided in paragraph (a)(1) or (a)(3) of this section, the facility must meet the applicable provisions of the 1985 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference). Incorporation of the 1985 edition of the National Fire Protection Association's Life Safety Code (published February 7, 1985; ANSI/NFPA) was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 that govern the use of incorporations by reference.[1]

(1) A facility is considered to be in compliance with this requirement as long as the facility—

(i) On November 26, 1982, complied with or without waivers, with the requirements of the 1967 or 1973 editions of the Life Safety Code and continues to remain in compliance with those editions of the Code; or

(ii) On May 9, 1988, complied, with or without wavers, with the 1981 edition of the Life Safety Code and continues to remain in compliance with that edition of the Code.

(2) After consideration of State survey agency findings, HCFA, or in the case of a nursing facility (including a dually participating facility), the State survey agency may waive specific provisions of the Life Safety Code which, if rigidly applied would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of residents or personnel.

(3) The provisions of the Life Safety Code do not apply in a State where HCFA finds, in accordance with applicable provisions of sections 1819(d)(2)(B)(ii) and 1919(d)(2)(B)(ii) of the Act, that a fire and safety code imposed by State law adequately protects patients, residents and personnel in long term care facilities.

(b) *Emergency power.*

(1) An emergency electrical power system must supply power adequate at least for lighting all entrances and exits; equipment to maintain the fire detection, alarm, and extinguishing systems; and life support systems in the event the normal electrical supply is interrupted.

(2) When life support systems are used, the facility must provide emergency electrical power with an emergency generator (as defined in NFPA 99, Health Care Facilities) that is located on the premises.

(c) *Space and equipment.* The facility must—

(1) Provide sufficient space and equipment in dining, health services, recreation, and program areas to enable staff to provide residents with needed services as required by these standards and as identified in each resident's plan of care; and

(2) Maintain all essential mechanical, electrical, and patient care equipment in safe operating condition.

(d) *Resident rooms.* Resident rooms must be designed and equipped for adequate nursing care, comfort, and privacy of residents.

(1) Bedrooms must—

(i) Accommodate no more than four residents;

(ii) Measure at least 80 square feet per resident in multiple resident bedrooms, and at least 100 square feet in single resident rooms;

(iii) Have direct access to an exit corridor;

(iv) Be designed or equipped to assure full visual privacy for each resident;

(v) In facilities initially certified after September 30, 1990, except in private rooms, each bed must have ceiling suspended curtains, which extend around the bed to provide total visual privacy in combination with adjacent walls and curtains;

(vi) Have at least one window to the outside; and

(vii) Have a floor at or above grade level.

(2) The facility must provide each resident with—

(i) A separate bed of proper size and height for the convenience of the resident;

(ii) A clean, comfortable mattress;

(iii) Bedding appropriate to the weather and climate; and

(iv) Functional furniture appropriate to the resident's needs, and individual closet space in the resident's bedroom with clothes racks and shelves accessible to the resident.

(3) HCFA, or in the case of a nursing facility the survey agency, may permit variations in requirements specified in paragraphs (d)(1) (i) and (ii) of this section relating to rooms in individual cases when the facility demonstrates in writing that the variations—

(i) Are in accordance with the special needs of the residents; and

(ii) Will not adversely affect residents' health and safety.

(e) *Toilet facilities.* Each resident room must be equipped with or located near toilet and bathing facilities.

(f) *Resident call system.* The nurse's station must be equipped to receive resident calls through a communication system from—

(1) Resident rooms; and

(2) Toilet and bathing facilities.

(g) *Dining and resident activities.* The facility must provide one or more rooms designated for resident dining and activities. These rooms must—

(1) Be well lighted;

(2) Be well ventilated, with nonsmoking areas identified;

(3) Be adequately furnished; and

(4) Have sufficient space to accommodate all activities.

(h) *Other environmental conditions.* The facility must provide a safe, functional, sanitary, and comfortable

[1] The Code is available for inspection at the Office of the Federal Register Information Center, room 8301, 1110 L Street NW., Washington, DC Copies may be obtained from the National Fire Protection Association, Batterymarch Park, Quincy, MA 02200. If any changes in this code are also to be incorporated by reference, a notice to that effect will be published in the **Federal Register**.

environment for the residents, staff and the public. The facility must—

(1) Establish procedures to ensure that water is available to essential areas when there is a loss of normal water supply;

(2) Have adequate outside ventilation by means of windows, or mechanical ventilation, or a combination of the two;

(3) Equip corridors with firmly secured handrails on each side; and

(4) Maintain an effective pest control program so that the facility is free of pests and rodents.

§ 483.75 Administration.

A facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

(a) *Licensure.* A facility must be licensed under applicable State and local law.

(b) *Compliance with Federal, State, and local laws and professional standards.* The facility must operate and provide services in compliance with all applicable Federal, State, and local laws, regulations, and codes, and with accepted professional standards and principles that apply to professionals providing services in such a facility.

(c) *Relationship to other HHS regulations.* In addition to compliance with the regulations set forth in this subpart, facilities are obliged to meet the applicable provisions of other HHS regulations, including but not limited to those pertaining to nondiscrimination on the basis of race, color, or national origin (45 CFR part 80); nondiscrimination on the basis of handicap (45 CFR part 84); nondiscrimination on the basis of age (45 CFR part 91); protection of human subjects of research (45 CFR part 46); and fraud and abuse (42 CFR part 455). Although these regulations are not in themselves considered requirements under this part, their violation may result in the termination or suspension of, or the refusal to grant or continue payment with Federal funds.

(d) *Governing body.* (1) The facility must have a governing body, or designated persons functioning as a governing body, that is legally responsible for establishing and implementing policies regarding the management and operation of the facility; and

(2) The governing body appoints the administrator who is—

(i) Licensed by the State where licensing is required; and

(ii) Responsible for management of the facility.

(e) *Required training of nurse aides*—(1) *General rule.* Effective October 1, 1990, a facility must not use any individual working in the facility as a nurse aide for more than 4 months, on a full-time, temporary, per diem, or other basis, unless:

(i) That individual has completed a training and competency evaluation program, or a competency evaluation program approved by the State, and

(ii) That individual is competent to provide nursing and nursing related services.

(2) *Rule for non-full-time employees.* A facility may not use an individual as a nurse aide on a temporary, per diem, leased, or any basis other than a permanent employee after January 1, 1991 unless the individual meets the requirements in paragraph (e)(1) (i) and (ii) of this section.

(3) *Competency evaluation programs for current employees.* A facility must provide, for individuals used as nurse aides as of January 1, 1990, a competency evaluation program approved by the State, and preparation necessary for the individual to complete the program by October 1, 1990.

(4) *Competency.* Effective October 1, 1990, a facility may permit an individual to serve as a nurse aide or provide services of a type for which the individual has not demonstrated competence only when—

(i) The individual is in a training or competency evaluation program approved by the State; and

(ii) The facility has asked and not yet evaluated a reply from the State registry for information concerning the individual.

(5) *State nurse aide registries checks.* A facility must check with all State nurse aide registries it has reason to believe contain information on an individual before using that individual as a nurse aide.

(6) *Required retraining.* When an individual has not performed paid nursing or nursing-related services for a continuous period of 24 consecutive months since the most recent completion of a training and competency evaluation program, the facility must require the individual to complete a new training and competency evaluation program.

(7) *Regular in-service education.* The facility must provide regular performance review and regular in-service education to ensure that individuals used as nurse aides are competent to perform services as nurse aides. In-service education must include training for individuals providing nursing and nursing-related services to residents with cognitive impairments.

(8) *Definition of nurse aide.* For purposes of this section, the term, *nurse aide,* means any individual providing nursing or nursing-related services to residents in a facility. This definition does not include an individual who volunteers to provide such services without pay, who is a registered dietitian, or who is a licensed health professional.

(9) *Definition of licensed health professional.* For purposes of this section, the term "licensed health professional" means a physician; physician assistant; nurse practitioner; physical, speech, or occupational therapy assistant; registered professional nurse; licensed practical nurse; or licensed or certified social worker.

(f) *Proficiency of Nurse aides.* The facility must ensure that nurse aides are able to demonstrate competency in skills and techniques necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care.

(g) *Staff qualifications.* (1) The facility must employ on a full-time, part-time or consultant basis those professionals necessary to carry out the provisions of these requirements.

(2) Professional staff must be licensed, certified, or registered in accordance with applicable State laws.

(h) *Use of outside resources.* (1) If the facility does not employ a qualified professional person to furnish a specific service to be provided by the facility, the facility must have that service furnished to residents by a person or agency outside the facility under an arrangement described in section 1861(w) of the Act or an agreement described in paragraph (h)(2) of this section.

(2) Arrangements as described in section 1861(w) of the Act or agreements pertaining to services furnished by outside resources must specify in writing that the facility assumes responsibility for—

(i) Obtaining services that meet professional standards and principles that apply to professionals providing services in such a facility; and

(ii) The timeliness of the services.

(i) *Medical director.* (1) The facility must designate a physician to serve as medical director.

(2) The medical director is responsible for—

(i) Implementation of resident care policies; and

(ii) The coordination of medical care in the facility.

(j) *Laboratory services.* (1) The facility must provide or obtain clinical laboratory services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.

(i) If the facility provides its own laboratory services, the services must meet the applicable conditions for coverage of the services furnished by laboratories specified in part 493 of this chapter;

(ii) If the facility provides blood bank and transfusion services, it must meet the requirements for laboratories specified in part 493 of this chapter.

(iii) If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory must be approved or licensed to test specimens in the appropriate specialties and/or subspecialties of service in accordance with part 493 of this chapter;

(iv) If the facility does not provide laboratory services on site, it must have an agreement to obtain these services only from a laboratory that meets the requirements of part 493 of this chapter or from a physician's office.

(2) The facility must—

(i) Provide or obtain laboratory services only when ordered by the attending physicians;

(ii) Promptly notify the attending physician of the findings;

(iii) Assist the resident in making transportation arrangements to and from the source of service, if the resident needs assistance.

(iv) File in the resident's clinical record laboratory reports that are dated and contain the name and address of the issuing laboratory.

(k) *Radiology and other diagnostic services.* (1) The facility must provide or obtain radiology and other diagnostic services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.

(i) If the facility provides its own diagnostic services, the services must meet the applicable conditions of participation for hospitals contained in § 482.26 of this subchapter.

(ii) If the facility does not provide its own diagnostic services, it must have an agreement to obtain these services from a provider or supplier that is approved to provide these services under Medicare.

(2) The facility must—

(i) Provide or obtain radiology and other diagnostic services only when ordered by the attending physician;

(ii) Promptly notify the attending physician of the findings;

(iii) Assist the resident in making transportation arrangements to and from the source of service, if the resident needs assistance; and

(iv) File in the resident's clinical record signed and dated reports of x-ray and other diagnostic services.

(l) *Clinical records.* (1) The facility must maintain clinical records on each resident in accordance with accepted professional standards and practices that are—

(i) Complete;

(ii) Accurately documented;

(iii) Readily accessible; and

(iv) Systematically organized.

(2) Clinical records must be retained for—

(i) The period of time required by State law; or

(ii) Five years from the date of discharge when there is no requirement in State law; or

(iii) For a minor, three years after a resident reaches legal age under State law.

(3) The facility must safeguard clinical record information against loss, destruction, or unauthorized use;

(4) The facility must keep confidential all information contained in the resident's records, regardless of the form or storage method of the records, except when release is required by—

(i) Transfer to another health care institution;

(ii) Law;

(iii) Third party payment contract; or

(iv) The resident.

(5) The clinical record must contain—

(i) Sufficient information to identify the resident;

(ii) A record of the resident's assessments;

(iii) The plan of care and services provided;

(iv) The results of any preadmission screening conducted by the State; and

(v) Progress notes.

(m) *Disaster and emergency preparedness.* (1) The facility must have detailed written plans and procedures to meet all potential emergencies and disasters, such as fire, severe weather, and missing residents.

(2) The facility must train all employees in emergency procedures when they begin to work in the facility, periodically review the procedures with existing staff, and carry out unannounced staff drills using those procedures.

(n) *Transfer agreement.* (1) In accordance with section 1861(l) of the Act, the facility (other than a nursing facility which is located in a State on an Indian reservation) must have in effect a written transfer agreement with one or more hospitals approved for participation under the Medicare and Medicaid programs that reasonably assures that—

(i) Residents will be transferred from the facility to the hospital, and ensured of timely admission to the hospital when transfer is medically appropriate as determined by the attending physician; and

(ii) Medical and other information needed for care and treatment of residents, and, when the transferring facility deems it appropriate, for determining whether such residents can be adequately cared for in a less expensive setting than either the facility or the hospital, will be exchanged between the institutions.

(2) The facility is considered to have a transfer agreement in effect if the facility has attempted in good faith to enter into an agreement with a hospital sufficiently close to the facility to make transfer feasible.

(o) *Quality assessment and assurance.* (1) A facility must maintain a quality assessment and assurance committee consisting of—

(i) The director of nursing services;

(ii) A physician designated by the facility; and

(iii) At least 3 other members of the facility's staff.

(2) The quality assessment and assurance committee—

(i) Meets at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary; and

(ii) Develops and implements appropriate plans of action to correct identified quality deficiencies.

(3) A State or the Secretary may not require disclosure of the records of such committee except in so far as such disclosure is related to the compliance of such committee with the requirements of this section.

(p) *Disclosure of ownership.*

(1) The facility must comply with the disclosure requirements of §§ 420.206 and 455.104 of this chapter.

(2) The facility must provide written notice to the State agency responsible for licensing the facility at the time of change, if a change occurs in—

(i) Persons with an ownership or control interest, as defined in §§ 420.201 and 455.101 of this chapter;

(ii) The officers, directors, agents, or managing employees;

(iii) The corporation, association, or other company responsible for the management of the facility; or

(iv) The facility's administrator or director of nursing.

(3) The notice specified in paragraph (p)(2) of this section must include the

identity of each new individual or company.

PART 488—SURVEY AND CERTIFICATION PROCEDURES

D. Part 488 is amended as follows:

1. The authority citation for part 488 is revised to read as follows:

Authority: Secs. 1102 1814, 1861, 1865, 1866, 1871, 1880, 1881, 1883, 1913 of the Social Security Act (42 U.S.C. 1302, 1395f, 1395x, 1395bb, 1395cc, 1395hh, 1395qq, 1395rr and 1395tt).

§ 488.1 [Amended]

2–3. In § 488.1, in the definition of "Certification," "NFs" is substituted for "ICFs," and in the definition of "Provider of services or provider," "nursing facility," is added after the phrase "skilled nursing facility."

4. In § 488.3, the section heading and paragraphs (a)(1) and (a)(2) are revised to read as follows:

§ 488.3 Conditions of participation: Conditions for coverage and requirements for SNFs and NFs.

(a) * * *

(1) Meet the applicable statutory definition in section 1861, section 1819, or section 1919, section 1881 of the Act; and

(2) Be in compliance with the applicable conditions or requirements (for SNFs and NFs) prescribed in Subpart N, Q, or U of part 405, subpart C of part 418, part 482, or part 483, part 484, subpart A of part 491 or part 493 of this chapter.

* * * * *

§ 488.10 [Amended]

5. In 488.10, paragraph (a)(1), the phrase "or requirements (for SNFs and NFs)" is added after the phrase "conditions of participation".

6. Section 488.11 is revised to read as follows:

§ 488.11 State survey agency functions.

State and local agencies that have agreements under section 1864(a) of the Act—

(a) Survey and make recommendations regarding the issues listed in § 488.10;

(b) Conduct validation surveys as provided in § 488.6; and

(c) Perform other surveys and other appropriate activities and certify their findings to HCFA.

7. In § 488.18, paragraphs (a) and (b) are revised to read as follows:

§ 488.18 Documentation of findings.

(a) The findings of the State agency with respect to each of the conditions of participation or level A requirements (for SNFs and NFs) or conditions for coverage shall be adequately documented. Where the State agency certifies to the Secretary that a provider or supplier is not in compliance with the conditions or requirements (for SNFs and NFs), and therefore not eligible to participate in the program, such documentation includes, in addition to the description of the specific deficiencies which resulted in the agency's recommendation, a report of all consultation which has been undertaken in an effort to assist the provider or supplier to comply with the conditions, a report of the provider's or supplier's responses with respect to the consultation, and the State agency's assessment of the prospects for such improvements as to enable the provider or supplier to achieve compliance with the conditions or requirements (for SNFs and NFs) within a reasonable period of time. (See § 488.28 of this part.)

(b) If a provider or supplier is certified by the State agency as in compliance with the conditions or level A requirements (for SNFs and NFs) or as meeting the requirements for special certification (see § 488.54 of this part), with deficiencies not adversely affecting the health and safety of patients, the following information will be incorporated into the finding:

(1) A statement of the deficiencies which were found, and

(2) A description of further action which is required to remove the deficiencies, and

(3) A time-phased plan of correction developed by the provider and supplier and concurred with by the State agency, and

(4) A scheduled time for a resurvey of the institution or agency to be conducted by the state agency within 90 days following the completion of the survey.

§ 488.20 [Amended]

8. In § 488.20, paragraphs (a) and (c), "NFs" is substituted for "ICFs."

§ 488.24 [Amended]

9. In § 488.24, paragraphs (a) and (b), "NFs" is substituted for "ICFs."

§ 488.26 [Amended]

10. In § 488.26(a), "NFs" is substituted for "ICFs."

§ 488.28 [Amended]

11. In § 488.28, paragraphs (a) and (b), "NFs" is substituted for "ICFs."

12. In § 488.50, the introductory text in paragraph (a) is revised to read as follows:

Subpart B—Special Requirements

§ 488.50 Special requirements applicable to skilled nursing facilities with deficiencies.

(a) Where the facility is not in full compliance with the level B requirements contained in subpart B of part 483, the period of certification shall:

* * * * *

§ 488.56 [Amended]

13. In § 488.56, paragraph (a) the reference "483.20" is substituted for the reference "§ 405.1124" and in paragraph (b), introductory text, and (b)(2), the reference "§ 488.75(k)" is substituted for the reference "§ 405.1122".

PART 489—PROVIDER AGREEMENTS UNDER MEDICARE

G. Part 489 is amended as follows:

1. The authority citation for Part 489 is revised to read as follows:

Authority: Secs. 1102, 1861, 1864, 1866, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x, 1395aa. 1395cc, and 1395hh).

§ 489.53 [Amended]

2. In subpart E, § 489.53(a)(3), "NFs" is substituted for "ICFs" and in paragraph (b)(1), the phrase "Part 483, Part B" is substituted for the phrase "Part 405, Subpart K".

§ 489.60 [Amended]

3. In Subpart F, § 489.60(a), introductory text, the phrase "level A requirement specified in Subpart B of Part 483" is substituted for "level A requirement specified in Subpart K of Part 405".

PART 489—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM

E. Part 498 is amended as follows:

1. The authority citation for Part 498 continues to read as follows:

Authority: Secs. 205(a), 1102, 1869(c) 1871, and 1872 of the Social Security Act (42 U.S.C. 405(a), 1302, 1395ff(c), 1395hh and 1395ii, unless otherwise noted).

§ 498.3 [Amended]

2. In § 498.3, (b)(8), (d)(1), (2) and (10), "NFs" is substituted for "ICFs."

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

Dated: January 31, 1991.

Gail R. Wilensky,

Administrator, Health Care Financing Administration.

Approved: February 25, 1991.

Louis W. Sullivan,

Secretary.

[FR Doc. 91-22274 Filed 9-25-91; 8:45 am]

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42 CFR Parts 431, 433 and 483

RIN: 0938-AE50

[BPD-662-F]

Medicare and Medicaid Programs; Nurse Aide Training and Competency Evaluation Programs

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

ACTION: Final rule.

SUMMARY: This rule amends the Medicare and Medicaid regulations pertaining to facilities to incorporate Federal requirements that States have training and competency evaluation programs for nurse aides employed by Medicare participating skilled nursing facilities and Medicaid participating nursing facilities and also have a nurse aide registry.

The purpose of these provisions is to ensure that nurse aides have the education, practical knowledge, and skills needed to care for residents of facilities participating in the Medicare and Medicaid programs. These requirements implement, in part, sections 4201(a) and 4211(a) of the Omnibus Budget Reconciliation Act of 1987, section 6901(b) of the Omnibus Budget Reconciliation Act of 1989, and sections 4008 and 4801 of the Omnibus Budget Reconciliation Act of 1990.

EFFECTIVE DATE: These regulations are effective April 1, 1992. This effective date does not relieve States and facilities from their obligation to perform certain activities effective on earlier dates specified by the statute. A summary of statutory effective dates is given in the preamble of these regulations.

State agencies have until 90 days after receipt of a revised State plan preprint to submit their plan amendments and required attachments. We will not hold a State to be out of compliance with the requirements of these final regulations if the State submits the necessary preprint plan material by that date.

FOR FURTHER INFORMATION CONTACT: Martha Kuespert (301) 966-1782.

SUPPLEMENTARY INFORMATION:

I. Background

Facilities participating in the Medicare and Medicaid programs (skilled nursing facilities (SNFs) under Medicare and nursing facilities (NFs) under Medicaid) agree, as a requirement of participation, to comply with the requirements included in our regulations at 42 CFR part 483, Requirements for Long-Term Care Facilities. These requirements were recently revised to implement section 4201 and 4211 of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) (Pub. L. 100-203), enacted on December 22, 1987. OBRA '87 made substantive changes to the requirements of participation for Medicare and Medicaid facilities, the process by which they are surveyed and certified, and the actions permissible as a result of enforcement of those requirements.

As part of these sweeping revisions to the long-term care regulations, OBRA '87 added certain provisions to the Social Security Act (the Act) relating to nurse aide competency evaluation programs (CEPs) and nurse aide training and competency evaluation programs (NATCEPs). Prior to the enactment of OBRA '87, there were no Federal requirements concerning training and competency evaluation of nurse aides. Rather, conditions of participation for Medicare at 42 CFR 405.1121(h) and conditions for coverage for Medicaid at § 442.314 required only that all staff be suitably and appropriately trained.

Sections 4201(a) and 4211(a) of OBRA '87 added new sections 1819(b)(5), 1819(e)(1), 1819(f)(2), 1919(b)(5), 1919(e)(1), and 1919(f)(2) to the Act that—

- Prohibit facilities participating in the Medicare and Medicaid programs from using an individual as a nurse aide in the facility for more than four months unless the individual has completed a NATCEP or a CEP approved by the State and is competent to provide such services.
- Require the Secretary to establish standards for the training and competency evaluation of nurse aides.
- Require States to grant approvals only of CEPs and NATCEPs that meet the standards established by the Secretary. The failure of the Secretary to establish requirements does not relieve States of their responsibility to specify programs that meet the requirements in sections 1819(f)(2) and 1919(f)(2) of the Act.
- Prohibit States from approving a program offered by or in a SNF or NF that has been determined to be out of compliance with Federal long-term care facility requirements within the previous two years.
- Prohibit States from approving a program offered by or in a SNF or NF unless the State makes the determination, upon an individual's completion of the program, that the individual is competent to provide nursing and nursing-related services in SNFs or NFs.
- Require States to maintain a registry of all individuals who have successfully completed a NATCEP or a CEP.

Section 4211(d) of OBRA '87 also amended section 1903(a)(2) of the Act to specify the Federal financial participation (FFP) matching rate for NATCEP and CEP expenditures, and the availability of enhanced funding for those expenditures.

The Omnibus Budget Reconciliation Act of 1989 (OBRA '89) (Pub. L. 101-239), enacted December 19, 1989, made several changes to the OBRA '87 nurse aide training and competency evaluation requirements. Specifically, section 6901 of OBRA '89—

- Delayed until October 1, 1990, the requirement that nurse aides be trained and competent (section 6901(b)(1)).
- Allowed an individual to be considered to meet the requirements of completing a NATCEP under certain circumstances (section 6901(b)(4)(B) and (C)).
- Allowed States to waive the competency evaluation requirements in the case of nurse aides who, as of December 19, 1989 (the enactment date of OBRA '89) had worked for 24 consecutive months in the State for one or more facilities of the same employer (section 6901(b)(4)(D)).
- Clarified that NATCEPs must address care to cognitively impaired residents (section 6901(b)(3)(A)).
- Required NATCEPs and CEPs to offer nurse aides alternatives to a written examination (section 6901(b)(3)(D)).
- Prohibited approval of programs that charge nurse aides for course materials or testing (section 6901(b)(3)(D)).

Section 6901(b)(5) of OBRA '89 also amended section 1903(a)(2)(B) of the Act to clarify further the time period that temporary enhanced Federal funding is available for NATCEPs and CEPs. Section 1903(a)(2)(B) of the Act specifies that Federal financial participation (FFP) for NATCEPs and CEPs is available in the following amounts: for calendar quarters beginning on or after July 1, 1988 and before July 1, 1990, the