Memorandum regarding proposed revisions to the Division of Liquidation's delegations of authority.

Personnel actions regarding appointments, promotions, administrative pay increases, reassignments, retirements, separations, removals, etc.:

Names of employees authorized to be exempt from disclosure pursuant to the provisions of subsections (c)(2) and (c)(6) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(2) and (c)(6)).

Memorandum regarding the Corporation's supervisory activities.

Matters relating to the possible closing of certain insured banks:

Names and locations of banks authorized to be exempt from disclosure pursuant to the provisions of subsections (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

The meeting will be held in the Board Room on the sixth floor of the FDIC Building located at 550 17th Street, NW., Washington, DC.

Requests for further information concerning the meeting may be directed to Mr. Hoyle L. Robinson, Executive Secretary of the Corporation, at (202) 898–3813.

Dated: May 31, 1988.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[FR Doc. 88–12550 Filed 5–31–88; 5:06 am]

BILLING CODE 6714–01–M

FEDERAL RESERVE SYSTEM BOARD OF GOVERNORS

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 53 FR 18654, May 24, 1988.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 11:00 a.m., Tuesday, May 31, 1988.

CHANGES IN THE MEETING: Addition of the following closed item(s) to the meeting: Government in the Sunshine consideration of a personnel matter.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204.

Date: May 31, 1988.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 88–12554 Filed 5–31–88; 5:07 pm]

BILLING CODE 6210–01–M

FEDERAL RESERVE SYSTEM BOARD OF GOVERNORS

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: Notice forwarded to Federal Register on May 27, 1988.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 11:00 a.m., Monday, June 6, 1988.

CHANGES IN THE MEETING: Addition of the following closed item(s) to the meeting: Policy proposals regarding a drug testing program.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204.

Date: May 31, 1988.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 88–12555 Filed 5–31–88; 5:07 pm]

BILLING CODE 6210–01–M

NATIONAL COMMISSION ON LIBRARIES AND INFORMATION SCIENCE

DATE AND TIME: June 14–15, 1988.

PLACE: Embassy Suites Hotel, Crystal Ballroom A, 1881 Curtis Street, Denver, Colorado 80202.

STATUS:

June 14, 1988, 9:00 a.m.–10:00 a.m.—Closed
Sec. 1703.202(2) and (6) of the Code of Federal Regulations, 45 CFR, Part 1703
June 14, 1988, 10:00 a.m.–6:15 p.m.—Open
June 15, 1988, 9:00 a.m.–3:30 p.m.—Open

MATTERS TO BE DISCUSSED:

Chairman's Report
Approval of April 21, 1988 Minutes
Executive Director's Report
—FY 88 Third Quarter Program Report
—Administrative Report
Vice Chairman's Report
National Advisory Committee Presentation on Support for Minimum Equipment
Chief Officers of State Library Agency Report, Wayne Johnson, Wyoming
State Library Reports—
Wyoming, Wayne Johnson
Colorado, Nancy Bolt
Oklahoma, Robert Clark
1990 NCLIS Programs—Report and Discussion
Film on School Library Guidelines Teleconference
NCLIS Committee Reports
—Budget and Finance
—International
—Legislative
—Public Affairs
—White House Conference
Privatization of NTIS
FOIA Related Activities
Library Statistics Collection Program
Information Age Issues
Special Population Literacy Programs
NCLIS 1989 Meeting Sites
Information for Governance Program Report

Special provisions will be made for handicapped individuals by calling Jane McDuffie (202) 254–3100, no later than one week in advance of the meeting.

FOR FURTHER INFORMATION CONTACT: Daniel Carter, NCLIS Acting Executive Director, 1111 18th Street, NW., Suite 310, Washington, DC 20036 (202) 254–3100.

Dated: May 31, 1988.

Jane McDuffie,

Staff Assistant.

[FR Doc. 88–12656 Filed 6–1–88; 2:41 pm]

BILLING CODE 7527–01–M

Corrections

Federal Register
Vol. 53, No. 107
Friday, June 3, 1988

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents and volumes of the Code of Federal Regulations. 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 THE INTERIOR

Bureau of Land Management

[AZ-020-08-4212-13;A-23254]

Realty Action; Exchange of Public Lands; Maricopa, Mohave, Pima and Santa Cruz Counties, AZ

Correction

In notice document 88-7478 beginning on page 11142 in the issue of Tuesday, April 5, 1988, make the following correction:

On page 11142, in the second column, the 13th line should read "Township 15 South, Range 14 East.".

BILLING CODE 1505-01-D

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 87-ASW-38]

Revision of Transition Area; Jacksonville, TX

Correction

In rule document 88-11199 beginning on page 17919 in the issue of Thursday, May 19, 1988, make the following correction:

§ 71.181 [Corrected]

On page 17920, in the first column, in § 71.181, under **Jacksonville, TX**, in the seventh line, the longitude should read "95°12'55" W.".

BILLING CODE 1505-01-D

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 87-ASW-63]

Airworthiness Directives; Bell Helicopter Textron, Inc. (BHTI), Model 204B, 205A, 205A-1, and 212 Helicopters

Correction

In proposed rule document 88-7697 beginning on page 11678 in the issue of Friday, April 8, 1988, make the following corrections:

§ 39.13 [Corrected]

1. On page 11679, in the first column, in § 39.13, under **Bell Helicopter Textron, Inc. (BHTI)**, in the third paragraph, in the second line, "P/N 204-011-105-450" should read "P/N 204-011-450"; in the third line, remove "P/N"; remove the entire fourth line; and remove "rotor trunnion," from the fifth line.

2. On the same page, in the same column, in paragraph (a), the third line should read "for the main rotor mast, P/N 204-011-450 (all dash numbers), and main rotor trunnion, P/N 204-011-105-001,".

3. On the same page, in the same column, in paragraph (b), in the second line, "14,000" should read "14,900".

BILLING CODE 1505-01-D

Federal Register

Friday
June 3, 1988

Part II

Department of Agriculture

Food and Nutrition Service

7 CFR Part 250

Donation of Food for Use in the United States, Its Territories and Possessions and Areas Under Its Jurisdictions; Interim Rule With Request for Comments

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Part 250

Donation of Food for Use in the United States, Its Territories and Possessions and Areas Under Its Jurisdictions

AGENCY: Food and Nutrition Services, USDA.

ACTION: Interim rule with request for comments.

SUMMARY: This interim rule will amend the Food Distribution Program regulations (7 CFR Part 250) by: (1) Strengthening provisions for inventory controls, use of program funds, audits, storage facilities and management evaluation reviews; (2) restructuring to provide for greater ease in the reading and understanding of the regulations; and (3) revising provisions for the renewal of agreements. Those provisions relative to the processing of donated food which appeared on July 1, 1986 (51 FR 23719–24130) and July 2, 1987 (52 FR 24937–24978) in the **Federal Register** are included to provide for a complete version of the Food Distribution Program regulations.

DATES: Interim rule effective July 5, 1988, comments must be received on or before November 30, 1988. Comments are not being solicited on §§ 250.11(a), 250.15(c), 250.15(f)(1), 250.16(a)(4) (last sentence), 250.17(c), 250.17(b), 250.18(b), 250.18(c), 250.19(b)(2) and 250.30 and the definitions of "contract value of the donated foods," "Federal acceptance service," "multi-State processor," "refund application," "substituted food" and "substitution" as contained in § 250.3.

ADDRESS: Susan E. Proden, Chief, Program Administration Branch, Food Distribution Division, Food and Nutrition Service, Park Office Center, Alexandria, Virginia 22302.

Comments in response to this interim rule may be inspected at the address above during normal business hours (8:30 a.m. to 5:00 p.m. Monday through Friday).

FOR FURTHER INFORMATION CONTACT: Susan E. Proden, Chief, Program Administration Branch (703) 756–3660.

SUPPLEMENTARY INFORMATION:

Classification

This action has been reviewed under Executive Order 12291 and has not been classified major because it does not meet any of the three criteria identified under the Executive Order. This action will not have an annual effect on the economy of $100 million or more nor will it result in a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions. This action will not have 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.

This rule has been reviewed with regard to the Regulatory Flexibility Act (5 U.S.C. 601–612). Anna Kondratas, Administrator of the Food and Nutrition Service, has certified that this action will not have a significant economic impact on a substantial number of small entities. The reporting and recordkeeping requirements contained in this rule have been approved by the Office of Management and Budget in accordance with the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3507). The OMB approval numbers are noted at the relevant point of the regulations.

The Department is issuing this rule as an interim rule rather than a final rule. The Department has already solicited and considered public comments concerning this rulemaking effort. In a typical rulemaking, the Department would now issue a final rule. However, because this rulemaking involves extensive modifications to program operations, the Department has determined that additional public comments would be beneficial. Therefore, we are issuing this rule as an interim rule in order to provide distributing agencies and recipient agencies with the opportunity to comment based on actual operating experience with the new regulations.

Since the provisions that pertain to processing were published in final on July 1, 1986 (51 FR 23719–24130) the Department is not soliciting comments on §§ 250.17(b), 250.17(c), 250.18(b), 250.18(c), 250.19(b)(2) and 250.30 and the definitions of "contract value of the donated foods," "Federal acceptance service," "multi-State processor," and "refund application" as contained in Section 250.3 of this rule. Similarly, since comments have already been solicited on the provisions concerning the substitution of concentrated skim milk for nonfat dry milk under State processing contracts which were published as an interim rule on July 2, 1987 (52 FR 24973–24978), no additional comments are being solicited on the last sentence of § 250.16(a)(4) and the definitions of "substituted food" and "substitution" as contained in § 250.3 of this rule. In addition, § 250.15(c) (claims), § 250.15(f)(1) (use of funds accruing from claims) and § 250.21 (civil rights) were reserved in the proposed rule. The current regulatory provisions concerning claims and use of funds accruing from claims have been inserted into this rule at these sections to provide a complete version of Food Distribution Program regulations. However, any changes to these two provisions will be addressed in a separate rulemaking. Since these provisions reflect the current regulation, no comments are being solicited on them at this time.

The civil rights section has been amended to provide cross references to the Departmental regulations on civil rights. Comments on this section and all other provisions of this rule will be considered in the development of final regulations.

The Department also wishes to point out that this rule does not reflect any of the changes required by the recently enacted Commodity Distribution Reform Act of 1987 (Pub. L. 100–237). The Department will be issuing regulations concerning this Act in the near future.

This program is listed in the Catalog of Federal Domestic Assistance under No. 10.550 and is subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. (7 CFR Part 3015, Subpart V, and final rule related notice 48 FR 29114 (June 24, 1983)).

Background

The regulations governing the Food Distribution Program (7 CFR Part 250) outline the responsibilities of the Food and Nutrition Service (FNS) and distributing agencies concerning the distribution and use of federally donated foods. The current regulations provide for the distribution of donated foods to a variety of domestic outlets, including entities participating in the child nutrition programs and nutrition programs for the elderly, charitable institutions, nonprofit summer camps for children, and certain low-income households and disaster organizations.

Analysis of Comments

On August 19, 1985, FNS published a proposed rule in the **Federal Register** (50 FR 33470) to amend the Food Distribution Regulations (7 CFR Part 250) by: (1) Strengthening provisions for inventory controls, use of program funds, audits, storage facilities and management evaluation reviews; (2) restructuring to provide for greater ease in the reading and understanding of the regulations; and (3) revising provisions for the renewal of agreements; and

strengthening provisions for the processing of donated foods.

In an effort to assist FNS in revising Part 250, comments were solicited on the proposed changes. The proposed revision encompassed nearly all provisions contained in Part 250. Comments were not solicited on the regulations regarding the National Commodity Processing Program, which were subsequently moved to 7 CFR Part 252 and three provisions, claims (§ 250.15(c)), use of funds accruing from claims (§ 250.15(f)(1)), and civil rights (§ 250.21) were reserved for further consideration and development prior to proposal.

The general public was given 90 days for comment on the proposed revision. A total of 305 comment letters was received from various sources such as distributing agencies, recipient agencies, processors, distributors of processed end products, the American School Food Service Association, the National Association of State Agencies for Food Distribution and the American Institute of Certified Public Accountants.

Restructuring

In an effort to simplify the organization of Part 250, the proposed rule set forth the provisions under one part with separate subparts for: (1) General, (2) General Operating Provisions, (3) Processing and Labeling of Donated Foods, and (4) Eligible Recipient Agencies and Programs. The restructuring was intended to provide greater ease in reading and understanding of the regulations and to eliminate the need for a significant amount of repetition. The commenters overwhelmingly supported the restructuring of the regulations, as proposed. Thus, the interim rule is issued in the same format as the proposed rule.

The exerpts of legislative provisions were deleted in the proposed rule. However, summaries of section 4(a) of the Agriculture and Consumer Protection Act of 1973, as amended; sections 6 and 14 of the National School Lunch Act, as amended; section 32 of Pub. L. 74–320, as amended; section 311 of the Older Americans Act of 1965, as amended; section 416 of the Agricultural Act of 1949, as amended; and section 709 of the Food and Agriculture Act of 1965, as amended; were included under definitions. These are the primary legislative provisions authorizing the purchase and donation of food items. A few commenters were concerned about the elimination of the legislative quotations. It is the Department's opinion that a lengthy list of the full text of these provisions is unnecessary since a summary of the primary provisions relative to the purchase and donation of food for distribution to eligible recipient agencies is being retained under the definitions section. FNS will, however, make available a summary of all legislative authorities upon request.

Definitions

"Distributing agency"—Although the Department has always considered indian tribal organizations (ITOs) to be inherent in the definition of a "distributing agency," the Department is concerned that confusion may result from the lack of specific reference. In order to clarify this matter, the interim rule definition specifically refers to ITOs. "Nonresidential Child Care Centers"—In § 250.3 of the proposed rule the term "nonresidential child care centers" included reference to child care centers, day care homes and sponsoring organizations. In the interim rule, reference is made to "institution" instead. This term more accurately describes the entities which participate in the Child Care Food Program. The proposed definition unnecessarily included day care homes, which can only participate under the auspices of a sponsoring organization and failed to include outside-school-hours care centers.

"School"—is amended by revising the definition to reflect recent changes to the term in the National School Lunch Program. The changes consist of clarifying the eligibility of preprimary classes for the National School Lunch Program, and clarifying that school means an education unit of high school grade or under which is recognized as part of the education system in the State.

"Tuition"—As a result of the elimination of tuition limitation by Pub. L. 100–71, the tuition limitation in the definition of "school" and the definition of "tuition" have been deleted.

"School food authority"—is amended to reflect changes to the definition in the National School Lunch Program regulations which were necessary to recognize special accommodations between public schools and private schools or residential child care institutions, when approved by FNS.

"Substituted food" and "Substitution"—are new or expanded terms that appeared in the interim concentrated skim milk substitution rule which was published July 2, 1987 at 52 FR 24973. These terms are included in this rule to provide a complete text. No comments are being taken on these definitions in this rulemaking.

Eligibility Determinations for Recipient Agencies and Recipients

Section 250.11 of the proposed rule required that distributing agencies determine the eligibility of all applicants, enter into agreements with those which were determined to be eligible and make donated foods available.

A total of twenty comments was received on this requirement. Ten commenters were opposed to the provision. They maintained that requiring the distributing agency to determine the eligibility of and make donated foods available to all eligible organizations which apply for participation in the Temporary Emergency Food Assistance Program (TEFAP) was not feasible due to the limited amounts of donated foods which are currently being provided. The Department did not intend for this provision to apply to TEFAP. Agreements between distributing agencies and emergency feeding organizations are governed by § 251.2 of this subchapter, not § 250.11.

Commenters also recommended that they be allowed to impose minimum size requirements on recipient agencies. That is, commenters said they should have the authority to reject applications from very small organizations since the cost of administering the program to such organizations could be very high compared to the amount of commodities to be received. The Department does not believe that it is appropriate for a distributing agency to reject any recipient agency by establishing a minimum number of persons which a recipient agency must serve in order to receive donated foods. Rather, the Department considers the recipient agency's past performance practices to be the only justification for denying participation. Thus, this provision is retained in Section 250.11 of the interim rule with the clarification that in determining recipient agency eligibility that the agency's past performance be a factor in the determination.

The Department published a new § 250.11 regarding the verification of recipient agency eligibility on June 30, 1986 (51 FR 23518). However, the terms "State distributing agency" and "State agency" were inadvertently used in this section rather than "distributing agency." Since the Part 250 regulations use the term "distributing agency," we are replacing the words "State distributing agency" and "agency" with "distributing agency" to maintain consistency. The provisions of the June 30, 1986 rule and the proposed § 250.11

have been redesignated as § 250.11 (a) and (b), respectively.

Agreements

Agreements with Department—Section 250.12(a) of the proposed rule required distributing agencies to enter into an agreement with the Department prior to the beginning of a distribution program. The agreement was to be completed by September 30 of each year and be effective for no longer than one year. The same requirement applies to State Agencies on Aging which receive any cash in lieu of commodities in connection with nutrition programs for the elderly.

A total of eight comments was received from distributing agencies regarding this provision. Five commenters opposed the requirement on the basis that the provision generated more paperwork and that the completion date conflicted with most school calendars.

Since agreements are currently required annually, the only change in the proposal was that agreements be completed by September 30. As noted in the preamble of the proposed rule, the September 30 requirement was added to make the term of these agreements coincide with the fiscal year, facilitating compliance with reporting requirements which are generally on a fiscal year basis. Therefore, § 250.12(a) of this interim rule retains the provision as proposed.

Distributing Agency Agreement—Section 250.12(b) of the proposed regulations required that the agreements between distributing agencies, subdistributing agencies, recipient agencies, warehouses, carriers, etc. be in writing and be effective for no longer than one year.

Forty-three comments were received on this proposal. Thirty one commenters indicated that the requirement for an annual agreement would be time consuming, substantially increase workload and paperwork, tax an already insufficient staff, and detract from operational flexibility. Distributing agencies administering more than one program indicated that they need the flexibility of writing one agreement to cover a variety of programs.

In response to the commenters concerns, § 250.12(b) of the interim rule has been modified to permit the one year agreements to be extended at the option of both parties, for two additional one-year periods. As a part of each extension, the party contracting with the distributing agency must update all pertinent information and demonstrate that all donated foods received during the previous contract period have been accounted for. In order to ensure program integrity in light of the three-year contract cycle, contracts must include a termination clause whereby either party may terminate the agreement for cause with 30 days notice.

The provision regarding two one-year extensions of contracts does not apply to existing contracts. It applies only to contracts signed after the effective date of this rule. It is generally the policy of the Department not to apply a rule retroactively. In the case of agreements with subdistributing agencies and recipient agencies, the two extension options will reduce paperwork and workload. In the case of agreements for warehouses, etc., the option for two one-year extensions will mean that the distributing agency will need to engage in procurement procedures for that contract only once every three years. The Department believes that this three-year bidding cycle will reduce paperwork and provide added stability with respect to the contracted services, while maintaining adequate assurances that the procurement is conducted in a manner that provides open and free competition.

Also a new sentence has been added to § 250.12(b) to clearly specify the distributing agencies' ongoing responsibility for ensuring program integrity at the subdistributing agency level, and below.

Food Service Management Company Agreement—Section 250.12(c) of the proposed regulations required that recipient agencies enter into written agreements with food service management companies and that the agreements be effective no longer than one year.

Nine comments were received on this proposal. Commenters were concerned that this requirement to limit the agreement to one year was inconsistent with the National School Lunch Program (NSLP) regulations with respect to the duration of food service management company contracts.

The Department did not intend to create inconsistencies with existing regulations concerning food service management companies. Instead, the objective was to ensure accountability when food service management companies use donated foods in the preparation of meals under their contracts with recipient agencies. In the case of food service management company agreements with recipient agencies which participate in the Child Nutrition Programs, this provision was intended only to add some requirements concerning the use of commodities and not to create an inconsistency concerning the length of contracts. Therefore, this interim rule has been revised to limit the provision concerning contract length to those recipient agencies which do not participate in the Child Nutrition Programs: nonprofit summer camps for children, charitable institutions, and nutrition programs for the elderly. In addition, the interim rule has been modified to permit the one-year agreements to be extended at the option of both parties, for two additional one-year periods. As a part of each extension, the recipient agency and food service management company must update all pertinent information and demonstrate that the full value of all donated foods received during the previous contract period have been accounted for. In order to ensure program integrity in light of the potential three-year contract cycle for charitable institutions, nutrition programs for the elderly and nonprofit summer camps for children, agreements with these recipient agencies must include a termination clause whereby either party may terminate the agreement for cause with 30 days notice. The provision regarding two one-year extensions of contracts does not apply to existing contracts with food service management companies. It applies only to food service management company contracts signed after the effective date of this rule. It is generally the policy of the Department not to apply a rule retroactively. Finally, a cross-reference to the review requirements in § 250.19(b) has been added.

Transfer of Donated Foods

Section 250.13(a)(1) of the proposed rule required that recipient agencies receive authorization from the distributing agency and the appropriate FNSRO prior to transferring donated foods which have been provided as part of an approved food package or authorized program level of assistance and continued to require distributing agency approval of all other transfers. In addition, the proposed rule required all transfers to be documented on the FNS–155 or FNS–152.

Eighty-six comments were received on this proposed requirement. Some commenters felt the provision was overly burdensome and costly. Other commenters felt that the dual authorization requirement could result in food spoilage before the transfer could be made. Commenters recommended among other things that: (1) FNSRO approval be required only for those transfers made to recipient agencies not originally authorized to receive that particular donated food; (2) approval not be required for transfers

made between like recipient agencies; (3) approval be based on the value of the donated food being transferred; and (4) documentation be made available during reviews in lieu of requiring advance approval.

Subsequent to the proposed rule, sections 1564(a) and 1561 of Pub. L. 99–198 (the Food Security Act of 1985) authorized the Secretary to use commodities made available under section 32 of Pub. L. 74–320 (7 U.S.C. 612c) in the Temporary Emergency Food Assistance Program and amended section 32 to permit the transfer of section 32 commodities among the agencies originally receiving those donated foods. On May 13, 1987 (52 FR 17928), the Department published a final rule amending both the Food Distribution and TEFAP regulations regarding the transfer of section 32 commodities. This rule permits the transfer of section 32 commodities from Part 250 recipient agencies to Part 251 emergency feeding organizations and vice versa. Such transfers must be approved by both the distributing agency and the State agency administering the TEFAP, and must be documented in a manner that provides an audit trail.

In light of the concerns raised by the commenters on this provision, the Department is revising § 250.13(a)(1) in this interim rule to allow for transfer of donated foods which have been provided as part of an approved food package or authorized program level of assistance between like recipient agencies (schools to schools) with prior approval by only the distributing agency. The Department believes that permitting transfers of this class of donated foods between like recipient agencies with only the distributing agency's approval will give the distributing agency flexibility in administering the program while ensuring that ineligible recipient agencies do not receive the donated foods. However, the transfer of donated foods which have been provided as part of an approved food package or authorized program level of assistance between unlike recipient agencies (schools to charitable institutions), must be approved by the appropriate FNSRO. This rule adopts the provision of the proposed rule that transfers of donated food which are provided *in addition* to the authorized program level of assistance may be transferred between recipient agencies with the prior authorization of the distributing agency alone.

The necessary authorization for the transfer of section 32 commodities will depend on whether the section 32 commodities have been provided as a part of the authorized program level of assistance. The transfer of section 32 commodities from recipient agencies to TEFAP emergency feeding organizations will continue to be governed by the requirements set forth in the May 31, 1987 rule and incorporated into this rule (prior authorization of the distributing agency and the TEFAP State agency and documentation sufficient to provide an audit trail).

It has also come to the Department's attention that there is some confusion regarding the conditions on the transfer of commodities by summer camps at the end of the camping session. While the Department anticipates that there would be no commodities remaining at the end of the camping session, it should be noted that should there be remaining commodities, these may be transferred to other recipient agencies with the approval of the distributing agency.

In an effort to reduce the paperwork burden which would result from the requirement of the proposed rule that all transfers be documented on FNS–155 or FNS–152, the interim regulation requires only that transfers be documented in any manner that provides an audit trail. Such documentation must be retained in accordance with the recordkeeping requirements of §§ 250.16 and 251.10(a).

In addition, section 1506 of Pub. L. 99–198 amended section 4(b) of the Food Stamp Act to eliminate the current ban on the distribution of Federally donated foods directly to households in jurisdictions that operate the Food Stamp Program. Accordingly, this prohibition has been deleted from § 250.13(a)(1) of this interim rule.

Storage Facilities

Standards—Section 250.14(a) of the proposed rule outlined general standards for storage facilities and required distributing agencies, subdistributing agencies and recipient agencies responsible for the contracting of storage facilities to ensure that warehouse facilities meet existing Federal, State or local health department standards, whichever were more stringent.

Fifty-seven comments were received on the proposed provision. Forty-six commenters opposed the provision on the basis that it would increase workload and cost. The majority of the commenters stated that it is not feasible to expect agencies to compare Federal, State and local health department standards to determine which particular standard is more stringent for every requirement associated with storage practices. Several commenters recommended that the Department develop minimum standards in lieu of referring to Federal, State or local standards.

It appears that these commenters have misinterpreted the Department's intent concerning this requirement. This requirement does not mean that the agency contracting for the storage must itself conduct inspections to insure compliance with applicable Federal, State or local health standards. Nor did the Department intend that the distributing, subdistributing, recipient agency or the Department develop their own standards regarding proper storage. The Department believes that existing Federal, State and local regulations of the health conditions of storage facilities should provide sufficient protection of the Department's donated foods. However, the Department wishes to ensure that these storage facilities have actually received any inspection and/or approvals required under existing laws and regulations. As a result, § 250.14(a) has been revised to emphasize that the responsibility of the agency contracting for the storage facility is to ensure that the storage facility has obtained all required inspections and/or approvals and that they are current. This can be accomplished by reviewing documentation provided to the storage facility by the Federal, State and/or local health departments or by contacting the regulatory agencies for confirmation.

Several commenters recommended that the requirement regarding the use of pallets be deleted. Since the size of some storage areas does in fact prevent the use of pallets, § 250.14(a) of this rule requires that donated foods be stored off the floor in a manner that provides for adequate ventilation.

Reviews—Section 250.14(b) of the proposed rule required that distributing agencies ensure that an on-site review of the storage facilities be conducted prior to entering into or renewing a contract for the storage, handling and distribution of foods.

Forty comments were received concerning this requirement. Thirty-five of the commenters recommended that the requirement be revised or deleted because commenters felt there were insufficient staff and/or funds to conduct the reviews. Several of the commenters recommended that the review be conducted during the contract period as part of the management evaluation review and that the Department clarify that subdistributing agencies and recipient agencies are responsible for reviews of their respective storage facilities.

The Department believes that the review of storage facilities is essential for accountability. Distributing agencies can prevent claims by ensuring that storage facilities adhere to program regulations. Furthermore, the Department believes that oversight review of storage facilities is important, because improper storage is the primary cause of food loss claims. Clearly, it is essential that commodities be stored in a safe environment. Consequently, § 250.14(b) of this interim rule requires that all distributing agency level storage facilities be reviewed annually. In addition, distributing agencies must ensure that subdistributing and recipient agencies conduct annual reviews of their respective storage facilities. Documentation that will reflect compliance as well as documentation of corrective action taken in cases of noncompliance must be maintained on file at the distributing agency or local level as appropriate.

Contracts—Section 250.14(c) of the proposed rule required that distributing agencies, subdistributing agencies and recipient agencies enter into annual written contracts for the leasing of storage facilities.

Eighty-four comments were received on this proposal. Seventy commenters recommended that the requirement be deleted or revised. Several of the commenters expressed concern about the adverse effects such a requirement would have. For example, commenters indicated that: (1) Substantial savings are realized when contracts are entered into for longer periods of time; (2) in instances when contracts are entered into through the competitive bidding process, States would not only be required to go through this process every year but the requirement could also necessitate annual transfers between storage facilities; (3) this would eliminate free storage and adversely affect temporary or short-term storage.

The Department believes that a written contract is essential to clearly establish the liability between the two parties involved. Without such a contract, establishing claims when losses occur can be problematic. Therefore, this interim rule provides for an annual contract. In recognition of the benefits of a longer contract cycle, the interim rule has been modified to permit the one-year agreements to be extended at the option of both parties, for two addtional one-year periods. As a part of each extension, the storage facility must update all pertinent information and demonstrate that all donated foods received during the previous contract period have been accounted for.

The provision regarding two one-year extensions of contracts does not apply to existing contracts with storage facilities. It applies only to storage facility contracts signed after the effective date of this rule. It is generally the policy of the Department not to apply a rule retroactively.

In addition, the Department is limiting to distributing agencies and subdistributing agencies the requirements in § 250.14(d) that storage facility contracts be in writing and be subject to a maximum three year bidding cycle. A corresponding change has been made to § 250.12(d). Recipient agencies have been exempted from this requirement because of the heavy paperwork burden involved in such a requirement, particularly in light of the typically small amount of commodities stored by recipient agencies. As pointed out by the commenters, these requirements could adversely affect the ability of recipient agencies to find temporary or short-term storage. The Department also agrees with the commenters' concern that the contract requirements might limit the availability of low-cost or free storage arrangements sometimes offered as a service to schools or other recipient agencies. For these reasons, the requirement for a written storage contract subject to a three-year bidding cycle has been limited to distributing agency and subdistributing agency storage contracts. However, there is nothing to prohibit the distributing agency from requiring recipient agencies to have a written contract.

With respect to the assurances the contract must contain, the interim rule requires (1) annual rather than semi-annual inventories as proposed (2) reconciliation of the annual physical inventory with the inventory records, and (3) termination of the contract for cause by either party upon 30 days notice, rather than for any reason and with 60 days notice as proposed. The changes involving the inventories are discussed in the next section. The Department believes that the changes in the time for notice prior to the termination and the reasons therefore is necessary in light of the potential three year periods which will be permitted between bidding for contracts.

Physical Inventory—Accountability and monitoring of donated foods are two areas that have been under close scrutiny as a result of nationwide audits conducted both by the Department's Office of Inspector General (OIG) and the General Accounting Office (GAO). OIG found that the system presently in use is inefficient for monitoring levels of donated foods.

To ensure stricter inventory controls and accountability of donated foods, § 250.14(d) of the proposed rule required distributing agencies, subdistributing agencies, and recipient agencies to conduct semi-annual physical inventories of all storage facilities being used for the handling, storage and distribution of donated foods by June 30 and December 30 of each year. The physical inventory information was to be submitted to the appropriate FNSRO as part of the monthly inventory report for the months of June and December.

Eighty-five comments were received regarding this proposed requirement. Seventy-five of the commenters expressed concern that the requirement would increase costs and that there were insufficient staff to conduct such inventories. Commenters made the following recommendations: (1) Delete the semi-annual physical inventory requirement; (2) conduct physical inventories annually; (3) limit inventories to facilities owned or used by distributing agencies and recipient agencies; (4) limit inventories to distributing agency contracted facilities; or (5) review inventories during management evaluation reviews.

In recognition of the points raised by commenters while taking into consideration the concerns of the Office of the Inspector General (OIG) and recommendations of the General Accounting Office (GAO), § 250.14(d) of this interim rule requires that during the annual review required by § 250.14(b) a physical inventory be taken of the storage facility and reconciled with the storage facility's inventory records and that the reconciliation be kept on file by the agency which contracted with or maintained the storage facility. While a perpetual inventory is not specifically required by this rule, in the Department's view a daily accounting of the usage of each donated food is an essential part of good management practice. A perpetual inventory record should show: (1) Dates of all transactions; (2) quantities withdrawn; and (3) balance of food in storage. The physical inventory will then serve as a check on the accuracy of the inventory records. Any major differences in the two inventories, however, must be investigated thoroughly. Corrective action must be taken immediately and reported to the distributing agency. Since this rule requires that the physical inventory information be maintained on file, § 250.17(b) which required submission of this information to the

FNSRO, has been deleted in this interim rule.

Excessive inventories—Section 250.14(e) of the proposed rule limited the inventory level of distributing agencies, subdistributing agencies and recipient agencies to a six month supply, unless a justification for a higher level was approved.

A total of eighty comments was received on this provision. Seventy-four commenters recommended that the provision be deleted or revised for the following reasons: (1) Some products are offered only once a year; and (2) the Department's policy for shipping only truckload lots gives some States a year's allotment at one time. However, several commenters endorsed the requirement, as proposed.

The provision limiting the inventory level to a six-month supply, unless justification for a higher level is approved, is retained in § 250.14(e) of this interim rule. Audits by OIG and GAO have disclosed major problems associated with excessive inventory levels. The reports indicated that excessive inventories resulted in increased storage costs, greater potential for infestation and spoilage and difficulty in effectively using the product. In addition, in instances when a food item may be offered only once, the limited supply of a food item is sufficient justification for either the distributing agency or FNSRO to approve a higher inventory level. Also, the Department is trying to eliminate inconsistencies in the commodity program whenever possible. Retaining the six-month inventory level provision will make the Food Distribution Program consistent with the current inventory limitations on processors participating under the National Commodity Processing System and State processing contracts.

Financial Management

Section 813 of Pub. L. 100–77 extended the date for prohibiting the assessment of fees for the intrastate cost of storage and transportation under Part 251 of this chapter through September 30, 1988. Accordingly, this nondiscretionary requirement has been included in § 250.15(a)(2) of this interim rule.

Claims for Improper Distribution, Loss of, or Damage to Donated Foods and Use of Funds Accruing from Claims

Section 250.6(m) of the current regulations requires the distributing agencies to pursue claims arising in their favor immediately upon receipt of information regarding commodity loss, damage, or improper distribution. Certain exemptions from claims actions are provided for in instances of minimal inventory shortages or losses. Section 250.6(k) of the current regulations contains provisions concerning the use of funds accruing from claims, as well as the use of funds accruing from other aspects of program operations. At the time the overall revisions to Part 250 were proposed, a determination was made that further consideration should be given to the procedures for pursuing claims and the use of funds accrued as a result of such claims action. Thus, §§ 250.15(c) and (f)(1) were reserved in the proposed rule. Because a proposed rule soliciting comments on these procedures has not been published, the provisions specified in § 250.6(m) and (k) of the current rule have been incorporated into this interim rule. Since these provisions are merely being incorporated from the current regulations, no comments are being solicited at this time. The Department intends to publish a proposed rule addressing these provisions at a later date.

Use of Program Funds

Allowable Administrative Expenses—Section 250.15(f)(2) of the proposed rule listed some examples of unallowable expenses and also referenced the Office of Management and Budget (OMB) Circular A–87, which outlines in more detail the expenditures for which program funds cannot be used. Since this circular describes allowable expenses the Department did not believe it was necessary to repeat the entire listing in the proposed rule.

A total of nine comments was received on this provision. The majority of commenters were in favor of the provision. Some commenters recommended that OMB Circular A–122 also be included since distributing agencies have contracts with private nonprofit organizations.

Although the proposed rule referenced OMB Circular A–87, the Department recognizes that it is more appropriate to reference the portion of the Department's Uniform Federal Assistance regulations, 7 CFR Part 3015, Subpart T, which implements the OMB Circulars concerning Cost Principles, including A–87 and A–122. Therefore, this interim rule references 7 CFR Part 3015, Subpart T rather than the circulars. This provision has also been redrafted to make clear that the list of unallowable costs is not exhaustive.

Excess Funds—There are two ways which funds can accrue to distributing agencies as a result of program operations: (1) Through the collection of distribution charges; and (2) through the sale of containers, salvage of donated foods, insurance collection or recoveries from loss or damage claims. Currently the regulations specifically spell out the uses of these two categories of funds. Distributing agencies are required to review at least once each fiscal year the receipt and expenditure of funds to ensure that fund balances are not in excess of program needs. If funds are found to be excessive, the distributing agency is required to reduce such funds. If excess funds accumulate as a result of collection of distribution charges, such excess funds should be used to reduce such charges or be returned to the contributor. If excess funds accrue from the sale of containers, salvage of donated foods, insurance or other recoveries from loss or damage claims, such funds shall be used to reduce distribution charges, purchase additional foods or be paid to the Department.

Section 250.15(f)(3) of the proposed regulations provided precise guidelines for determining what constitutes "excess funds". Since distributing agencies use these funds for different purposes, no specific dollar limit was proposed. The term "excess funds" was defined as funds exceeding the previous three month's expenditures. The total expenditures for the previous three months is the "maximum" amount of funds which the distributing agency may have in its account. Funds which exceed this amount were considered in excess of program needs unless the distributing agencies provided justification of the need for such funds and the justification was approved by FNSRO. In some instances, the FNSRO may have considered funds equal to or less than the expenditures for the previous three months to be in excess of what was needed. In such instances the distributing agency was required to reduce such funds. Expenditures of a nonrecurring nature were not included in the determination of total expenditures for the previous three months.

A total of forty-four comments was received on the proposed definition. Three commenters were in favor of the definition of excess funds, while forty-one commenters were opposed. Generally, commenters contended that basing the definition on the previous three months' expenditures might be too restrictive. Commenters provided a wide range of timeframes on which to base this definition. The main concern was that distributing agencies must have enough funds to conduct normal business during the months of high expenditures and low revenues.

In order to provide distributing agencies with more flexibility,

§ 250.15(f)(3) of the interim rule defines excess funds differently depending on the source of the funds. As stated above, there are several ways distributing agencies can accrue funds; through the collection of distribution charges and through the sale of containers, salvage of donated foods, insurance collection or recoveries from loss or damage claims. Since the allowable uses of the funds depends on the source of the funds, in this interim rule distributing agencies are required to maintain separate accounts for the two types of funds: an operating account based on distribution charges and a salvage account based on the sale of containers, salvage and claims, etc. At a maximum, the operating account funds shall not exceed the sum of the previous year's highest three-month expenditures. Funds exceeding this maximum shall be considered in excess of program needs unless the distributing agency provides sufficient justification as to the need for such funds and receives approval from the FNSRO. The FNSRO may determine that funds equal to or less than the expenditures for the previous year's highest three months are in excess of what is needed. In such instances, the distributing agency shall also reduce such funds. As required in the proposed rule, if excess funds accumulate by reason of collection of distribution charges, such funds shall be used to reduce such changes or shall be returned to the contributor.

The salvage account fund will normally have irregular deposits and irregular expenses. Since nonrecurring unbudgeted expenditures will be made out of the salvage account, the interim rule sets no limit on this account. FNSRO must, however, give prior approval to each deposit or expenditure which is in excess of $2,500. Since the interim rule does not set a limit on the amount of funds which can accrue from the sale of containers, salvage of donated foods, insurance collection, or recoveries of claims for the loss or damage of donated foods, the portion of the proposed rule concerning the use of excess funds of this type has been deleted. The use of the salvage account funds is governed by paragraph (f)(1) and (f)(2).

Maintenance of records

The proposal in § 250.16(a)(4) required processors or other entities which contract with a distributing agency, subdistributing agency or recipient agency to keep records. While the Department considers food service management companies and warehouses to fall in the category of "other entities", to avoid confusion the interim rule has been amended to specifically name these two groups.

Distributing agency-sponsored audits. Section 250.18(b) of the proposed rule required each distributing agency to provide for audits of all food distribution program operations that include examination of records pertaining to donated food acquisition, storage, distribution, processing activities within the State (except for that of multi-State processors) and financial information.

Fifty-three comments were received on this requirement. Fifty-one commenters opposed the provision. The majority of the commenters were concerned that the cost outweighed the benefits and that the audits served no useful purpose since they were mainly fiscal in nature. Most commenters recommended that the requirement be deleted.

In response to the comments received, this interim rule eliminates the distributing agency-sponsored audit provision. The Department has determined that strengthening the review requirements (§ 250.19(b)), which focus on program operations, is a much more effective means of ensuring appropriate oversight of program administration. Fiscal matters will continue to be reviewed in audits conducted under the Single Audit Act.

Reviews

The current regulations contain minimal monitoring provisions applicable only to distributing agencies and State Agencies on Aging. Section 250.19 of the proposed rule strengthened the monitoring provisions to ensure increased accountability.

Section 250.19(b) of the proposal required to FNS to establish evaluation procedures to determine whether distributing agencies have carried out the provisions of this Part and FNS guidelines and instructions. Since this requirement involves internal departmental procedures, rather than the review requirements for distributing agencies, it has been removed from this interim rule. The Department will, however, be providing further assistance and guidance to distributing agencies to ensure that the procedures established for reviews will encompass all operations covered by this Part. As a result of the deletion of this requirement, proposed § 250.19(c) and (d) have been redesignated in the interim rule as § 250.19(b) and (c), respectively.

Section 250.19(c) of the proposed rule required annual reviews by the distributing agency of all distributing agency level storage facilities, all processors (other than multi-State processors), and most food service management companies; the proposed rule also required periodic reviews of recipient agencies that received donated food but were not subject to reviews under the other FNS program regulations. Thus, the distributing agency would review charitable institutions, nonprofit summer camps for children, and nutrition programs for the elderly. Because of variances within States, the proposed rule did not establish minimum review frequencies for these recipient agencies but specifically requested that commenters make recommendations about the frequency of reviews required for adequate coverage.

Forty-five comment letters were received on the requirement for a formal State monitoring system, and all but three expressed opposition to one or more provisions. The most frequent objection was that the added responsibilities for distributing agencies would increase costs for activities for which no Federal administrative funds are provided. Nevertheless, twenty-eight commenters saw the need for some degree of periodic monitoring of recipient agencies. However, none recommended that more than 50 percent of the outlets in any category be reviewed each year. Of the seventeen comment letters expressing views on the frequency of onsite visits to recipient agencies, nine recommended that charitable institutions, nutrition programs for the elderly and summer camps all be placed on a 4-year review cycle for the Food Distribution Program similar to that required for the Assessment Improvement and Monitoring System (AIMS) under the regulations for the National School Lunch Program (7 CFR Part 210). Alternate recommendations were that reviews of these recipient agencies be conducted every 2 years, 3 years or 5 years.

Based on the commenters' recommendations and the Department's experience with reviews for other programs, § 250.19(b) of the interim rule establishes a 4-year cycle for review of charitable institutions, nonprofit summer camps and nutrition programs for the elderly with annual on-site visits required for not less than 25 percent each year. The 25 percent of the recipient agencies chosen to be reviewed each year must result in all recipient agencies being reviewed once every four years. The interim rule also clarifies the scope of these reviews. Sections 250.19(b)(1)(i) and (iv) require reviews to include on-site reviews of storage facilities used by these recipient

agencies and a review of all contracts between the recipient agency and food service management companies.

Several commenters were concerned about the emission from the proposed rule of a monitoring requirement for Child Nutrition Program outlets. These commenters pointed out that, while program regulations under Part 210, 225, and 226 require periodic reviews of schools and institutions receiving commodities, there is no requirement to review the commodity activities of those recipient agencies. Such a review should include an examination of ordering, storage, use and accountability procedures. The commenters recommended that these outlets be required to be reviewed periodically by distributing agencies.

The Department recognizes this concern and upon re-evaluation may decide to require that these Child Nutrition Programs be reviewed. However, since the proposed rule omitted such requirements, the Department will address this matter in a proposed rule or other means to ensure that these outlets are monitored.

The provision of § 250.19(c)(1) of the proposed rule required an annual review of all food service management companies except those contracting with schools. Because of commenters' concerns, the final rule requires a biennial review.

The interim rule retains the requirement for an annual review of all distributing agency level storage facilities as also reflected in § 250.14(b). The interim rule also clarifies that these reviews must be conducted on-site. As required by § 250.14(b), the distributing agency shall ensure that local-level storage facilities are reviewed by appropriate recipient agency personnel.

Section 250.19(b) also requires distributing agencies to conduct review of single State processors once every two years rather than annually as proposed. The Department determined that the frequency of once every two years will provide sufficient control based on reconsideration of the value of commodities going to the processors. If, in the performance of its review functions the distributing agency discovers deficiencies or potential problems, corrective action should be taken to eliminate the deficiency immediately.

Nondiscrimination—Section 250.21 of the proposed rule was reserved for the program's nondiscrimination provisions. The Department determined that further consideration be given to developing expanded provisions on prohibitions against discrimination on the grounds of age, sex, or handicap as required by Title IX of the Education Amendments of 1972, section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975.

Upon reconsideration the Department has determined that there is no need to publish a separate Food Distribution Program rule covering these prohibitions since there are Department-wide regulations (7 CFR Parts 15, 15a and 15b) already in place that are binding on all programs. Therefore, § 250.21 of this interim rule states the applicable prohibitions against discrimination on the grounds of age, sex, handicap, race, color or national origin and provides reference to the Department's regulations and instructions concerning civil rights.

State Processing of Donated Foods

As discussed above in the Supplementary Information section, the Department published in the **Federal Register** two regulations concerning State processing of donated food. Since comments have already been taken on these rules, the Department is not accepting any further comments pursuant to this rulemaking. These provisions are only included to provide a complete version of the Food Distribution Program regulations for reference purposes.

Nonprofit Summer Camps for Children

Section 1562 of Pub. L. 99–198 amended section 4(b) of the Agriculture and Consumer Protection Act of 1973 to change the age limit of children from "under 18" to "18 years of age and under". Accordingly, this nondiscretionary requirement has been included in § 250.40(a)(2) of the interim rule. This change in law is also reflected in a change in the definition of adults from persons 18 years of age and over to persons 19 years of age and over.

Section 250.40(a)(1)(xi) of the proposed rule required that the agreement between the camp and distributing agency include an assurance that excess commodity inventory be returned to the distributing agency. A total of eight comments were received and all of the commenters opposed the provision. Commenters suggested that remaining inventories be redonated at the distributing agency to other recipient agencies at the end of the camping session. Commenters also suggested that foods be transferred per instructions of the distribution agency.

Section 250.40(a)(3) as proposed required distributing agencies to transfer all donated foods remaining in summer camps at the end of the camping session to other recipient agencies. The Department notes, however, that some confusion may have resulted from the use of the terms "transfer" and "redonate." Section 250.13 uses the term transfer when commodities are moved from one recipient agency to another within a State and redonate when a distributing agency is unable to use the commodities and requests the FNSRO to move them to another distributing agency. To be consistent with this usage, § 250.40(a)(1)(xi) has been revised to require summer camps, at the distributing agency's option, to transfer any remaining commodities in accordance with § 250.13(a) or to return them to the distributing agency for redonation. A parallel change has been made to § 250.40(a)(3), including cross references to the transfer and redonation provisions in § 250.13.

In addition, § 250.40(a)(1)(x) has been changed to require assurance that a reconciliation of the physical inventory will be conducted at the end of the camping session. This change is necessary to be consistent with the annual reconciliation requirement of § 250.14(d).

Charitable Institutions

Under section 416 of the Agricultural Act of 1949, as amended, charitable institutions are eligible to receive commodities to the extent that they serve needy persons.

Section 250.41 of the proposed rule established a uniform means of determining the needy population of charitable institutions. In order to eliminate the varying and often unreliable methods for determining the number of needy persons served by a charitable institution, the proposed regulations required the distributing agency to determine the number of needy persons by: (1) Determining the percentage of subsidized income by dividing the subsidized income by total subsidized and nonsubsidized income; and (2) multiplying that percentage by the average daily number of participants. For the purpose of this section "subsidized income" was defined as income from public tax funds which is provided on behalf of participants that have been determined to be in need of financial assistance through a means-tested program such as Medicaid or income received through private federally tax-exempt contributions which provide for the care of participants the institution has determined to be in need of financial assistance. "Nonsubsidized income" was defined as all other income,

including payments made by institutional participants for services received and payments made on behalf of participants by persons legally responsible for their support. At a minimum, any time the number of participants in an institution or the amount of income increased or decreased by ten percent, the institution was required to notify the distributing agency. The distributing agency was then to revise financial and participation data to reflect such changes.

A total of thirty-two comments were received on the minimum requirement for reporting changes in the population or income of an institution. A few commenters recommended that hospital and nursing home caseloads be determined by Medicaid patient count as an alternative to the percent of subsidized income method. Twenty-eight commenters opposed the provision on the basis that it was unrealistic, unmanageable, too time consuming and that it would increase cost, paperwork and workload.

In response to commenters' concerns, the Department has decided to permit an alternative method to determine the needy population of charitable institutions. This alternative method allows institutions to count the number of people receiving benefits under a means-tested program. For example, if an institution had 100 patients and 10 of those patients were receiving benefits under a means-tested program, i.e. Medicaid, then that number will be the basis for determining the amount of donated foods that institution will receive. Thus, the interim rule requires distributing agencies to determine the number of needy persons being served in a charitable institution by using the subsidized income formula or by counting the number of needy persons receiving benefits under another means-tested program.

The Department is also eliminating the requirement for reporting ten percent changes in the population or income. The income and average daily participation figures reflected in the agreement shall be used in determining the number of needy persons being served by the institution in accordance with the above formulas. These figures will be based on the institution's financial and participation data for the previous year.

Section 250.41 of the proposed rule also required that the agreement include assurance that the tax exempt status be maintained. Upon reconsideration the Department has decided to delete this provision since verification of tax exempt status is included in the updated information the distributing agency obtains from the charitable institution each year.

In addition, the definition of "charitable institution" in Section 250.3 of the proposed rule required that a charitable institution not only be nonprofit, but also operate a nonprofit meal service. A total of thirty-four comments was received. Four commenters agreed with the provision while thirty commenters objected for reasons such as the increased administrative burden associated with the review of an organization's financial records which would have to be done in order to determine if the meal service is nonprofit. Based on the commenters' concerns, the Department has re-evaluated its position on this provision and has deleted the nonprofit meal service language from the definition and deleted the definition of "nonprofit meal service".

Some commenters recommended that Veteran Administration (VA) hospitals and post-secondary schools be included in the definition of charitable institutions. Since donated foods are provided by the Commodity Credit Corporation directly to the VA hospitals, these hospitals are not included in the definition. The Department has no legislative authority to provide commodities to post-secondary schools.

Correctional Institutions—There is no specific legislative authority for USDA food donations to nonfederal, adult correctional institutions. However, the Department has determined that institutions which carry on programs of rehabilitation for their inmates may be classified as "charitable institutions" within the intent of section 416 of the Agricultural Act of 1949, as amended. In order to distinguish between eligible correctional institutions and ineligible penal institutions, Section 250.41(a)(2) of the proposed rule adopted the eligibility criteria for adult correctional institutions to receive food donations as contained in FNS Instruction 706-3. In order to receive donated foods, adult correctional facilities must conduct rehabilitation programs which are (1) available to a majority of inmates and (2) of sufficient scope to permit participation (for a minimum of 10 hours per week per inmate) by either a majority of the total inmate population or a majority of sentenced inmates.

A total of six comments was received on this requirement. Four commenters opposed the provision, suggesting that the ten hour per week rehabilitative program be eliminated.

As stated in the program rule, in the absence of express legislative authority for USDA food donations to nonfederal adult correctional institutions, the Department determined that such institutions which carry on programs of rehabilitation for their inmates may be classified as "charitable institutions". The Department believes that this is consistent with the requirements of section 416 of the Agriculture Act of 1949, as amended. Thus, § 250.41(a)(2) is retained as proposed.

Nutrition Program for the Elderly

The first sentence in § 250.42(a) of the proposed rule stated that distributing agencies shall enter into an agreement with the State Agency on Aging responsible for administering programs funded under Titles III or VI of the Older Americans Act of 1965 in accordance with § 250.12(b) unless the State Agency on Aging has elected to receive all cash in lieu of donated foods. As commenters pointed out, the election of cash in lieu does not prevent the State Agency on Aging from obtaining certain commodities in addition to the cash in lieu of the per meal rate of donated food. Therefore, this sentence has been deleted.

In addition, § 250.42 of the proposed regulations specified that no adjustments in commodity allocations would be made on the basis of meal reports or estimates received after the close of the third Federal fiscal quarter of the year to which they pertain. Only two comments were received on this provision; one in favor and one opposed. The Department is retaining the provision as proposed so as to avoid overallocation or underallocation of food.

Finally, § 250.42(b) has been amended to reflect the change to the authorized level of assistance made by section 122(c) of Pub. L. 100-175 (enacted on November 29, 1987).

Emergency Food Assistance

Disaster Assistance—Section 250.43 and 250.44 of the proposed rule clarified the responsibilities of the distributing agency and disaster organizations in the use of donated foods during a major disaster, emergency or other situations of distress.

Section 250.43 of the proposed rule described the procedures for obtaining donated foods in instances when the Secretary has determined that a major disaster or emergency exists. The section also revised the procedures set forth in FNS Instruction 708-2 regarding household distribution of commodities on Indian reservations in cases of a major disaster or emergency. Under the instruction, Indian tribal organizations could receive donated foods for household distribution in any instance

of major disaster or emergency, without meeting some of the requirements for disaster assistance in other areas in which the Food Stamp Program is in operation. Under § 250.43(c) of the proposed rule, Indian tribal organizations would have to meet the same criteria as those set forth for other jurisdictions where the Food Stamp Program is in operation before receiving donated foods for household distribution.

A total of nine comments were received. The commenters opposed various provisions in the section regarding the distribution of commodities during disaster and emergency situations. Commenters felt that it was time consuming to fill out applications especially in an emergency and it was not efficient for States to wait for approval from the Secretary in order to meet specific needs. Commenters also felt that in an emergency all displaced persons should be considered in need regardless of income or social status.

Section 250.43 has been revised in the interim rule to make clear that it is the President who declares major disasters and emergencies pursuant to the Disaster Relief Act of 1974, but it is the Secretary who determines that, as a result of the major disaster or emergency, the type of assistance in the form of donated foods that is necessary. In addition, the interim rule provides that disaster assistance may continue as long as the Secretary deems necessary, rather than only for the duration of the major disaster or emergency. This change parallels the language of section 409 of the Disaster Relief Act.

Finally, the Department has decided to retain the limitation on the household distribution of donated foods in areas where the Food Stamp Program is in operation. The proposed rule permitted the distribution of donated foods to households in areas served by the Food Stamp Program only so long as the Secretary finds that the commercial channels of trade have been disrupted. This limitation originated from a former provision of section 4(b) of the Food Stamp Act of 1977 (7 U.S.C. 2013(b)) which permitted the distribution of commodities to households in areas in which the Food Stamp Program was in operation only on a temporary basis under programs authorized by law to meet disaster relief need. This limitation, together with the provision of section 5(h) of the Food Stamp Act of 1977 (7 U.S.C. 2014(h)), which permits the distribution of food stamps to disaster victims only after the normal channels or trade have been disrupted and then resumed, gave rise to the policy contained in the proposed rule.

As noted earlier in the preamble, the general prohibition on household distribution of donated food has been deleted from section 4(b) of the Food Stamp Act of 1977. However, the Department believes that it is duplicative to permit the continuation of the household distribution of donated food once emergency food stamps become available. Therefore, the limitation on the distribution of commodities for household use to the period in which normal channels of trade are disrupted is being retained in § 250.43(a) of this interim rule.

With respect to the commenters' concern that delays would result from the need to obtain approval by the Secretary prior to commencing household distribution of commodities, the Department wishes to point out that § 250.43(c) required only the prior approval of the FNSRO. The Department believes that any delay would be insignificant and that the advance approval is necessary to ensure accountability.

Section 250.43(b)(2) of the interim rule has also been amended to clarify the authority of the distributing agency to use donated foods from any sources within the State in a disaster. The Department believes that it is imperative that distributing agencies have the right to use donated foods so that they can coordinate and direct all intrastate donation of food during a disaster.

Situations of Distress—Section 250.44 described the procedures for obtaining donated foods in situations of distress in which the need for food assistance cannot be met under other provisions of Part 250. Donations under this section may only be made for special group food assistance.

Section 250.44 of the proposed rule expanded the current regulations to clarify the responsibilities of the distributing agency in the use of donated foods during situations of distress. In addition, a limit was placed on the distribution period to no longer than 30 days and required that the donated foods is provided only to groups which are composed predominantly of needy persons.

Six comments were received on this provision. The majority of the commenters misunderstood the provision believing that if referred to disasters. One commenter recommended that the current language be retained.

The Department has reevaluated its position on this provision because in situations of distress, it is extremely difficult to determine who is needy and to determine how long the situation will last. In reviewing the proposed language on situations of distress, the Department determined that it was unclear what situations were "distress situations" and which would be considered "disasters." Revisions (as previously noted) have been made to the sections on disaster assistance to make those disaster provisions more explicit. In the case of situations of "distress", the Department feels that the language in the current rule more clearly depicts the difference between a disaster and situations of distress. Finally, the proposed rule limited the duration of food assistance in a distress situation to no more than 30 days. The Department, however, believes that such a restriction is unnecessary since the Secretary has the authority to determine the duration of the food assistance provided. Therefore, Section 250.44 is being revised to contain the provisions appearing in Section 250.10 of the current rule.

Food Distribution Program on Indian Reservations

The Department proposed in § 250.47(a) that distributing agencies which operate a food distribution program on an Indian reservation comply with § 250.30 regarding State processing of donated food. This section was inadvertently included in the proposal. Compliance with § 250.30 has been removed from this interim rule since distributing agencies for Indian reservations receive only approved food packages for distribution to households. Paragraph (a) has also been revised to clarify that if there is a conflict between the cited Part 250 section and Parts 253 and 254 that the Parts 253 and 254 will take precedence.

Paragraph (b) of this interim rule includes a reference to Part 254 Food Distribution Program for Indian Households in Oklahoma. Reference to Part 254 was inadvertently omitted in the proposal. However, since this part also sets the conditions for Food Distribution Program administration by eligible Oklahoma tribes, reference to Part 254 is included in this interim rule.

School Food Authorities

All references to schools in § 250.48 of the interim rule have been changed to school food authorities. This is being done to clarify the rule because school food authorities, not schools, are the ones that sign agreements with the distributing agency and which administer the program at the school level.

Proposed paragraph (b)(1) *Quantities* required the distributing agency to

develop a system to update and review caseload information by June 30 and December 30. The provision has been changed to require that an estimate of the average daily number of meals be submitted as early as practicable each school year but not later than September 1. This change merely incorporates the requirement as provided in 7 CFR 210.19(b).

Offer and Acceptance System—Section 250.48(e)(2) of the proposed rule prohibited the refusal of donated foods in instances when an offer-and-acceptance system is being maintained. Use of the offer-and-acceptance system permits school food authorities to order only the amounts and varieties of donated foods they desire for the school lunch program on the basis of advance notification by the distributing agency. Thus, the refusal provision is not warranted in instances when an offer-and-acceptance system is being maintained.

A total of fifteen comments was received on this provision. Nine commenters opposed the requirement and indicated that a refusal clause is needed to help discourage waste. Other commenters expressed concern that the requirement would result in increased storage costs.

The interim rule retains this provision as proposed. The Department believes that if the offer-and-acceptance system is utilized correctly that schools will not need the 20 percent refusal provision.

Nonresidential Childcare Institutions

Section 250.49(b) of the proposed rule required the distributing agency to develop a system to update and review caseload information by June 30 and December 30 of each year. The provision has been revised in this interim rule to require that an estimate of the average daily number of meals be submitted by the State agency to the distributing agency by June 1 of each year. This change is necessary to maintain consistency with the requirement for reporting the average daily number of meals as contained in 7 CFR 226.6(g).

Service Institutions

Section 250.50(b) of the proposed rule required that service institutions submit the most recent written caseload information by April 30 of each year. This date has been changed in the interim rule to June 1 to incorporate the requirement as provided in 7 CFR 225.5(b).

Special Supplemental Food Program for Women, Infants and Children (WIC) Program

State agencies which administer the WIC program are eligible to receive donated foods from the Department. Section 250.51 of the proposed rule outlined the procedures by which State agencies may request the donated foods for distribution to WIC Program participants. Those donated foods which are included in the WIC food package must be paid for by the State agencies with funds allocated to the State for the WIC Program. Donated foods which are provided to participants in addition to the quantities authorized for the food package are made available to the State agency free of charge. Since no comments were received on this provision, § 250.51 is retained in this interim rule as proposed.

List of Subjects in 7 CFR Part 250

Aged, Agricultured commodities, Business and industry, Food assistance programs, Food donations, Food processing, Grant programs—social programs, Infants and children price support programs, Reporting and recordkeeping requirements, School breakfast and lunch programs, Surplus agricultural commodities.

7 CFR Chapter II is amended by revising Part 250 to read as follows:

SUBCHAPTER B—GENERAL REGULATIONS AND POLICIES—FOOD DISTRIBUTION

PART 250—DONATION OF FOODS FOR USE IN THE UNITED STATES, ITS TERRITORIES AND POSSESSIONS AND AREAS UNDER ITS JURISDICTION

Subpart A—General

Sec.

Subpart B—General Operating Provisions

Subpart C—Processing and Labeling of Donated Foods

Subpart D—Eligible Recipients Agencies and Programs

Subpart E—Where to obtain Information

Authority: Sec. 32, Pub. L. 74–320, 49 Stat. 744 (7 U.S.C. 612c); Pub. L. 75–165, 50 Stat. 323 (15 U.S.C. 713c); secs. 6, 9, Pub. L. 79–396, 60 Stat. 231, 233 (42 U.S.C. 1755, 1758); Sec. 416, Pub. L. 81–439, 63 Stat. 1058 (7 U.S.C. 1431); Sec. 402, Pub. L. 81–665, 68 Stat. 843 (22 U.S.C. 1922); Sec. 210, Pub. L. 84–540, 70 Stat. 202 (7 U.S.C. 1859); Sec. 9, Pub. L. 85–931, 72 Stat. 1792 (7 U.S.C. 1431b); Pub. L. 86–756, 74 Stat. 899 (7 U.S.C. 1431 note); Sec. 709, Pub. L. 89–321, 79 Stat. 1212 (7 U.S.C. 1446a–1); Sec. 3, Pub. L. 90–302, 82 Stat. 117 (42 U.S.C. 1761); Secs. 409, 410, Pub. L. 93–288, 88 Stat. 157 (42 U.S.C. 5179, 5180); Sec. 2, Pub. L. 93–326, 88 Stat. 286 (42 U.S.C. 1762a); Sec. 16, Pub. L. 94–105, 89 Stat. 522 (42 U.S.C. 1766); Sec. 1304(a) Pub. L. 95–113, 91 Stat. 980 (7 U.S.C. 612c note); Sec. 311, Pub. L. 95–478, 92 Stat. 1533 (42 U.S.C. 3030a); Sec. 10, Pub. L. 95–627, 92 Stat. 3623 (42 U.S.C. 1760); Sec. 1114(a), Pub. L. 97–98, 95 Stat. 1269 (7 U.S.C. 1431e); Title II, Pub. L. 98–8, 97 Stat. 35 (7 U.S.C. 612c note); (5 U.S.C. 301), unless otherwise noted.

Subpart A—General

§ 250.1 General purpose and scope.

This part prescribes the terms and conditions under which donated foods may be obtained from the Department by Federal, State and private agencies for use in any State in child nutrition programs, nonprofit summer camps for children, charitable institutions, nutrition programs for the elderly, the Commodity Supplemental Food Program, the Special Supplemental Food Program for Women, Infants, and Children, the Food Distribution Programs on Indian Reservations and the assistance of needy persons.

§ 250.2 Administration.

(a) *Delegation to FNS.* Within the Department, FNS shall act on behalf of the Department in the administration of

the program. FNS will provide assistance to distributing agencies and evaluate all levels of program operations to assure that the goals of the program are achieved in the most effective and efficient manner possible.

(b) *Delegation to distributing agency.* The distributing agency is responsible for effective and efficient administration of program operations within its jurisdiction and shall administer the program in accordance with the requirements of this Part and FNS guidelines and instructions. Distributing agencies may impose additional requirements for participation that are not inconsistent with the provisions of this Part, except that this provision shall not apply to distribution to households on all or part of an Indian reservation which is participating in the Food Distribution Program under Part 253 and Part 254 of this chapter. The distributing agency shall provide guidance to subdistributing agencies and recipient agencies on all aspects of program operations.

(c) *Personnel.* Each distributing agency shall provide adequate personnel, to administer the program in accordance with this part.

§ 250.3 Definitions.

"Charitable institutions" means:

(a) A nonpenal, noneducational public (Federal, State or local) institution,

(b) A nonprofit, tax exempt, private hospital, or

(c) Any other nonprofit, noneducational, tax exempt private institution organized to provide charitable or public welfare services in the same place without marked changes and, at the Department's option, approved by a public welfare agency as meeting a definite need in the community by administering to needy persons, and provides a meal service on a regular basis. Charitable institutions include any institution defined as "service institution"; "nonresidential child care institution"; or "school" which is not a commodity school or does not participate in a child nutrition program. For purposes of this paragraph, tax exempt shall mean exempt from income tax under the Internal Revenue Code, as amended, and a charitable institution shall be considered "noneducational" even though educational courses are given, where such courses are incidental to the primary purpose of the charitable institution.

"Child nutrition program" means the National School Lunch Program, the School Breakfast Program, the Summer Food Service Program for Children, or the Child Care Food Program (Parts 210, 220, 225, and 226 respectively of this chapter).

"Commodities" means foods donated, or available for donation, by the Department under any of the legislation referred to in this part (see "Donated Foods").

"Commodity school" means a school that does not participate in the National School Lunch Program under Part 210 of this chapter but which operates a nonprofit school food service under agreement with the State educational agency or FNSRO as provided for under Part 210 of this Chapter and receives donated foods, or donated foods and cash or services of a value of up to 5 cents per lunch in lieu of donated foods under Part 240 of this Chapter for processing and handling of the donated foods.

"Contract value of the donated foods" means the price assigned by the Department to a donated food which shall reflect the Department's current acquisition price, transportation and, if applicable, processing costs related to the food.

"Contracting agency" means the distributing agency, subdistributing agency, or recipient agency which enters into a processing contract.

"Department" means the United States Department of Agriculture or the Commodity Credit Corporation, whichever is the donor under the pertinent legislation.

"Disaster organizations" means organizations authorized by appropriate Federal or State officials to assist disaster victims.

"Disaster victims" means persons who, because of acts of God or manmade disasters, are in need of food assistance, whether or not they are victims of a major disaster or an emergency as defined in this section.

"Discount system" means a system whereby a recipient agency purchases end products directly from a processor at an established wholesale price minus the contract value of the donated foods contained in the end products.

"Distributing agency" means a State, Federal or private agency, or Indian Tribal Organization (ITO) which enters into an agreement with the Department for the distribution of donated foods to eligible recipient agencies and recipients and the Food and Nutrition Services of the Department when it accepts title to commodities from the Commodity Credit Corporation (CCC) for distribution to eligible recipient agencies pursuant to the National Commodity Processing System. A distributing agency may also be a recipient agency.

"Distributor" means a commercial food purveyor or handler who is independent of a processor and both sells and bills for the end products delivered to recipient agencies.

"Donated foods" means foods donated, or available for donation, by the Department under any of the legislation referred to in this part (see "Commodities").

"Emergency" means any hurricane, tornado, storm, flood, high water, wind-driven water, tidal wave, tsunami, earthquake, volcanic eruption, landslide, mudslide, snowstorm, drought, fire, explosion, or other catastrophe in any part of the United States which requires Federal emergency assistance to supplement State and local efforts to save lives and protect property, health, and safety or to avert or lessen the threat of a disaster.

"End product" means a product containing any amount of donated foods which have been processed.

"Federal acceptance service" means the acceptance service provided by:

(a) The applicable grading branches of the Department's Agricultural Marketing Service (AMS),

(b) The Department's Federal Grain Inspection Service, and

(c) The National Marine Fisheries Service of the U.S. Department of Commerce.

"Fiscal year" means the period of 12 months beginning October 1 of any calendar year and ending September 30 of the following year.

"FNS" means the Food and Nutrition Service of the Department of Agriculture.

"FNSRO" means the appropriate Food and Nutrition Service Regional Office of the Food and Nutrition Service of the Department of Agriculture.

"Food service management company" means a commercial enterprise or a nonprofit organization which is or may be contracted with by a recipient agency to manage any aspect of its food service in accordance with § 250.12(c) of this part or in accordance with Parts 210, 220, 225, or 226 of this chapter.

"Household" means a group of related or non-related individuals, exclusive of boarders, who are not residents of an institution, but who are living as one economic unit and for whom food is customarily purchased and prepared in common. It also means a single individual living alone.

"In-kind replacement" means replacement of lost donated foods with a quantity of the same foods of U.S. origin that are of equal or better quality than the lost foods and that are of at least equal monetary value to the Department's cost of replacing the lost foods.

"Major disaster" means any hurricane, tornado, storm, flood, high water, wind-driven water, tidal wave, tsunami, earthquake, volcanic eruption, landslide, mudslide, snowstorm, drought, fire, explosion, or other catastrophe in any part of the United States which, in the determination of the President, causes damage of sufficient severity and magnitude to warrant major disaster assistance under the Disaster Relief Act of 1974 (42 U.S.C. 5121), above and beyond emergency services by the Federal Government, to supplement the efforts and available resources of States, local governments, and disaster relief organizations in alleviating the damage, loss, hardship, or suffering caused thereby. (This definition is taken from the Disaster Relief Act of 1974.)

"Multi-State processor" means:

(a) A processor which has entered into a processing contract with contracting agencies in more than one State, or

(b) A processor which has entered into a processing contract with one or more contracting agencies located in a State other than the one in which either the processor's plant or business office is located.

"Needy persons" means:

(a) Persons provided service by charitable institutions, who, because of their economic status, are in need of food assistance,

(b) All the members of a household who are certified as in need of food assistance, and

(c) Disaster victims.

"Nonprofit school food service" means all food service operations conducted by the school food authority principally for the benefit of school children, all of the revenue from which is used solely for the operation or improvement of such food services.

"Nonprofit summer camps for children" means nonprofit camps which do not participate in the Summer Food Service Program for Children authorized under section 13 of the National School Lunch Act, as amended (42 U.S.C. 1761), and in which, during the months of May through September, meal services are conducted for children of high school grade and under.

"Nonresidential child care institution" means any institution (as defined in Part 226 of this chapter) which participates in the Child Care Food Program authorized under section 17 of the National School Lunch Act, as amended (42 U.S.C. 1766).

"Nutrition program for the elderly" means a project conducted by a recipient of a grant or contract under Title III or Title VI of the Older Americans Act of 1965, as amended (42 U.S.C. 3030a).

"Offer-and-acceptance system" means a procedure whereby a school food authority is given the opportunity to order only the amounts and varieties of donated foods it desires for its school lunch program on the basis of advance notification by the distributing agency.

"Performance supply and surety bond" means a written instrument issued by a surety company which guarantees performance and supply of end products by a processor under the terms of a processing contract.

"Processing" means:

(a) The conversion of a donated food or donated foods into a different end product or

(b) The repackaging of a donated food or donated foods.

"Processing fee" means the amount charged to a contracting agency for a processor's services.

"Processor" means a commercial facility, other than a food service management company, which processes donated foods.

"Program" means the Food Distribution Program.

"Recipient agencies" means nonprofit summer camps for children, charitable institutions, nutrition programs for the elderly, disaster organizations, school food authorities, schools, nonresidential child care institutions, service institutions, and welfare agencies receiving foods for their own use or for distribution to eligible recipients.

"Recipients" means the needy persons receiving commodities for household consumption.

"Refund application" means an application by a recipient agency in any form acceptable to the processor which certifies purchase of end products and requests a refund of the contract value of the donated foods contained in the end products purchased.

"Refund system" means a system whereby a recipient agency purchases a processor's end products and receives from the processor a payment equivalent to the contract value of the donated foods contained in the end products.

"School" means:

(a) An educational unit of high school grade or under, recognized as part of the educational system in the State and operating under public or nonprofit private ownership in a single building or complex of buildings. The term "high school grade or under" includes classes of preprimary grade when recognized as part of the education system of the States;

(b) Any public or nonprofit private classes of preprimary grade when they are conducted in those schools defined in paragraph (a) of this definition having classes of primary or of higher grade;

(c) Any public or nonprofit private residential child care institution, or distinct part of such institution, which operates principally for the care of children, and if private, is licensed to provide residential child care services under the appropriate licensing code by the State or a subordinate level of government, *except for* residential summer camps which participate in the Summer Food Service Program for Children, Job Corps centers funded by the Department of Labor and private foster homes. The term "residential child care institutions" includes, but is not limited to: homes for the mentally, emotionally or physically impaired, and unmarried mothers and their infants; group homes; halfway houses; orphanages; temporary shelters for abused children and for runaway children; long-term care facilities for chronically ill children; and juvenile detention centers. A long-term care facility is a hospital, skilled nursing facility, intermediate care facility, or distinct part thereof, which is intended for the care of children confined for 30 days or more; or

(d) With respect to the Commonwealth of Puerto Rico, nonprofit child care centers certified as such by the Governor of Puerto Rico.

"School food authority" means the governing body which is responsible for the administration of one or more schools and which has the legal authority to operate a nonprofit school food service therein or otherwise approved by FNS to operate the NSLP.

"School year" means the period of 12 months beginning July 1 of any calendar year and ending June 30 of the following calendar year.

"Secretary" means the Secretary of Agriculture.

"Section 4(a)" means section 4(a) of the Agriculture and Consumer Protection Act of 1973, as amended (7 U.S.C. 612c note). Section 4(a) authorizes the purchase of foods for distribution to maintain the traditional level of assistance for food assistance programs as are authorized by law, including institutions, supplemental feeding programs, disaster areas, summer camps for children, the Trust Territory of the Pacific Islands, and Indians whenever a tribal organization requests distribution of federally-donated foods under section 4(b) of the Food Stamp Act of 1977 (7 U.S.C. 2013(b)).

"Section 6" means section 6 of the National School Lunch Act, as amended

(42 U.S.C. 1755). Section 6 authorizes the purchase of foods for distribution to schools and institutions participating in child nutrition programs under the National School Lunch Act and specifies the level of assistance which is to be provided.

"Section 14" means section 14 of the National School Lunch Act, as amended (42 U.S.C. 1762a). Section 14 authorizes the purchase of foods for distribution to maintain the annually programmed level of assistance for programs carried on under the National School Lunch Act, the Child Nutrition Act of 1966, and Title III of the Older Americans Act of 1965.

"Section 32" means section 32 of Public Law 74–320, as amended (7 U.S.C. 612c). Section 32 authorizes the Department to purchase nonbasic perishable foods available under surplus-removal operations, for the purpose of encouraging the domestic consumption of such foods by diverting them from the normal channels of trade or commerce.

"Section 311" means section 311 of the Older Americans Act of 1965, as amended (42 U.S.C. 3030a). Section 311 authorizes the purchase of commodities for nutrition programs for the elderly.

"Section 416" means section 416 of the Agricultural Act of 1949, as amended (7 U.S.C. 1431). Section 416 authorizes the Department to donate basic nonperishable foods acquired through Federal price-support operations for use by needy persons, for use in nonprofit school lunch programs and nonprofit summer camps for children, and for use in charitable institutions to the extent that needy persons are served.

"Section 709" means section 709 of the Food and Agricultural Act of 1965, as amended (7 U.S.C. 1446a–1). Section 709 authorizes the purchase of adequate supplies of dairy products to meet the requirements of schools, domestic relief distribution, and other programs authorized by law when the stocks of the Commodity Credit Corporation are insufficient to meet those requirements.

"Service institutions" means camps or sponsors (as those terms are defined in Part 225 of this Chapter) which participate in the Summer Food Service program authorized under section 13 of the National School Lunch Act, as amended (42 U.S.C. 1761).

"Similar replacement" means replacement of lost donated foods with a quantity of similiar foods of U.S. origin of the same types as those normally donated by the Department and of at least equal monetary value to the Department's cost of replacing the lost foods. Such replacement shall be subject to the approval of the FNSRO.

"State" and "United States" means any one of the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

"State Agency on Aging" means:

(a) the State agency that has been designated by the Governor and approved by the United States Department of Health and Human Services (DHHS) to administer nutrition programs for the elderly under Title III of the Older Americans Act of 1965, as amended or

(b) The Indian tribal organization which has been approved by DHHS to administer nutrition programs for the elderly under Title VI of such act.

"Students in home economics" means students in regular classes wherein they are taught general home economics including food preparation, cooking, serving, nutrition, food purchasing, child care and health.

"Subdistributing agency" means an agency performing one or more distribution functions for a distributing agency other than, or in addition to, functions normally performed by common carriers or warehousemen. A subdistributing agency may also be a recipient agency.

"Substituted food" means domestically produced food that is purchased or manufactured by a processor and is substituted for donated food.

"Substitution" means:

(a) The replacement of donated foods with like quantities of domestically produced commercial foods of the same generic identity and of equal or better quality (i.e. cheddar cheese for cheddar cheese, nonfat dry milk for nonfat dry milk, etc.); or

(b) In the case of donated nonfat dry milk, substitution as defined under (a) of this definition or replacement with an equivalent amount, based on milk solids content, of domestically produced concentrated skim milk.

"Welfare agency" means a public (Federal, State or local) or private agency offering assistance on a charitable or welfare basis to needy persons, who are not residents of an institution, and to Tribal councils designated by the Bureau of Indian Affairs.

Subpart B—General Operating Provisions

§ 250.10 Eligible distributing and subdistributing agencies.

(a) *State and Federal agencies.* Federal agencies and such State agencies as are designated by the Governor of the State, or by the State legislature, and approved by the Secretary are eligible to become distributing agencies.

(b) *Private agencies.* Where distributing agencies are not permitted by law to make distribution to private recipient agencies, or to any class of private recipient agency, private agencies which agree to make distribution of donated food on a State-wide basis and which apply directly to FNS, and are approved by the Secretary are eligible to become distributing agencies.

(c) *Subdistributing agencies.* If distributing agencies use subdistributing agencies to distribute donated foods, the distributing agencies' responsibilities to the Department for overall management and control of the distribution program shall not be delegated to such subdistributing agencies.

§ 250.11 Eligibility determination for recipient agencies and recipients.

(a) *Verification of recipient agency eligibility.* Distributing agencies at the request of FNS shall:

(1) Verify that recipient agencies registered to participate in the National Commodity Processing (NCP) Program have a current agreement with the distributing agency to receive donated food in accordance with § 252.1(c) and

(2) Report the results of such verification to FNS within timeframes determined by FNS.

(b) *Eligibility of recipient agencies and recipients.* Distributing agencies shall determine the eligibility of any agency which submits an application for participation in the program. Distributing agencies shall consider the past performance of recipient agencies when approving applications for participation. Once a recipient agency has been determined to be eligible for participation in the program, the distributing agency shall enter into an agreement with the agency in accordance with § 250.12(b) and make donated food available. Distributing agencies shall impose upon welfare agencies the responsibility for determining that recipients to whom welfare agencies distribute donated foods are eligible: *Provided, however:* That the State agency or FNSRO administering the applicable program shall determine the eligibility under this Part of school food authorities participating under Part 210 or Part 220, or sponsors participating in the Summer Food Service Program for Children under Part 225, of this chapter, and of nonresidential child care institutions participating in the Child Care Food Program under Part 226 of this chapter.

§ 250.12 Agreements and contracts.

(a) *Agreements with Department.* Prior to the beginning of a distribution program, distributing agencies shall enter into written agreements with the Department which shall incorporate the terms and conditions set forth in this Part. When requested by the Department an eligible agency shall present evidence of its authority to enter into such agreements. The agreements shall be effective for no longer than one year and must be completed by September 30 of each year. In addition, agreements between the Department and State Agencies on Aging which elect to receive cash in lieu of commodities shall also be effective for no longer than one year and must be completed by September 30 of each year.

(b) *Distributing agency agreements.* Distributing agencies shall enter into written agreements with all subdistributing agencies, recipient agencies, warehouses, carriers, or other entities to which distributing agencies deliver donated foods under their distribution program. Distributing agencies shall be responsible for ensuring that program integrity is maintained by all entities with whom agreements are entered into. All agreements shall contain such terms and conditions as the distributing agency deems necessary to ensure that:

(1) The distribution and use of donated foods is in accordance with this Part,

(2) Subdistributing agencies, recipient agencies, warehouses, carriers, or other persons to whom donated foods are delivered by the distributing agency are responsible to the distributing agency for any improper distribution or use of donated foods or for any loss of, or damage to, donated foods caused by their fault or negligence,

(3) Subdistributing agencies and recipient agencies have and preserve a right to assert claims against other persons to whom donated foods are delivered for care, handling or distribution, and

(4) Subdistributing agencies and recipient agencies will take action to obtain restitution in connection with claims for improper distribution, use or loss of, or damage to, donated foods.

To the extent that bills of lading and warehouse receipts satisfy the above-stated criteria, the distributing agency may consider such documents as appropriate agreements. The agreement shall be in effect for not longer than one year and shall provide that it may be extended at the option of both parties for two additional one year periods. Agreements may be terminated for cause by either party upon 30 days notice. At the time the agreement is extended, the party contracting with the distributing agency must update all pertinent information and must demonstrate that all donated food received during the prior contract period has been accounted for.

(c) *Food service management company agreements.* Food service management companies may be employed to conduct the food service operations of nonprofit summer camps for children, charitable institutions, nutrition programs for the elderly, schools, nonresidential child care institutions, and service institutions. In instances when a food service management company is employed to provide such services, the recipient agency shall enter into a written contract with the food service management company which shall expressly provide that:

(1) Any donated foods received by the recipient agency and made available to the food service management company shall be utilized solely for the purpose of providing benefits for the employing agency's food service operation and it is the responsibility of the recipient agency to demonstrate that the full value of all donated foods is used solely for the benefit of the recipient agency; and

(2) The books and records of the food service management company pertaining to the food service operation of the agency shall be available for a period of three years from the close of the fiscal year to which they pertain.

All food service management contracts shall be subject to review by the distributing agency for compliance with requirements of this section in accordance with § 250.19(b)(1). In the case of nonprofit summer camps for children, charitable institutions and nutrition programs for the elderly, the contract shall be in effect for no longer than one year and shall provide that it may be extended at the option of both parties for two additional one-year periods. Contracts may be terminated for cause by either party upon 30 days notice. At the time the contract is extended, the nonprofit summer camp for children, charitable institution or nutrition program for the elderly must update all pertinent information and must demonstrate that all donated food received during the previous contract period has been accounted for.

(d) *Storage facility contracts.* When contracting for storage facilities, distributing agencies and subdistributing agencies shall enter into a written contract for the lease of storage facilities in accordance with § 250.14(c).

(e) *Processing contracts.* When contracting for the processing of donated foods, contracting agencies shall enter into agreements with processors in accordance with § 250.30(c).

§ 250.13 Distribution and control of donated foods.

(a) *Availability and use of donated foods.* (1) *Availability and use.* Donated foods shall be available only for distribution and use in accordance with the provisions of this Part and, with respect to distribution to households on all or part of an Indian reservation, of Part 253 and 254 of this chapter. Donated foods not so distributed or used (for any reason) shall not be sold, exchanged or otherwise disposed of without the approval of the Department. Donated foods which are provided as part of an approved food package or authorized program level of assistance may be transferred between like recipient agencies with only prior authorization of the distributing agency Donated foods which are provided in addition to the State's authorized program level of assistance may be transferred between recipient agencies which are eligible to receive such foods with the prior authorization of the distributing agency. However, the transfer of donated foods between unlike recipient agencies (schools to charitable institutions), which have been provided as part of an approved food package or authorized program level of assistance, must be approved by the appropriate FNSRO. Food donation under section 32 of Pub. L. 74–320 (7 U.S.C. 612c) may also be transferred by recipient agencies to emergency feeding organizations which are distributing donated foods under 7 CFR Part 251. A transfer between recipient agencies and emergency feeding organizations may be made only with the prior approval of the distributing agency and the State agency responsible for administering TEFAP. All transfers of donated foods shall be documented. Such documentation shall be maintained in accordance with the recordkeeping requirements in §§ 250.16 and 251.10(a).

(2) *Allocations.* As foods become available for donation, FNS shall notify distributing agencies regarding the donated foods, the class or classes of recipient agencies or recipients eligible to receive them, and any special terms and conditions of donation and distribution which attach to a particular donated food in addition to the general terms and conditions set forth herein.

Every attempt shall be made to deliver the donated foods in accordance with requested schedules. However, the Department shall not be responsible for delay in delivery or for nondelivery of donated foods due to any cause.

(3) *Minimum donations.* Foods shall be donated only in such quantities as will protect the lower carload freight rate, except as deemed in the best interest of the program as determined by the Department.

(4) *Quantities.*

(i) The quantity of donated foods to be made available for donation under this Part shall be determined in accordance with the pertinent legislation and the program obligations of the Department, and shall be such as can be effectively distributed to further the objectives of the pertinent legislation.

(ii) Donated foods shall be requested and distributed only in quantities which can be consumed without waste in providing food assistance for persons eligible under this part. Distributing agencies shall impose similar restrictions on recipient agencies.

(5) *Demonstrations and tests.* Notwithstanding any other provision of this Part, a quantity of any food donated for use by any recipient agency or recipient may be transferred by the distributing agency or by the recipient agency to bona fide experimental or testing agencies, or for use in workshops, or for demonostrations or tests relating to the utilization of such donated food by the recipient agency or recipient. No such transfer by any recipient agency shall be made without the approval of the appropriate distributing agency.

(b) *Processing and other costs.* The Department shall pay such processing, reprocessing, transporting, handling and other charges accruing up to the time of transfer of title to distributing agencies as is deemed in the best interest of the Department.

(c) *Transfer of title.* Title to donated foods shall pass to distributing agencies upon their acceptance of donated foods at time and place of delivery, limited, however, by the obligation of the distributing agency to use such donated foods for the purposes and upon the terms and conditions set forth in this part.

(d) *Distribution of donated foods to recipient agencies or recipients*—(1) *Distribution.* Donated foods shall be distribute only to recipient agencies an recipients eligible to receive them under this part (see Subpart D). Distributing agencies shall require that welfare agencies and disaster organizations distributed donated foods only to recipients eligible to receive them under this part. It shall not be deemed a failure to comply with the provisions of this part if recipient agencies serve meals containing donated foods to persons other than those who are eligible under this part, when such persons share common preparation, serving or dining facilities with eligible persons (needy persons, children, participants in nutrition programs for the elderly) and at least one of the following is true:

(i) Such other persons are common beneficiaries with the eligible persons of the program of the recipient agency, or

(ii) Such other persons are few in number compared to the eligible persons and receive their meals as an incident of their service to the eligible persons.

Such other persons include, but are not limited to teachers, disaster relief workers, and staff members. Nothing in this paragraph shall be construed as authorizing allocation or issuance of donated foods to recipient agencies in greater quantity than that authorized for the assistance of persons eligible under this part.

(2) *Normal food expenditures.* Section 416 donated foods shall not be distributed to any recipient agencies or recipients whose normal food expenditures are reduced because of the receipt of donated foods.

(e) *Improper distribution, loss of or damage to donated foods.* (1) If a distributing agency improperly distributes or uses any donated foods or causes loss of or damage to a donated food through its failure to provide proper storage, care or handling, the provisions set forth in § 250.15(c) shall apply.

(2) In instances when it is determined by a distributing agency that a claim exists against a subdistributing agency, recipient agency, warehouse, carrier, processor or other person, the distributing agency shall pursue claims in accordance with § 250.15(c).

(f) *Disposition of damaged or out-of-condition foods.* Donated foods which are found to be damaged or out-of-condition and are declared unfit for human consumption by Federal, State or local health officials, or by other inspection services or persons deemed competent by the Department, shall be disposed of in accordance with instructions of the Department. Such instructions may direct that unfit donated food be:

(1) Sold in a manner prescribed by the Department with the net proceeds thereof remitted to the Department;

(2) Sold in a manner prescribed by the Department with the proceeds thereof retained for use in accordance with the provisions of § 250.15(f);

(3) Used in such manner as will serve a useful purpose as determined by the Department; or

(4) Destroyed in accordance with applicable sanitation laws and regulations.

Upon a finding by the Department that donated food are unfit for human consumption at the time of delivery to the distributing agency and when the Department or appropriate health officials require that such donated foods be destroyed, the Department may pay to the distributing agency any expenses incurred in connection with such donated foods as determined by the Department. The Department may, in any event, repossess damaged or out-of-condition donated foods.

(g) *Redonations.* Whenever a distributing agency has any donated food on hand which it cannot efficiently utilize, it shall immediately make a request to the appropriate FNSRO, in writing, for instructions as to the disposition of such donated food. Distributing agencies requesting authority from the Department to make redonation of any donated foods shall, upon the Department's request, have such donated foods federally inspected. Expenditures incurred by the distributing agency as a result of redonation shall be handled in accordance with § 250.15(e).

(h) *Embezzlement, misuse, theft, or obtainment by fraud of donated foods and donated food-related funds, assets, or property.* Notwithstanding paragraph (c) of this section concerning transfer of title to donated foods, whoever embezzles, willfully misapplies, steals, or obtains by fraud, donated foods or any funds, assets, or property deriving from donated foods or whoever receives, conceals, or retains such donated foods, funds, assets, or property for his/her own use or gain, knowing such donated foods, funds, assets, or property have been embezzled, willfully misapplied, stolen, or obtained by fraud shall be subject to Federal criminal prosecution under section 12(g) of the National School Lunch Act, as amended (42 U.S.C. 1760(g)) or section 4(c) of the Agriculture and Consumer Protection Act of 1973, as amended (7 U.S.C. 612c note). For the purpose of this paragraph "funds, assets, or property" include, but are not limited to funds accruing from the sources identified in § 250.15(f) (1) and (2), donated foods which have been processed into different end products as provided for under Subpart C of this part, and the containers in which donated foods have been received from the Department. Distributing agencies shall immediately notify FNSRO of any

suspected violation of section 12(g) or section 4(c) to allow the Department, in conjunction with the U.S. Department of Justice, to determine whether Federal criminal prosecution under section 12(g) or section 4(c) is warranted. Prosecution of violations by the Federal Government shall not relieve any distributing agency of its obligation to obtain recovery for improperly distributed or lost donated foods, as required by § 250.15(c).

§ 250.14 Storage facilities.

(a) *Standards for storage facilities.* Distributing agencies, subdistributing agencies and recipient agencies shall provide facilities for the handling, storage and distribution of donated foods which:

(1) Are sanitary and free from rodent, bird, insect and other animal infestation;

(2) Safeguard against theft, spoilage and other loss;

(3) Maintain foods at proper storage temperatures;

(4) Stock and space foods in a manner so that USDA-donated foods are readily identified;

(5) Store donated food off the floor in a manner to allow for adequate ventilation; and

(6) Take other protective measures as may be necessary.

Distributing agencies, subdistributing agencies and recipient agencies shall ensure that storage facilities have obtained all required Federal, State and/or local health inspections and/or approvals and that such inspection/approvals are current.

(b) *Reviews.* All distributing agency-level storage facilities shall be reviewed annually. Distributing agencies shall ensure that subdistributing and recipient agencies. Conduct annual reviews of their respective storage facilities. Documentation shall be maintained on file at the distributing agency or local level as appropriate to reflect compliance with this section, including documentation of corrective action in cases of noncompliance. Corrective action must be taken immediately on all deficiencies identified in the review and the result of the corrective action must be forwarded to the distributing agency. Where applicable, the distributing agency shall determine and pursue claims in accordance with § 250.15(c).

(c) *Contracts.* When contracting for storage facilities, distributing agencies and subdistributing agencies shall enter into written contracts to be effective for no longer than one year. The contract may be extended at the option of both parties for two additional one year periods. At the time the contract is extended, the storage facility must update all pertinent information and demonstrate that all donated foods received during the previous contract period have been accounted for. The contract shall, at a minimum, contain the following:

(1) Assurance that the storage facilities will be maintained in accordance with the standards specified in paragraph (a) of this section;

(2) Evidence that donated food shall be clearly identified;

(3) Assurance that an inventory system shall be maintained and an annual physical inventory will be conducted; and reconciled with the inventory records;

(4) Beginning and ending dates of the contract;

(5) A provision for immediate termination of the contract due to noncompliance on the part of the warehouse management;

(6) A provision allowing for termination of the contract for cause by either party upon 30 days written notification;

(7) The amount of any insurance coverage, which has been purchased to protect the value of food items which are being stored; and

(8) Express written consent for inspection and inventory by the distributing agency, subdistributing agency, recipient agency, the Comptroller General, the Department or any of their duly authorized representatives.

(d) *Physical inventory.* During the annual review required by § 250.14(b), distributing agencies, subdistributing agencies and recipient agencies shall take a physical inventory of all storage facilities. Such inventory shall be reconciled annually with the storage facility's inventory records and maintained on file by the agency which contracted with or maintained the storage facility. Food items which have been lost, stolen or found to be out-of-condition shall be identified during the physical inventory and reported by the subdistributing or recipient agency to the distributing agency. Potential excessive inventory, as described in paragraph (e) of this section, shall be reported by the subdistributing or recipient agency to the distributing agency. Corrective action shall be taken immediately on all deficiencies and inventory discrepancies and the results of the corrective action forwarded to the distributing agency. Where applicable, the distributing agency shall determine and pursue claims in accordance with § 250.15(c).

(e) *Excessive inventories.* (1) The distributing agency shall determine if a subdistributing or recipient agency's inventories are excessive based on:

(i) The rate of distribution;

(ii) Anticipated distribution; and

(iii) Other concerns such as logistical and economic considerations.

(2) In no case may the inventory level of each donated food in storage exceed a six-month supply unless sufficient justification for additional inventory has been submitted and approved. Subdistributing agencies and recipient agencies shall submit justification to the distributing agency in instances where more than a six-month inventory is needed. Justification shall be submitted by the distributing agency to the FNSRO for approval in instances where more than a six-month inventory is needed at the distributing agency level.

(3) The distributing agency shall take corrective action to ensure that excess inventories at all levels are eliminated and shall document actions taken to reduce excessive inventories.

§ 250.15 Financial management.

(a) *Distribution charges.* (1) Except as provided in paragraph (a)(2) of this section, recipient agencies may be required to pay part or all of the intrastate costs of distribution through a system of charges assessed by the distributing or subdistributing agencies. Any system of assessment operated by the distributing or subdistributing agency shall have the prior approval of and be subject to review by the FNSRO. The charges assessed shall be used solely in accordance with the provisions of paragraph (f) of this section.

(2) For the period May 1, 1983, through September 30, 1988, whenever a commodity is donated to a State without charge or credit against entitlement, recipient agencies may not be assessed for any part of the intrastate costs of storage and transportation of such commodity that is in excess of the distributing or subdistributing agency's direct costs for such storage and transportation minus any amount that the Department provides to the State to pay such costs under Part 251 of this chapter.

(3) Under no circumstances shall recipients be required to make any payments in money, materials, or services for or in connection with the receipt of donated foods, nor shall voluntary contributions be solicited (except for the nutrition programs for the elderly) in connection with the receipt of donated foods for any purpose.

(b) *Sale of containers.* When containers or packing materials in which donated foods are received are disposed of by sale, the proceeds of such sale shall be used solely in accordance with

the provisions of paragraph (f)(2) of this section.

(c) *Claims.* If a distributing agency improperly distributes or uses any donated foods, or causes loss of or damage to a donated food through its failure to provide proper storage, care, or handling, the distributing agency shall, at the Department's option.

(1) Replace the donated food in its distribution program in kind, or, in the case of section 6 donated foods, where replacement in kind may not be practicable, with other similar foods, or

(2) Pay to the Department the value of the donated food as determined by the Department.

Upon the happening of any event creating a claim in favor of a distributing agency against a subdistributing agency, recipient agency, warehouseman, carrier or other person, for the improper distribution, use, or loss of, or damage to, a donated food, the distributing agency shall take action to obtain recovery. All amounts collected by such action shall, at the Department's option, be used in accordance with the provisions of paragraph (c)(1) of this section, or, except for amounts collected on claims involving section 6 donated foods, shall be expended for program purposes in accordance with the provisions of paragraph (f) of this section. Determinations by a distributing agency that a claim has or has not arisen in favor of the distributing agency against a subdistributing agency, recipient agency, warehouseman, carrier or other person, shall, at the option of the Department, be approved by the Department prior to the distributing agency taking action thereon. Where prior approval has not been given by the Department, a distributing agency's claim determinations shall be subject to review by the Department. In the case of an inventory shortage, when the loss of any one commodity does not exceed one percent of the total quantity of the donated food distributed or utilized from any single storage facility during the fiscal year in which the loss occurred, or during the period for which an audit was conducted by representatives of the Department, or, if approved by FNS, during the period for which an audit was conducted by the distributing agency, if the distributing agency finds that: (i) The cause of the shortage cannot be established, (ii) the lost donated foods were held in non-commercial storage or other facilities owned or operated by the distributing agency, a subdistributing agency or a recipient agency, and (iii) there is no indication that the loss was the result of negligence or continued inefficiency in operations, the distributing agency need not take any further claims action, but the factual basis for not taking further claims action shall be subject to review by the Department. Furthermore, distributing agencies shall not be required to file or pursue a claim for a loss which does not exceed an amount established by State law, regulations, or procedure as a minimum amount for which a claim will be made for State losses generally, but no such claim shall be disregarded where there is evidence of violation of Federal or State statutes. Distributing agencies which fail to pursue claims arising in their favor, or fail to provide for the right to assert such claims, or fail to require their subdistributing agencies and recipient agencies to provide for such rights in accordance with § 250.12(b), shall be responsible to the Department for replacing the donated foods or paying the value thereof in accordance with the provisions of paragraph (c)(1) or (2) of this section. Distributing agencies which pursue claims arising in their favor, but fail to obtain full restitution shall not be liable to the Department for any deficiency unless the Department determines that the distributing agency fraudulently or negligently failed to take reasonable action to obtain restitution. The Department may, at its option, require assignment to it of any claim arising from the distribution of donated foods.

(d) *Demurrage.* Demurrage or other charges which accrue after a car or truck has been placed for unloading by the delivering carrier, or which accrue because placement of a car or truck is prevented, shall be borne by the distributing agency, except that demurrage or other charges may be borne by the Department where such charges accrue because of actions by the Department and without the fault or negligence of the distributing agency.

(e) *Redonation expenditures.* In accordance with § 250.13(g), whenever a distributing agency requests authority to make redonation of any donated foods and the Department requests that the donated foods be federally inspected, these inspections will be made at the expense of the distributing agency. Any donated foods which the Department determines are acceptable for redonation shall be moved at the distributing agency's expense to the closest point within the FNS region in which the State is located where it can be utilized, or to a closer point outside the region, if such a transfer is mutually agreed to by the Department and the distributing agency. In those instances in which the distributing agency satisfactorily demonstrates to the Department that the need for any redonation resulted from no fault or negligence on its part, the Department shall assume such transportation costs as it determines to be proper. Whenever a redonation is made at the request of the Department, the Department shall pay all transportation and handling costs in connection with such redonation and shall pay to the distributing agency all storage and handling costs accrued on the donated foods at the time of redonation, as determined by the Department, except when the request is made as a result of negligence on the part of the distributing agency.

(f) *Use of funds accruing in operation of the program.* (1) *Funds accruing from claims.* Funds accruing from recoveries from loss or damage claims (which are authorized under paragraph (c) of this section to be expended for program purposes) shall be used only for the payment of expenses of the food distributing program, including transportation, storage and handling or donated foods, salaries of persons directly connected with the program, and other administrative expenses. In accordance with paragraph (f)(4) of this section, the receipt and expenditure of funds so accrued shall be reviewed by the distributing agency to determine that fund balances are not in excess of program needs.

(2) *Other funds.* Funds accruing from the sale of containers, packing materials, salvage of donated foods, distribution charges, or insurance shall be returned to the Department or used only for the payment of expenses of the program which will improve program operations including, but not limited to, transportation, storage and handling of donated foods, salaries of persons directly connected with the program and other program-related expenses. Funds accruing from the collection of distribution charges which are determined to be in excess of program needs pursuant to paragraph (f)(4) of this section shall be used in accordance with that paragraph. Funds accruing from the operation of the program shall not be used for those costs which are unallowable under the cost Principles in the Department's Uniform Federal Assistance Regulations, 7 CFR Part 3015, Subpart T. These unallowable costs include, but are not limited to:

(i) Bad debts;
(ii) Contingencies;
(iii) Contributions and donations;
(iv) Entertainment;
(v) Fines and penalties;
(vi) Governor's expenses;
(vii) Interest and other financial costs;

(viii) Legislative expenses; and

(ix) Losses on other grants.

(3) *Segregation of funds.* Distributing agencies and subdistributing agencies shall maintain two separate accounts for funds accruing from program operations. Funds accruing from the collection of distribution charges shall be maintained in an operating account. Funds accruing from the sale of containers, salvage of foods, insurance and recoveries of claims for the loss or damage of donated foods shall be maintained in a salvage account.

(4) *Excess funds.* The distributing agency shall review the receipt and expenditures of funds annually to ensure that fund balances are not in excess of program needs. At a maximum, the operating account fund shall not exceed the sum of the previous year's highest three-month expenditures. Funds exceeding this maximum shall be considered in excess of program needs unless the distributing agency provides sufficient justification as to the need for such funds and receives approval from the FNSRO. FNSRO may determine that funds equal to or less than the expenditures for the previous year's highest three months are in excess of what is needed. In such instances, the distributing agency shall reduce the excess funds in the operating account by reducing distributing charges or returning the funds to the contributor. The salvage account will have no set limit. FNSRO must, however, give prior approval to each deposit to or expenditure from the salvage fund which is in excess of $2,500. The distributing agency shall impose upon subdistributing agencies and recipient agencies similar provisions for the use of such funds accruing from the operation of their programs.

§ 250.16 Maintenance of records.

(a) *General requirements.* (1) Accurate and complete records shall be maintained with respect to the receipt, distribution/use and inventory of donated foods including:

(i) End products processed from donated foods and

(ii) The determination made as to liability for any improper distribution, use of, loss of, or damage to, such foods and the results obtained from the pursuit of claims by the distributing agency.

Such records shall also be maintained with respect to the receipt and disbursement of funds arising from the operation of the distribution program, including the determination as to the amount of payments to be made by any processor, upon termination of processing contracts.

(2) Distributing agencies shall require all subdistributing and recipient agencies to maintain accurate and complete records with respect to the receipt, distribution/disposal and inventory of donated foods, including end products processed from donated foods, and with respect to any funds which arise from the operation of the distribution program, including refunds made to recipient agencies by processors in accordance with § 250.30(k).

(3) Unless a distributing agency maintains an offer-and-acceptance system in accordance with § 250.48(e), the distributing agency shall maintain accurate and complete records with respect to amounts and value of commodities refused by school food authorities. School food authorities shall also be required to maintain such records of refusals.

(4) Each processor, food service management company, warehouse, or other entity which contracts with a distributing agency, subdistributing agency or recipient agency shall be required to keep accurate and complete records with respect to the receipt, distribution/disposal, storage and inventory of such foods similar to those required of distributing agencies under this paragraph. Where donated foods have been commingled with commercial foods, the processor shall maintain records which permit an accurate determination of the donated-food inventory. The processor shall also be required to keep formula, recipes, daily or batch production records, loadout sheets, bills of lading, and other processing and shipping records to substantiate the use made of such foods and their subsequent redelivery, in whatever form, to any distributing agency, subdistributing agency or recipient agency. Processors must maintain records which will permit a determination regarding compliance with the contracting provisions required by § 250.30(f) (3) and (4) as well as maintain records used as the basis for compiling the processor performance reports required by § 250.30(m).

(5) All recipient agencies shall be required to keep accurate and complete records showing the data and method used to determine the number of eligible persons served by that agency.

(6) Failure by a distributing agency, subdistributing agency, recipient agency, processor, food service management company, warehouse or other entity to maintain records required by this Section shall be considered prima facie evidence of improper distribution or loss of donated foods and the agency, processor or entity shall be subject to the provisions of § 250.13(e).

(b) *Length of maintenance.* All records required by this Section shall be retained for a period of three years from the close of the fiscal year to which they pertain. However, in instances when claims action and/or audit findings have not been resolved, the records shall be retained as long as required for the resolution of such action or findings.

§ 250.17 Reports

(a) *Monthly Report of Receipt and Distribution of Donated Foods (FNS–155).* Distributing agencies shall complete and submit to the FNSRO monthly inventory reports covering the receipt and distribution of donated foods on Form FNS–155 or other format approved by FNS. The report shall be submitted no later than 30 calendar days after the end of the reporting month. The distributing agency shall submit a list of individual food orders received for each food item delivered by the Department as an attachment to the FNS–155.

(b) *Processing inventory reports.* Distributing agencies shall complete and submit a quarterly processing inventory report in accordance with § 250.30(o).

(c) *Performance reports.* Monthly reports of performance shall be submitted by processors to distributing agencies in accordance with § 250.30(m).

(d) *Other reports.* Distributing agencies shall complete and submit other reports relative to distribution operations in such form as may be required from time to time by the Department.

(Reporting requirements contained in paragraph (a) approved by the Office of Management and Budget under control number 0584–0001. Reporting requirements contained in paragraph(d) approved by the Office of Management and Budget under control numbers 0584–0028, 0584–0109, 0584–0288 and 0584–0293).

§ 250.18 Audits.

(a) *Right of inspection and audit.* The Secretary, the Comptroller General of the United States, or any of their duly authorized representatives, may inspect and inventory donated foods in storage or the facilities used in the handling or storage of such donated foods, and may inspect and audit all records, including financial records, and reports pertaining to the distribution of donated foods and may review or audit the procedures and methods used in carrying out the requirements of this Part at any reasonable time. Subdistributing agencies, recipient agencies, processors, food service management companies and warehouses shall be required to

permit similar inspection and audit by such entities or their representatives. Fiscal matters shall continue to be reviewed in audits under the Single Audit Act (31 U.S.C. 7501–07) and the Department's Uniform Federal Assistance Regulations (7 CFR Part 3015).

(b) *Independent CPA audits of multi-State processors.* (1) For any year in which a multi-State processor receives more than $250,000 in donated foods, the processor shall obtain an independent CPA (certified public accountant) audit for that year. Multi-State processors which receive $75,000 to $250,000 in donated food each year shall obtain an independent CPA audit every two years and those which receive less than $75,000 in donated foods each year shall obtain an independent CPA audit every three years. Those multi-State processors which are in the two or three-year audit cycle shall move into the next audit cycle at the point in time in which the value of donated foods received reaches $75,000 or $250,000 in any year. In instances in which the Department determines that the audit is not acceptable or that the audit has disclosed serious deficiencies, the processor shall be subject to additional audits at the request of FNS.

(2) Audits shall be conducted in accordance with the auditing provisions set forth under the Uniform Federal Assistance Regulations (7 CFR Part 3015, Subpart I) and the FNS Audit Guide for Multi-State Processors. At the discretion of FNS, auditors will be required to attend training sessions conducted by the Department.

(3) The costs of the audits, including those costs associated with training, shall be borne by the processors.

(4) Audit findings relative to those elements associated with the processing of donated food shall be submitted to the processor and to FNS concurrently.

(5) Noncompliance with the audit requirements in paragraph (b)(1) of this section will render the processor ineligible to enter into another processing contract with any contracting agency until the required audit has been conducted and deficiencies corrected.

(6) *Processor response.* Multi-State processors shall develop a written response to FNS addressing deficiencies which have been identified in the audit. Such responses shall include:

(i) Corrective action which has already been taken to eliminate the deficiency;

(ii) Corrective action which the processor proposes to take to eliminate the deficiency;

(iii) The timeframes for the implementation and completion of the corrective action;

(iv) A determination of what caused the deficiency; and

(v) Deficiencies which have been identified that the processor takes exception to and an explanation for the exception.

Multi-State processors shall submit a written response to FNS in accordance with timeframes established by FNS.

§ 250.19 Reviews.

(a) *General.* Each distributing agency shall establish a review system in order to assess the effectiveness of its food distribution program in meeting the requirements of these regulations.

(b) *Responsibilities of distributing agencies.* (1) Each distributing agency shall establish review procedures encompassing eligibility, food ordering procedures, storage practices, inventory controls, reporting and recordkeeping requirements and compliance with nondiscrimination provisions. The procedures shall include:

(i) An on-site review of all charitable institutions, nutrition programs for the elderly and nonprofit summer camps for children under agreement in accordance with § 250.12(b) at least once every 4 years, with not fewer than 25 percent of each of these recipient agency categories being reviewed each year. These reviews shall also include on-site reviews of storage facilities to ensure compliance with § 250.14(a);

(ii) An on-site review at least once every 2 years of all processors except those that are multi-State processors as defined in § 250.3, with no fewer than 50 percent being reviewed each year;

(iii) An annual on-site review of each storage facility utilized by the distributing agency. On-site reviews conducted by FNS may be considered as contributing to the fulfillment of the minimum coverage required by this paragraph; and

(iv) A biennial review of all food service mangement companies under contract with recipient agencies in accordance with § 250.12(c) which are not under contract with a school participating in the National School Lunch Program or a Commodity School under Part 210 of this chapter, or a school participating in the School Breakfast Program under Part 220 of this chapter.

(2) Each distributing agency shall design and implement a system to verify sales of end products to all recipient agencies under that distributing agency's authority in instances when a processor transfers end products to a distributor and the distributor sells the end product to the recipient agencies at a discount and the distributor receives a refund from the processor. At a minimum, such a system must:

(i) Provide for the quarterly review of a statistically valid sample of sales information of all processors which contract with the distributing agency or contracting agencies under the authority of the distributing agency, including multi-State processors;

(ii) Support the projection of a claim against the processor when, in the review of the sample, it is determined that the value of donated foods has not been passed on to recipient agencies or when end products have been improperly distributed; and

(iii) Provide for the assessment of claims against the processor in accordance with FNS Instruction 410–1 Non-Audit Claims, Food Distribution Program, in instances when deficiencies have been identified. Distributing agencies may delegate the responsibility of sales verification to processors. In such instances, the distributing agency must establish guidelines which the processor must follow in conducting sales verification. These guidelines must ensure that a statistically valid sample of sales is verified quarterly. Processors shall report their findings to the distributing agency on a quarterly basis in accordance with § 250.30(m).

Distributing agencies must review the processor's sales verification system and the processor's findings for adequacy and submit a copy of the review report of the system findings to the appropriate FNSRO.

(3) The distributing agency shall submit a report of review findings to each entity reviewed. The report shall include:

(i) Each deficiency found;

(ii) The factors contributing to each deficiency;

(iii) Recommendations for needed corrective action, including timetables for completion and/or claims action to be pursued, if any; and

(iv) Provisions for evaluating effectiveness of corrective actions.

A copy of each processor review report shall be provided to the appropriate FNSRO.

(4) Distributing agencies shall monitor progress toward completion and the effectiveness of corrective actions taken in eliminating program deficiences.

(5) In addition to the review requirements of paragraph (b)(1) of this section, each distributing agency shall make a continuing evaluation of all recipient agencies, and processors by monitoring performance reports, food

requests, participation data, and data regarding refunds and discounts to recipient agencies and distributors for the receipt of end products.

(6) Distributing agencies shall, where applicable, require that subdistributing agencies monitor and review their operations in accordance with this paragraph.

(c) *Responsibilities of State Agencies on Aging.* State Agencies on Aging which receive cash payments in lieu of donated foods in accordance with the provisions of § 250.42(c) shall monitor use of such cash after disbursement to nutrition programs for the elderly to ensure that the amounts so received are expended solely for the purchase of U.S. agricultural commodities and other foods of U.S. origin for such programs.

§ 250.20 Sanctions.

Any distributing agency which has failed to comply with the provisions of this Part or any instructions or procedures issued in connection with it or any agreements entered into pursuant to it, may, at the discretion of the Department, be disqualified from further participation in any distribution program. Reinstatement may be made at the option of the Department. Disqualification shall not prevent the Department from taking other action through other available means when considered necessary, including prosecution under applicable Federal statutes.

§ 250.21 Civil rights.

Distributing agencies, subdistributing agencies and recipient agencies shall comply with the Department's nondiscrimination regulations (7 CFR Parts 15, 15a, and 15b) and the FNS civil rights instructions to ensure that in the operation of the program no person is discriminated against because of race, color, national origin, age, sex or handicap.

§ 250.22 Complaints.

Distributing agencies shall investigate promptly complaints received in connection with the distribution or use of donated foods. Irregularities which are disclosed shall be corrected immediately. Serious irregularities shall be promptly reported to the Department. Distributing agencies shall maintain or file evidence of such investigations and actions. The Department also reserves the right to make investigations and shall have the final determination as to when a complaint has been properly handled. Complaints alleged on the basis of race, color, national origin, age, sex or handicap shall be handled in accordance with § 250.21.

Subpart C—Processing and Labeling of Donated Foods

§ 250.30 State processing of donated foods.

(a) *General.* This section sets forth the terms and conditions under which distributing agencies, subdistributing agencies, or recipient agencies may enter into contracts for the processing of donated foods and prescribes the minimum requirements to be included in such contracts. This section does not pertain to food service management companies.

(b) *Permissible contractual arrangements.* (1) A distributing agency, subdistributing agency, or recipient agency may contract for processing, pay the processing fee, and deliver the end products to eligible recipient agencies through its own distribution system.

(2) A distributing agency or subdistributing agency may contract for processing on behalf of one or more recipient agencies. All recipient agencies eligible to receive the donated foods to be processed may receive end products made from those foods and produced under such processing contracts by virtue of the distributing agency—recipient agency agreement required by § 250.12(b). Under this arrangement and subject to the approval of the distributing agency:

(i) Processors shall utilize either a discount or a refund system as defined in § 250.3 when they sell end products directly to recipient agencies, or

(ii) When selling end products through a distributor, processors shall utilize either a refund system or a system which provides refunds to distributors and discounts to recipient agencies through a distributor in accordance with paragraph (e) of this section.

(3) Distributing agencies shall permit subdistributing agencies and recipient agencies to enter into processing contracts with a processor under arrangements similar to those described in paragraph (b) (1) or (2) of this section.

(c) *Requirements for processing contracts.* (1) Contracts with processors shall be in a standard written form and be reviewed by the appropriate FNSRO. Processing contracts shall terminate no later than one year after they have been entered into and shall not be extended without being renegotiated. Distributing agencies shall develop criteria for use in evaluating and selecting processing contracts. The selection criteria shall be used in selecting or rejecting processors in a manner that ensures equitable treatment of processors. The selection criteria shall, at a minimum, include:

(i) The nutritional contribution which the end product will provide;

(ii) The marketability of the end product;

(iii) The distribution method which the processor intends to utilize;

(iv) Price and yield schedule data;

(v) Any applicable labeling requirements; and

(vi) The ability of the processor to meet the terms and conditions set forth in the regulations.

These criteria will be reviewed by the appropriate FNSRO during the management evaluation review of the distributing agency. Distributing agencies and subdistributing agencies which enter into contracts on behalf of recipient agencies but which do not limit the types of end products which can be sold or the number of processors which can sell end products within the State are not required to follow the selection criteria. In addition to utilizing these selection criteria, when a contracting agency enters into a contract both for the processing of donated food and the purchase of the end products produced from the donated food, the procurement standards set forth in Attachment O to OMB Circular A-102 must be followed. Recipient agencies which purchase end products produced under Statewide agreements are also required to comply with Attachment O of OMB Circular A-102. Contracting agencies shall not enter contracts with processors which cannot demonstrate the ability to meet the terms and conditions of the regulations and the distributing agency agreements; furnish prior to the delivery of any donated foods for processing, a performance bond, an irrevocable letter of credit or an escrow account in an amount sufficient to protect the contract value of donated food on hand and on order; demonstrate the ability to distribute end products to eligible recipient agencies; provide a satisfactory record of integrity, business ethics and performance and provide adequate storage.

(2) Standard form contracts shall be prepared or reviewed by the appropriate State legal staff to assure conformity with the requirements of these regulations and of applicable Federal, State and local laws.

(3) The contract shall be signed for the processor by the owner, a partner, or a corporate officer duly authorized to sign the contract, as follows:

(i) In a sole proprietorship, the owner shall sign the contract;

(ii) In a partnership, a partner shall sign the contract;

(iii) In a corporation, a duly authorized corporate officer shall sign the contract.

(4) At a minimum, each processing contract shall include:

(i) The names and telephone numbers of the contracting agency and processor;

(ii) A description of each end product, the quantity of each donated food and any other ingredient which is needed to yield a specific number of units of each end product (except that the contracting agency may permit the processor to specify the total quantity of any flavorings or seasonings which may be used without identifying the ingredients which are, or may be, components of flavorings or seasonings), and the yield factor for each donated food. The yield factor is the percentage of the donated food which must be returned in the end product to be distributed to eligible recipient agencies. For substitutable donated foods, at least 100 percent of the donated foods provided to the processor must be physically contained in the end products, with no allowable tolerance;

(iii) The contract value of each donated food to be processed and, where processing is to be performed only on a fee-for-service basis, the processing fee to the contracting agency for a specified number, weight or measure of the end products to be delivered;

(iv) A provision for:

(A) Termination of the contract upon thirty days written notice by the contracting agency or the processor and

(B) Immmediate termination of the contract when there has been noncompliance with its terms and conditions by the contracting agency or the processor;

(v) In the event of contract termination, a provision for disposition of donated foods and end products in the processor's inventories or payment of funds in accordance with paragraph (j) of this section;

(vi) A provision for inspection and certification during processing, where applicable, by the appropriate acceptance service in accordance with paragraphs (g) and (h) of this section;

(vii) A provision that end products containing donated foods that are not substitutable under paragraph (f) of this section shall be delivered only to recipient agencies eligible to receive such foods;

(viii) Provisions that the processor shall:

(A) Fully account for all donated foods delivered into its possession by production and delivery to the contracting agency or eligible recipient agencies of an appropriate number of units of end products meeting the contract specifications, and where end products are sold through a distributor, that the processor remains full accountable for the donated foods until refunds or any other credits equal to their contracted value have been made to eligible recipient agencies in accordance with paragraph (k) of this section or to distributing agencies in accordance with paragraph (n)(2) of this section;

(B) Furnish to the contracting agency prior to the delivery of any donated foods for processing documentation that a performance supply and surety bond from a surety company listed in the most recent U.S. Department of Treasury Circular 570, an irrevocable letter of credit or an escrow account has been obtained in an amount that is sufficient to protect the contract value of all donated foods. Since the distributing agency is held liable by FNS for any donated foods provided to a processor the distributing agency shall determine the dollar value of the performance supply and surety bond, irrevocable letter of credit or the escrow account taking into consideration the

(*1*) Value of donated foods on hand;

(*2*) Value of donated foods on order and

(*3*) Anticipated usage rate during the contract period;

(C) Use or dispose of the containers in which donated foods are received from the Department in accordance with the instructions of the contracting agency;

(D) Apply as credit against the processing fee or return to the contracting agency:

(*1*) Any funds received from the sale of containers, and

(*2*) The market value or the price received from the sale of any by-products of donated foods or commercial foods which have been substituted for donated foods;

(E) Substitute donated foods with commercially purchased foods only in accordance with paragraph (f) of this section;

(F) Meet the requirements of paragraph (i) of this section for labeling end products;

(G) Maintain accurate and complete records pertaining to the receipt, disposal, and inventory of donated foods in accordance with § 250.16;

(H) Submit processing performance reports in accordance with paragraph (m) of this section; and

(I) Submit annual reconciliation reports and make payments to distributing agencies for any outstanding refund applications or excessive inventories in accordance with paragraph (n)(2) of this section;

(ix) A provision that approval of the contract by distributing agency shall not obligate that agency or the Department to deliver donated foods for processing;

(x) A description of the processor's quality control system and assurance that an effective quality control system will be maintained for the duration of the contract;

(xi) In instances when the processor is a multi-State processor as defined in § 250.3, a provision that the processor agrees to obtain an independent audit by a certified public accountant in accordance with § 250.18(b);

(xii) A requirement that inventory drawdowns shall be limited to the actual amount of donated foods contained in the end product. Additional commodity required to account for production loss shall be obtained from non-donated foods;

(xiii) In instances when end products are sold through a distributor a description of the system which will be utilized for the sale of the end products to a recipient agencies;

(xiv) In instances when the distributing agency has delegated the responsibility for sales verification for end products provided by a distributor to recipient agencies at a discount, assurance that the processor will submit sales verification data to the distributing agency in accordance with § 250.30(m)(l); and

(xv) A provision that the contracting agency shall give the processor a list of all recipient agencies eligible to purchase end products under the contract.

(5) The processor shall not assign the processing contract or delegate any aspect of processing under a subcontract or other arrangement without the written consent of the contracting agency and the distributing agency.

(d) *End products sold by processors.* When recipient agencies pay the processor for end products, the processing contract shall include:

(1) The processor's established wholesale price schedule for quantity purchases of specified units of end products, and

(2) An assurance that the price of each unit of end product purchased by eligible recipient agencies shall be discounted by the stated contract value of the donated foods contained therein, or a refund equal to such value made upon proof of purchase by an eligible recipient agency in accordance with paragraph (k) of this section.

(e) *End products sold by distributors.* When a processor transfers end products to one or more distributors for sale and delivery to recipient agencies, such sales shall be under either a refund

system as defined in § 250.3 or a system which provides refunds to distributors and discounts to recipient agencies. The processor shall make refund payments to distributors or recipient agencies in accordance with paragraph (k) of this section.

(f) *Substitution of donated foods with commercial foods.* (1) The processing contract may provide for substitution of donated foods as defined in § 250.3. If the provision allowing substitution is included, the contract shall stipulate that:

(i) Only butter, cheese, corn grits, corn meal, flour, macaroni, nonfat dry milk, peanut butter, peanut granules, roasted peanuts, rice, rolled oats, rolled wheat, shortening, vegetable oil, spaghetti, and such other food as FNS specifically approves may be substituted (substitution of meat and poultry items shall not be permitted),

(ii) All components of commercial foods substituted for those donated must be of U.S. origin and be identical or superior in every particular of the donated-food specification as evidenced by certification performed by, or acceptable to, the applicable Federal acceptance service, and

(iii) Substitution is allowed without advance approval by the distributing agency only when:

(A) It is necessary to replace donated food with commercial food to meet the 100 percent yield requirement; or

(B) The donated and commercial foods have been commingled through the use of joint storage tanks or bins; or

(C) The processing contract permits the use of concentrated skim milk which has been purchased or manufactured by the processor for donated nonfat dry milk.

(2) Documentation must be maintained by both parties in accordance with § 250.16. When there is substitution, the donated foods shall be used by the processor and shall not otherwise be sold or disposed of in bulk form. The applicable Federal acceptance service shall, upon request by the Department, the contracting agency or the distributing agency determine if the quality analysis meets the requirements set forth by the Agricultural Stabilization and Conservation Service (ASCS) in the original inspection of donated foods and, in the case of concentrated skim milk replacing donated nonfat dry milk, determine if the concentrated skim milk contains the amount of milk solids as specified in the contract. When donated foods are nonsubstitutable, the applicable Federal acceptance service shall ensure against unauthorized substitutions, and verify that quantities of donated foods used are as specified in the contract.

(3) When concentrated skim milk is used to replace donated nonfat dry milk, the contract shall also specify (in addition to the requirements in paragraph (c) of this section):

(i) The percent of milk solids that, at a minimum, must be contained in the concentrated skim milk;

(ii) The weight ratio of concentrated skim milk to donated nonfat dry milk;

(A) The weight ratio is the weight of concentrated skim milk which equals one pound of donated nonfat dry milk, based on milk solids;

(B) In calculating this weight, nonfat dry milk shall be considered as containing 96.5 percent milk solids;

(C) If more than one concentration of concentrated skim milk is to be used, a separate weight ratio must be specified for each concentration;

(iii) The processor's method of verifying that the milk solids content of the concentrated skim milk is as stated in the contract;

(iv) A requirement that inventory drawdowns of donated nonfat dry milk shall be limited to an amount equal to the amount of concentrated skim milk, based on the weight ratio, used to produce the end product;

(v) A requirement that the contract value of donated food for a given amount of concentrated skim milk used to produce an end product is the value of the equivalent amount of nonfat dry milk, based on the weight ratio of the two foods;

(vi) A requirement that the concentrated skim milk shall be produced in a USDA approved plant or in a plant approved by the appropriate regulatory authority for the processing of Grade A milk products; and

(vii) A requirement that documentation sufficient to substantiate compliance with the contract provisions shall be maintained in accordance with § 250.16(a)(4).

(4) Except as specified in paragraph (f)(iii) of this section, processors must receive approval from the distributing agency prior to any substitution. Distributing agencies may approve a processor's request for substitution only when the distributing agency's inability to maintain the necessary inventory of donated food at the processor would disrupt the production of end products.

(5) Title to the substituted food shall transfer to the contracting agency upon the initiation of the processing of the end product containing the substituted food. Title to the equivalent amount of donated food shall transfer to the processor at the same time (except when the substitution is necessary to meet the 100 percent yield requirement or to otherwise replace missing or out-of-condition donated food). Once title has transferred, the processor shall use the substituted food in accordance with the terms and conditions of this part.

(g) *Meat and poultry inspection programs.* When donated meat or poultry products are processed or when any commercial meat or poultry products are incorporated into an end product containing one or more donated foods, all of the processing shall be performed in plants under continuous Federal meat or poultry inspection, or continuous State meat or poultry inspection in States certified to have programs at least equal to the Federal inspection programs. In addition to FSIS inspection, all donated meat and poultry processing shall be performed under AMS acceptance service grading. The cost of this service shall be borne by the processor. In the event the processor can demonstrate that grading is impractical, exemptions in the use of acceptance services shall be approved by the distributing agency prior to processing each order. Exemptions in the use of acceptance service graders will be authorized on the basis of each order to be processed provided the processor can demonstrate:

(1) That even with ample notification time, the processor cannot secure the services of a grader,

(2) That the cost for a grader would be unduly excessive relative to the value of foods being processed and that production runs cannot be combined or scheduled to enable prorating of the costs of services among the purchasers of end products, or

(3) The documented urgency of the recipient agency's need for the end product precludes the use of acceptance services.

Prior to approving a processor's request to waive the acceptance service requirement the distributing agency shall ensure, based on the processor's past performance, that the quality of the end product produced will in no way be adversely affected as a result of waiving the requirement.

(h) *Certification by acceptance service.* (1) All processing activities of donated foods shall be subject to review and audit by the Department, including the applicable Federal acceptance service. The contracting agency may also require acceptance and certification by such acceptance service in addition to the requirements set forth in paragraph (g) of this section.

(2) In the case of substitutable donated foods, in deciding whether to require acceptance and certification, the

contracting agency should consider the dollar value of the donated foods delivered to the processor.

(3) When contracting agencies require certification in accordance with paragraph (h) (1) or (2) of this section, the degree of acceptance and certification necessary under the processing contract shall be determined by the appropriate Federal acceptance service after consultation with the distributing agency concerning the type and volume of the donated foods and anticipated value of end products to be processed. The cost of this service shall also be borne by the processor.

(i) *Labeling end products.* (1) Except when end products contain donated foods that are substituted under paragraph (f) of this section, the exterior shipping containers of end products and, where practicable, the individual wrappings or containers of end products, shall be clearly labeled "Contains Commodities Donated by the United States Department of Agriculture. This Product Shall Be Sold Only to Eligible Recipient Agencies."

(2) Labels on all end products shall meet applicable Federal labeling requirements.

(3) When a processor makes any claim with regard to an end product's contribution toward meal requirements of any child nutrition program, the processor shall follow procedures established by FNS, the Food Safety and Inspection Service of the Department, the National Marine Fisheries Service of the U.S. Department of Commerce or other applicable Federal agencies for approval of such labels.

(j) *Termination of processing contracts.* (1) When contracts are terminated or completed and the processor has commodities remaining in inventory, the processor shall be directed, at the option of the distributing agency and the FNSRO, to do the following:

(i) With respect to nonsubstitutable commodities, the processor shall:

(A) Return the commodities to the contracting agency;

(B) Pay the contracting agency for the commodities based on the Department's replacement costs, determined by using the most recent data provided by the Department; or

(C) Pay the contracting agency for the commodities based on the contract value stated in the processor's contract;

(ii) With respect to substitutable commodities, the processor shall:

(A) With the concurrence of any affected contracting agencies, transfer the donated foods to the accounts of other contracting agencies with which the processor has contracts;

(B) Return the foods donated to the contracting agency;

(C) Replace the commodities with the same foods of equal or better quality as certified in accordance with paragraph (f)(2) of this section and deliver such foods to the contracting agency;

(D) Pay the contracting agency for the commodities based on the Department's replacement costs, determined by using the most recent data provided by the Department; or

(E) Pay the contracting agency for the commodities based on the contract value stated in the processor's contract.

(2) When a processor's contract is terminated at the processor's request or due to noncompliance or negligence on the part of the processor and commodities remaining in the processor's inventory are transported pursuant to paragraph (j)(1)(i)(A), (j)(1)(ii)(B) or (j)(1)(ii)(C) of this section, the processor shall pay the transportation costs.

(3) Funds received by distributing agencies upon termination of contracts shall be used in accordance with FNS Instruction 410–1, Non-Audit Claims, Food Distribution Program.

(k) *Refund payments.* (1) When end products are sold to recipient agencies in accordance with the refund provisions of paragraph (d) or (e) of this section, each recipient agency shall submit refund applications to the processor within 60 days of the date of purchase of end products in order to receive benefits. The recipient agency shall also forward a copy of the refund application to the distributing agency at the same time.

(2) In instances when refunds are to be provided to distributors which have sold end products to recipient agencies at a discount, distributors shall submit refund applications to processors within 60 days of the date of sale to recipient agencies in order to receive benefits.

(3) Not later than 10 days after receipt of the application by the processor, the processor shall make a payment to the recipient agency or distributor equal to the stated contract value of the donated foods contained in the purchased end products covered by the application. Copies of requests for refunds and payments to recipient agencies and/or distributors shall be forwarded to the appropriate distributing agency by the processor.

(l) *Contract approvals.* Distributing agencies shall review and approve processing contracts entered into by subdistributing and recipient agencies prior to the delivery of commodities for processing under such contracts. The distributing agency which enters into or approves a processing contract shall provide a copy of the contract and of these regulations to the processors, forward a copy of the contract to the appropriate FNSRO, and retain a copy for its files.

(m) *Performance reports.* (1) Processors shall be required to submit to distributing agencies monthly reports of performance under each processing contract. Processors contracting with agencies other than a distributing agency shall submit such reports to the distributing agency having authority over that particular contracting agency. Performance reports shall be received no later than the final day of the month following the reporting period. The report shall include:

(i) A list of all recipient agencies purchasing end products under the contract;

(ii) Donated-food inventory at the beginning of the reporting period;

(iii) Amount of donated foods received during the reporting period;

(iv) Amount of donated foods transferred to and/or from existing inventory;

(v) Number of units approved end products delivered to each eligible recipient agency during the reporting period and the number of pounds of each donated food represented by these delivered end products;

(vi) Donated food inventory at the end of the reporting period;

(vii) Number of pounds of each donated food represented in sales to distributors;

(viii) List of all contracting agencies and their locations with which the processor has processing contracts;

(ix) In instances in which sales verification has been delegated to the processor pursuant to § 250.19(b)(2), sales verification findings shall be reported as an attachment to the September, December, March and June performance reports in whatever format the distributing agency deems necessary; and

(x) A certification statement that sufficient donated foods are in inventory or on order to account for the quantities needed for production of end products for State processing contracts and that the processor has on hand or on order adequate quantities of foods purchased commercially to meet the processor's production requirements for commercial sales.

(2) In addition to reporting the information identified in paragraph (m)(1) of this section, processors which substitute concentrated skim milk for donated nonfat dry milk shall also report the following information for the reporting period:

(i) The number of pounds of nonfat dry milk used in commercial products sold to outlets which are not recipient agencies; and

(ii) The number of pounds of concentrated skim milk, and the percent of milk solids contained therein, used in end products sold to recipient agencies.

(3) Distributing agencies shall review and analyze reports submitted by processors to ensure that performance under each contract is in accordance with the provisions set forth in this section.

(n) *Inventory controls.* (1) Distributing agencies shall monitor processor inventories to ensure that the quantity of donated foods for which a processor is accountable is the lowest cost-efficient level but in no event more than a six-month supply based on the processor's average monthly usage, unless a higher level has been specifically approved by the distributing agency on the basis of a written justification submitted by the processor. Under no circumstances should the amount of donated foods ordered by the contracting agency for processing purposes be in excess of anticipated usage or beyond the processor's ability to accept and store the donated foods at any one time. Distributing agencies shall make no further distribution to processors whose inventories exceed these limits until such inventories have been reduced.

(2) For processors substituting concentrated skim milk for donated nonfat dry milk, distributing agencies shall review the processors' monthly performance reports to ensure that:

(i) Donated nonfat dry milk inventory is being drawn down based on the amount of milk solids contained in the concentrated skim milk which was used in end products sold to eligible recipient agencies;

(ii) An amount of milk solids equivalent to the amount in the donated nonfat dry milk is contained in end products sold to eligible recipient agencies; and

(iii) Donated nonfat dry milk is not being sold in bulk form.

(3) Processors shall complete and submit annual reconciliation reports to distributing agencies within 90 days following the end of the contract period. As a part of this annual reconciliation, processors shall pay distributing agencies for the contract value of donated foods.

(i) For any donated foods for which a timely refund application has not been submitted in accordance with paragraph (k) of this section and

(ii) For inventories in excess of a six-month supply.

In instances when the distributing agency has assigned an inventory level other than a six-month level, the processor shall pay the contract value of any donated food in excess of that level.

(4) Distributing agencies shall certify the accuracy of the annual reconciliation report and forward it to the FNSRO. All monies shall be used in accordance with FNS Instruction 410–1, Non-Audit Claims, Food Distribution Program.

(5) Distributing agencies shall not submit food requisitions for processors reporting no sales activity during the prior year's contract period unless documentation is submitted by the processor which outlines specific plans for product promotion or sales expansion.

(o) *Processing inventory reports.* (1) Distributing agencies shall submit to the FNSRO not later than 60 days following the close of each Federal fiscal quarter a report showing separately for each processor under agreement with contracting agencies within the State:

(i) The donated food inventory at the beginning of the previous quarter;

(ii) Amount of donated foods received during the quarter;

(iii) Amount of donated foods transferred to and/or from existing inventory;

(iv) Amounts of donated foods used during the quarter;

(v) Inventory at the close of the quarter;

(vi) Each contracting agency and its location with which the processor has processing contracts.

(2) In addition to reporting the information identified in paragraph (o)(1) of this section, for each processor which substitutes concentrated skim milk for donated nonfat dry milk the distributing agency shall also report the following information for the reporting period:

(i) The number of pounds of nonfat dry milk used in commercial products sold to nonprogram outlets; and

(ii) The number of pounds of concentrated skim milk and the percent of milk solids contained therein used in end products sold to recipient agencies.

(p) *Cooperation with administering agencies for child nutrition programs.* If the distributing agency which enters into or approves contracts for end products to be used in a child nutrition program does not also administer such program, it shall collaborate with the administering agency by:

(1) Giving that agency an opportunity to review all such contracts to determine whether end products to be provided contribute to required nutritional standards for reimbursement under the applicable regulations for such program (7 CFR Parts 210, 225, and 226) or are otherwise suitable for use in such program;

(2) Consulting with the agency with regard to the labeling requirements for the end products; and

(3) Otherwise requesting technical assistance as needed from that agency.

(q) *FNSRO review of contracts and inventory reports.* The FNSRO shall:

(1) review all processing contracts and provide guidance, including written recommendations for termination, where necessary, to distributing agencies concerning any contracts which do not meet the requirements of this section;

(2) Allow distributing agencies 30 days to respond to any recommendation concerning contracts not meeting the requirements of this section;

(3) Review and analyze the processing inventory reports required by paragraph (o) of this section to ensure that no additional donated foods shall be distributed to processors with excess inventories until such inventories have been reduced;

(4) Assist distributing agencies in reducing such inventories; and

(5) Review annual reconciliation reports required by paragraph (n) of this section and ensure that payments for outstanding refund applications or excessive inventories have been made.

(r) *Availability of copies of processing contracts.* Contracts entered into in accordance with this Section are public records and FNS will provide copies of such contracts to any person upon request. The FNSRO will retain copies of processing contracts submitted by distributing agencies for a period of three years from the close of the Federal fiscal year to which they pertain.

(s) *Processing activity guidance.* Distributing agencies shall develop and provide a processing manual or similar procedural material for guidance to contracting agencies, recipient agencies, and processors. Distributing agencies must revise these materials as necessary to reflect policy and regulatory changes. This guidance material shall be provided to contracting agencies, recipient agencies and processors at the time of the approval of the initial agreement by the distributing agency, when there have been regulatory or policy changes which necessitate changes in the guidance materials, and upon request. The manual shall include, at a minimum, statements of the distributing agency's policies and procedures on (1) contract approval, (2) monitoring and review of processing activities, (3) recordkeeping and

reporting requirements, (4) inventory controls, and (5) refund applications.

(Approved by the Office of Management and Budget under control number 0584-0007)

Subpart D—Eligible Recipient Agencies and Programs

§ 250.40 Nonprofit summer camps for children.

(a) *Distribution.* (1) The distributing agency shall distribute donated food only to those summer camps which have entered into a written agreement for participation in the program with the distributing agency in accordance with § 250.12(b). Prior to entering into a written agreement, the summer camp shall provide verification of its tax exempt status under the Internal Revenue Code. In addition to the terms and conditions set forth in § 250.12(b), the written agreement shall, at a minimum, include:

(i) The name and location of the summer camp(s);

(ii) Number of camps or sites;

(iii) Number of sessions to be offered during camping season;

(iv) Number of adults and children participating in the activities of the summer camp at each session;

(v) Total number of days meals will be served;

(vi) Total number of meals to be served daily;

(vii) Assurance that tax exempt status will be maintained;

(viii) Indication of whether the summer camp(s) will employ the services of a food service management company;

(ix) Assurance that a brochure or public announcement of open admission policy will be provided and that the summer camp agrees to maintain racial/ethnic data;

(x) Assurance that a physical inventory will be conducted and reconciled at the end of the camping session; and

(xi) Assurance that any excess inventory will, at the distributing agency's option, be returned to the distributing agency for redonation or transferred in accordance with § 250.13(a)(1).

(2) Distributing agencies shall distribute donated foods only after determining that the number of adults participating in camp activities, as compared with the number of children 18 years of age and under, is not unreasonable in light of the nature of the camp and the characteristics of the children in attendance. Persons 19 years of age and over, including program directors, counselors and others who engage in recreational, educational, and direct administrative functions, are to be considered as adults participating in the activities of a summer camp. Employees whose presence on camp premises is solely for the purpose of performing duties such as cooking, gardening, property maintenance or similar support functions are not considered as adults participating in summer camp activities. In addition, persons such as nurses, therapists, and attendants who perform professional, supervisory, or custodial services are not considered as adults participating in the activities of a summer camp if they perform services essential to the participation of mentally, emotionally, or physically handicapped children.

(3) Distributing agencies shall authorize the transfer or redonation of all donated foods remaining in summer camps at the end of the camping season in accordance with § 250.13 (a) or (g) respectively.

(4) Nonprofit summer camps for children may employ food service management companies to conduct food service operations in accordance with § 250.12(c).

(b) *Quantities and value of donated foods.* Distribution of donated food to eligible summer camps shall be made on the basis of the average number of meals to be served daily to children as evidence by the most recent written caseload factor information contained in the agreement.

(c) *Types of donated foods authorized for donation.* Nonprofit summer camps for children are eligible to receive donated foods under section 416, section 32, section 709 and section 4(a).

§ 250.41 Charitable institutions.

(a) *Distribution.* (1) The distributing agency shall distribute donated food only to those charitable institutions which have entered into a written agreement for participation in the program with the distributing agency in accordance with § 250.12(b). Prior to entering into a written agreement, the charitable institution shall provide verification of the institution's tax exempt status under the Internal Revenue Code. In addition to the terms and conditions set forth in § 250.12(b), written agreements shall, at a minimum, include:

(i) The name and location of the charitable institution;

(ii) Total number of days meals will be served;

(iii) Average daily number of participants;

(iv) Total number of meals by type to be served daily to needy persons;

(v) Data that shows the number of needy persons receiving benefits under another means-tested program or financial data that show the total annual amount of funds received by the institution that are derived, respectively, from (A) subsidized income and (B) nonsubsidized income. For the purpose of this Section "subsidized income" shall mean income from public tax funds which are provided on behalf of participants that have been determined to be in need of financial assistance through a means-tested program such as Medicaid or income received through private federally tax exempt contributions which are provided for the care of participants which the institution had determined to be in need of financial assistance. "Nonsubsidized income" shall mean all other income, including payments made on behalf of participants by persons legally responsible for their support;

(vi) Indication of whether the charitable institution will employ the services of a food service management company to conduct its food service operations;

(vii) Assurance that proper inventory controls will be maintained; and

(viii) Assurance that all reports will be submitted as required by the distributing agency.

(2) Adult correctional institutions are eligible to receive donated foods as charitable institutions, to the extent that needy persons are served, if they conduct rehabilitation programs that are:

(i) Available to either a majority of the total inmate population (including inmates awaiting trial or sentencing) or to a majority of sentenced inmates; and

(ii) Of sufficient scope to permit participation for a minimum of 10 hours per week per inmate by either a majority of the total inmate population or a majority of sentenced inmates.

Prior to entering into an agreement for donation of foods to an adult correctional institution, the distributing agency shall require the institution's director or other repsonsible official to provide a written statement certifying that the institution conducts such rehabilitation programs. The statement shall be reviewed annually and maintained as part of the agreement.

(3) Charitable institutions may employ food service management companies to conduct food service operations in accordance with § 250.12(c).

(b) *Quantities of donated foods.* Distribution of donated foods to eligible charitable institutions shall be made on the basis of the average number of meals served daily to needy persons. To determine the number of needy persons being served, the distributing agency

shall determine the proportion of subsidized income by dividing the subsidized income by the total subsidized and nonsubsidized income (as defined in paragraph (a)(1) of this section) and multiplying that number by the average daily number of participants as required in § 250.41(a)(1)(v), or by simply counting the number of participants that receive benefits under another a means-tested program. The distributing agency shall use the income and average daily participation figures reflected in the agreement in determining the number of needy persons being served by the institution in accordance with the above formula. Income and participation figures shall be based on the institution's records for the previous year. The distributing agency shall obtain updated pertinent information by September 30 of each fiscal year.

(c) *Types of donated foods authorized for donation.* Charitable institutions are eligible to receive donated foods under section 416, section 32, section 4(a), and section 709.

(Approved by the Office of Management and Budget under control number 0584-0305)

§ 250.42 Nutrition programs for the elderly.

(a) *Distribution.* Distributing agencies shall distribute donated foods only to nutrition programs for the elderly which have entered into an agreement for donation of commodities in accordance with § 250.12(b). Food service management companies may be employed to conduct food service operations in accordance with § 250.12(c).

(b) *Quantities and value of donated foods.* (1) *Quantities.* Distribution of donated foods to nutrition programs for the elderly shall be based on the level of assistance per meal as required by the Older Americans Act of 1965, as amended, and on the number of eligible meals served within the State as evidenced by written caseload factor information provided by the State Agency on Aging.

(2) *Value.* (i) For the fiscal years 1986 through 1991, the quantity of donated foods to be made available to each State Agency on Aging for distribution to nutrition programs for the elderly shall be valued at not less than 56.76 cents for each meal which such State Agency on Aging, in accordance with regulations and guidelines authorized by the Commissioner on Aging, United States Department of Health and Human Services, reports as having been served or, where necessary, estimates will be served within the State or to Indian Tribal Organizations during the year: *Provided, however,* That:

(A) This quantity will be reduced to the extent that a State Agency on Aging elects to receive cash in lieu of donated foods in accordance with paragraph (c) of this section and

(B) The quantity of donated foods to be provided to any State Agency on Aging for any fiscal year shall not be adjusted on the basis of meal reports or estimates submitted after July 1 of such fiscal year.

(ii) Notwithstanding the provisions of paragraph (b)(2)(i) of this section, in any fiscal year in which compliance with paragraph (b)(2)(i) of this section costs more than the amounts authorized to be appropriated under the Older Americans Act of 1965, as amended for that fiscal year, the Secretary shall reduce the cents per meal level determined pursuant to paragraph (b)(2)(i) of this section for that fiscal year as necessary to meet the authorization of appropriations for that fiscal year. If such action is necessary, the per meal level will be reduced uniformly for each meal served during that fiscal year.

(c) *Cash in lieu of donated foods.* (1) Any State Agency on Aging may, for the purposes of the programs authorized by Titles III and VI of the Older Americans Act of 1965, as amended, elect to receive cash payments in lieu of all or any portion of the donated foods that it would otherwise receive under paragraph (b) of this section during any fiscal year.

(2) When a State Agency on Aging elects to receive cash payments in lieu of donated foods, that election shall be binding on the State Agency on Aging for the entire fiscal year to which it pertains, and FNS shall make cash payments to the State Agency on Aging equivalent in value to the donated foods that would otherwise have been provided. Cash payments shall be made for each fiscal quarter by means of Letters of Credit issued by FNS through the appropriate U.S. Treasury Regional Disbursing Office or, where applicable, by means of U.S. Treasury checks, based on the best data available to FNS as to the number of meals to be served by nutrition programs for the elderly administered by each State Agency on Aging during that fiscal quarter.

(3) In instances when it is necessary to reduce the annual level of assistance specified in paragraph (b)(2)(i) of this section, the level will be reduced in accordance with paragraph (b)(2)(ii) of this section. Once it has been established that the reduced per meal level will be sufficient to avoid any further adjustment, any remaining funds (up to the level of assistance specified in paragraph (b)(2)(i) of this section) will be disbursed so that each State will receive an equal amount on a per meal basis.

(4) To be eligible for reimbursement by FNS, claims for cash payment for meals served by nutrition programs for the elderly shall be submitted by State Agencies on Aging and Indian Tribal Organizations no later than 90 days following the close of the Federal fiscal quarter for which payment is claimed.

(5) The State Agency on Aging desiring to receive funds under this paragraph shall enter into a written agreement with FNS pursuant to § 250.12(a) to:

(i) Promptly and equitably disburse any cash it receives in lieu of donated foods to nutrition programs for the elderly after consideration of the needs of such programs and the availability of other resources, including any donated foods available under paragraph (b) of this section;

(ii) Establish such procedures as may be necessary to ensure that the cash disbursements are used by nutrition programs for the elderly solely for the purpose of purchasing U.S. agricultural commodities and other foods of U.S. origin for their food service operations;

(iii) Maintain and retain for 3 years from the close of the Federal fiscal year to which they pertain complete and accurate records of:

(A) All amounts received and disbursed under paragraph (c) of this section and

(B) The manner in which consideration was given to the needs and resources as required by paragraph (c)(5)(i) of this section; and

(iv) Permit representatives of the Department and of the General Accounting Office of the United States to inspect, audit, and copy such records at any reasonable time.

(6) Funds provided under paragraph (c) of this section shall be subject to the Department's Uniform Federal Assistance Regulations (7 CFR Part 3015).

(d) *Types of donated foods authorized for donation.* Nutrition programs for the elderly are eligible to receive donated foods under section 416, section 32, section 311, section 709, and section 14.

§ 250.43 Disaster organizations.

(a) *Eligibility.* In instances in which the President has declared a major disaster or emergency pursuant to section 301 of the Disaster Relief Act of 1974, as amended (42 U.S.C. 5141) and the Secretary has determined that as a result of the major disaster or emergency low-income households are

unable to purchase adequate amounts of nutritious food, disaster organizations may be eligible to receive donated foods for congregate meal service or household distribution to disaster victims. Disaster organizations shall remain eligible for disaster assistance for as long as the Secretary determines necessary, taking into consideration the consequences of the major disaster or emergency on the earning power of the disaster victims; *Except*, that in areas where the Food Stamp Program is in operation, donated foods may be distributed for household use only so long as the Secretary finds that the commercial channels of trade have been disrupted because of a major disaster or emergency. Prior to providing donated foods to disaster organizations, the distributing agency shall require the disaster organization to make application for the receipt and distribution of donated foods in accordance with paragraphs (b) and (c) of this section. Such applications shall be confirmed in writing and maintained in accordance with the recordkeeping requirements of this part.

(b) *Distribution of donated foods for use in providing congregate meal service.* (1) In order to obtain donated foods for use in providing congregate meal service, disaster organizations shall request approval from the appropriate distributing agency, giving the following information to the extent possible:

(i) Description of major disaster or emergency situation;

(ii) Number of people requiring meals and congregate meal service period;

(iii) Quantity and types of food needed for congregate meal service; and

(iv) Number and location of sites providing congregate meal service.

(2) Following its approval of the request for donated foods, the distributing agency is authorized and shall make appropriate donated foods available from any sources within the State to the disaster organization and within 24 hours shall report to the appropriate FNSRO the information listed in paragraph (b)(1) of this section.

(c) *Household distribution.* In order to obtain donated foods for household distribution in areas served by the Food Stamp Program when commercial food distribution channels are disrupted, the distributing agency shall request prior approval by the appropriate FNSRO. In the request, the distributing agency shall cite the following information:

(i) Description of major disaster or emergency situation;

(ii) Number of households affected;

(iii) Anticipated distribution period;

(iv) Method of distribution available; and

(v) Quantity and types of food needed for distribution.

(d) *Quantities and value of donated foods.* The distributing agency shall make donated foods available to eligible disaster organizations based on the caseload factor information provided by the disaster organization.

(e) *Types of donated foods authorized for donation.* Disaster organizations providing major disaster or other emergency food assistance under this Part are eligible to receive donated foods under section 416, section 32, section 709, section 4(a) and sections 409 and 410 of the Disaster Relief Act of 1974 (42 U.S.C. 5181–82), as amended.

(f) *Summary report.* Within 30 days following termination of the disaster assistance, the distributing agency shall provide a summary report to the appropriate FNSRO using Form FNS–292, Report of Coupon Issuance and Commodity Distribution for Disaster Relief.

(g) *Replacement.* To the extent donated foods are available, FNS will replace donated foods used from the States' stocks for major disaster and emergency assistance. The distributing agency shall request the replacement of foods used for major disaster and other emergency food assistance, in writing to FNSRO, no later than 30 days following termination of the disaster assistance.

§ 250.44 Special group food assistance programs.

In situations of distress in which needs for food assistance cannot be met under other provisions of this part, a distributing agency may, upon request to and approval by the Secretary, distribute donated foods to any institution, or to any association of persons engaged in charitable activities, for use in conducting special group-feeding programs on a temporary basis for persons in need of such food assistance. Such distributions shall not exceed 30 days. The distributing agency, and any such institution or association, shall conduct any distribution under this Section in accordance with such instructions as the Secretary may specify, and any such institution or association shall give to the distributing agency an assurance that feeding programs will be conducted in accordance with the instructions.

§ 250.45 Commodity Supplemental Food Program.

(a) *Distribution.* The distributing agency shall distribute donated foods to the State agency which is designated by the State to administer the Commodity Supplemental Food Program for that State and which has entered into a written agreement with the Department for the administration of that program in accordance with 7 CFR Part 247, the regulations for that program. The State agency administering the Commodity Supplemental Food Program shall distribute donated foods to local agencies for use by eligible recipients in accordance with the provisions of 7 CFR Part 247 and with the provisions of this Part, and may enter into an agreement with the distributing agency for use of the distributing agency's facilities for distribution.

(b) *Quantities of donated foods.* Distribution of donated foods to the designated State agencies for the Commodity Supplemental Food Program shall be made on the basis of each State agency's quarterly estimate of need.

(c) *Types of donated foods authorized for donation.* State agencies distributing donated foods through the Commodity Supplemental Food Program are eligible to receive such foods under section 32, section 416, section 709 and section 4(a).

§ 250.46 Food Distribution Program in the Trust Territory of the Pacific Islands.

(a) *Distribution.* The distributing agency shall make donated foods available for distribution to households in the Trust Territory of the Pacific Islands by those welfare agencies which certify households in accordance with a plan of operation approved by FNS, as required by paragraph (d) of this section. Distribution of donated foods to households shall be made in accordance with the approved plan of operation.

(b) *Quantities and value of donated foods.* Distribution of donated foods shall be based on the actual number of households in need of food assistance.

(c) *Types of donated foods authorized for donation.* Agencies which make distribution to needy persons are eligible to receive foods under section 416, section 32, section 709 and section 4(a).

(d) *Plan of operation.* Prior to making distribution to agencies or households, the distributing agency shall submit a plan of operation for approval by the appropriate FNSRO. Such plans shall incorporate the procedures and methods to be used in certifying households in need of food assistance, in making distribution to households, and in providing a fair hearing to households whose claims for food assistance under the plan are denied or are not acted upon with reasonable promptness, or who are aggrieved by an agency's interpretation of any provision of the plan. No amendment to the plan of

operation of the distributing agency shall be made without prior approval of FNS, and FNS may require amendment of any plan as a condition of continuing approval. The distributing agency shall require welfare agencies making distribution to households to conduct distribution programs in accordance with all provisions of the plan of operation. At a minimum, the plan shall include the following:

(1) The name of the public welfare agency or agencies which will be responsible for certification of households;

(2) The manner in which donated food will be distributed, including, but not limited to, the identity of the agency that will distribute donated foods, the storage and distribution facilities to be used and the method of financing;

(3) *The specific criteria to be used in certifying households as in need of food assistance.* The income and resource standards establishes by the distributing agency for use by welfare agencies in determining the eligibility of applicant households, after October 1979, shall continue to be those standards used as of that date which were incorporated in a plan of operation approved by FNS, unless an amendment to such standard is required or approved by FNS;

(4) The method or methods that will be used to verify the information upon which the certification of eligibility is based, including the kinds of documentary evidence that applicants are required to furnish to obtain certification;

(5) Provisions for periodically reviewing the certifications of households to discover any change in their status which would necessitate a change in the determination of eligibility. The eligibility of households shall be reviewed at least every three months, except that such reviews may be made at longer periods, not to exceed 12 months, provided that such longer periods are based upon a determination by the certifying agency that the income and resources available to such households will probably remain essentially unchanged during such period;

(6) Provisions for identifying each person who has been designated to receive donated foods for a household;

(7) Assurance that the distribution of donated foods shall not be used as a means to further the political interest of any individual or party, and that there shall be no discrimination against recipients of donated foods because of race, color, national origin, sex, age or handicap;

(8) Assurance that:

(i) Citizenship or durational residence requirements shall not be imposed as a condition of eligibility and

(ii) Recipients shall not be required to make any payments in money, materials or services, for or in connection with the receipt of donated foods, and that they shall not be solicited in connection with the receipt of donated foods for voluntary cash contributions for any purpose;

(9) The manner in which the distributing agency plans to supervise the program; and

(10) Definitions of any terms used which cannot be determined by reference to Webster's New International Dictionary (third edition).

(e) *Operating expense funds*—(1) *Application for funds.* To receive administrative funds, the distributing agency shall submit Form AD–623, "Application for Federal Assistance," to the appropriate FNSRO at least three months prior to the beginning of the Federal fiscal year. Approval of the application by FNS shall be a prerequisite to payment of any funds to the distributing agency. The Department will make payments to the distributing agency to assist it in meeting operating expenses incurred in administering food distribution for needy persons.

(2) *Availability of funds.* FNS will review and evaluate the budget information submitted by the distributing agency in relationship to the distributing agency's plan of operation and any other factors which may be relevant to FNS' determination as to whether the estimated expenditures are reasonable and justified. FNS will give written notification to the distributing agency of:

(i) Its approval or disapproval of any or all of the estimated expenditures; and

(ii) The amount of funds which will be made available.

(3) *Payment of funds.* Payments shall be made to the distributing agency through a Letter of Credit or an advance by Treasury Check. These payments will be issued in accordance with Treasury Department procedures, Treasury Circular No. 1075 and through the appropriate Treasury Regional Disbursing Office (RDO).

(4) *Use of funds.* The distributing agency shall make every reasonable effort to ensure the availability of a food distribution program for needy persons in households and shall assign priority in the use of any funds received under this Section to accomplish that objective. Any remaining funds shall be used to expand and improve distribution to needy households. Such funds may be used for any costs which are not disallowed under Office of Management and Budget Circular A–87 (a copy of which may be obtained from FNS) and which are incurred in distributing donated foods to households, including determining eligibility of recipients, except for the purchase cost of land and buildings. In no event shall such funds be used to pay any portion of any expenses if reimbursement or payment therefore is claimed or made available from any other Federal source.

(5) *Accounting for funds.* The distributing agency which receives administrative funds under this Section shall establish and maintain an effective system of fiscal control and accounting procedures. The accounting procedures maintained by the distributing agency shall be such as to accurately reflect the receipt, expenditure and current balance of funds provided by FNS. The accounting procedures shall also provide for segregation of costs specifically identifiable to the Food Distribution Program from any other costs incurred by the distributing agency. Any budget revisions by the distributing agency which require the transfer of funds from an FNS approved cost category to another shall be in accordance with the budget revision procedures set forth in 7 CFR Part 3015 and shall be approved by FNS prior to any transfer of funds.

(6) *Return, reduction and reallocation of funds.* (i) FNS may require the distributing agency to return prior to the end of the Federal fiscal year any or all unobligated funds received under this section, and may reduce the amount it has apportioned or agreed to pay to the distributing agency if FNS determines that:

(A) The distributing agency is not administering the Food Distribution Program in accordance with its plan of operation approved by FNS and the provisions of this Part;

(B) The amount of funds which the distributing agency requested from FNS is in excess of actual need, based on reports of expenditures and current projections of program needs; or

(C) Circumstances or conditions justify the return, reallocation or transfer of funds to accomplish the purposes of this Part.

(ii) The distributing agency shall return to FNS within 90 days following the close of each Federal fiscal year any funds received under paragraph (e) of this section which are obligated at that time.

(7) *Financial reports.* The distributing agency shall submit quarterly and annual reports to FNS on Form SF–269 concerning the obligations, expenditure and status of funds received under this

Section. In addition, the distributing agency receiving funds under paragraph (e) of this section shall submit any other reports in such form as may be required from time to time by the Department.

(f) *Records, reports and audits.* The distributing agency shall:

(1) Maintain and retain for three years from the close of the Federal fiscal year to which they pertain, complete and accurate records of all amounts received and disbursed under paragraph (e) of this section,

(2) Keep such accounts and records as may be necessary to enable FNS to determine whether there has been compliance with this Section, and

(3) Permit representatives of the Department and of a General Accounting Office of the United States to inspect, audit and copy such records and accounts at any reasonable time.

§ 250.47 Food Distribution Program on Indian Reservations.

Distribution. (a) Distributing agencies which operate a food distribution program on Indian reservation shall comply with the provisions set forth in §§ 250.1, 250.2, 250.3, 250.10, 250.11, 250.12, 250.13 (with the exception of paragraph (d)(2)), §§ 250.14 and 250.15 to the extent that these provisions are not inconsistent with the regulations cited in paragraph (b) of this section. (b) In addition to complying with the provisions identified in paragraph (a) of this section, distributing agencies shall also comply with the provisions set forth in Part 253, Food Distribution Program on Indian Reservations or Part 254, Food Distribution Program in Oklahoma, as applicable.

§ 250.48 School food authorities and commodity schools.

(a) *Distribution.* School food authorities which participate in the National School Lunch Program or as commodity schools under Part 210 of this chapter or the School Breakfast Program under Part 220 of this chapter are eligible to receive donated foods. The distributing agency shall distribute donated foods only to those school food authorities whose eligibility for participation in the program has been confirmed in writing by the State agency or FNSRO administering the applicable program. Lists of participating school food authorities which have been provided to the distributing agency by the administering State agency or FNSRO may serve as written confirmation of eligibility. School food authorities may employ food service management companies to conduct food service operations in accordance with § 250.12(c) and Parts 210 and 220 of this chapter.

(b) *Quantities and value of donated foods.*—(1) *Quantities.* Distribution of donated foods to school food authorities which participate in the National School Lunch Program or as commodity school under Part 210 shall be made on the basis of the average daily number of meals by type to be served which meet the meal-type requirements prescribed in the regulations for the National School Lunch Program under Part 210 of this chapter, as evidenced by the most recent estimate of the average daily numbers of meals which must be provided by the administering State agency or FNSRO to the distributing agencies as early as practicable each school year but not later than September 1, as revised to reflect additions or deletions of eligible schools and any necessary adjustment in the number of meals served.

(2) *Value.* (i) For each school year, the national average value of donated foods to be made available to States for distribution to school food authorities participating in the National School Lunch Program (7 CFR Part 210), or where applicable, cash payments in lieu thereof, shall not be less than 11 cents for each lunch and shall be adjusted on July 1, 1982, and on each July 1 thereafter, to reflect changes in the Price Index for food used in schools and institutions as prescribed by Section 6(e) of the National School Lunch Act, as amended. These adjustments shall be computed to the nearest one-fourth cent and shall be made effective as of the beginning of each school year. Not less than 75 percent of the food distribution assistance shall be in the form of donated foods.

(ii) For each school year, the national average value of donated foods to be provided to States for distribution to commodity schools shall not be less than the amount specified in paragraph (b)(2)(i) of this section, plus an amount equal to the national average payment established under section 4 of the National School Lunch Act, as amended, for each lunch served by such schools: *Provided, however:* That this amount shall be reduced to the extent that FNS provides up to 5 cents per lunch of this value in cash in lieu of donated foods for donated food processing and handling expenses on behalf of such school food authorities in accordance with Part 240 of this chapter.

(c) *Cash in lieu of donated foods for schools.* Where a State has phased out its food distribution facilities prior to July 1, 1974, such State may, in accordance with Part 240 of this chapter, elect to receive cash payments in lieu of donated foods for use in school lunch programs which participate in the National School Lunch Program under Part 210 of this chapter.

(d) *Types of donated foods authorized for donation.* School food authorities which participate in the National School Lunch Program or as commodity schools under Part 210 of this chapter are eligible to receive donated foods under section 416, section 32, section 709, section 6 and section 14. School food authorities which participate in the School Breakfast Program under Part 220 are eligible to receive donated foods under section 416, section 32, section 709 and section 14.

(e) *Refusal of donated foods by school food authorities.* (1) Any school food authority participating in food service programs under the National School Lunch Act, as amended, may refuse, at the time they are offered, donated foods and other foods offered for delivery for lunches in any school year if such foods cannot be used effectively. The school food authority may receive, in lieu of the refused donated foods, other donated foods to the extent that they are available during the school year: *Provided, however:* That not more than 20 percent of the value of the donated foods offered to a school food authority for lunches during the school year shall be subject to replacement with other available donated foods unless replacement based on the refusal of more than 20 percent of such value is feasible and practical. Prior to making distribution to school food authorities, distributing agencies shall notify each school food authority of its right to refuse delivery and to receive other donated foods, if available, in lieu of those refused. Notification of donated food refusal rights shall be provided by means of a letter or by an addendum to the agreement required by § 250.12(b) to each school food authority prior to the beginning of each school year.

(2) If the distributing agency demonstrates on the basis of existing records that it is maintaining an effective offer-and-acceptance system as defined in § 250.3, there can be no refusal of donated foods as provided in paragraph (e)(1) of this section.

(f) *Use of donated foods in home economics courses.* School food authorities receiving donated foods under this Part may use such foods for the purpose of training students in home economics, including college students if the same facilities and instructors are used for training both high school and college students in home economics courses. Home economics includes classes in general home economics, food

purchases, nutrition, food preparation, cooking, child care and health.

§ 250.49 Nonresidential child care institutions.

(a) *Distribution.* The distributing agency shall distribute donated foods only to those nonresidential child care institutions whose eligibility for participation in Child Care Food Program has been confirmed in writing by the State agency of FNSRO administering the program, where applicable. Lists of participating nonresidential child care institutions which have been prepared by the administering State agency or FNSRO may serve as written confirmation of eligibility. Nonresidential child care institutions may employ food service management companies to conduct food service operations in accordance with § 250.12(c) and Part 226 of this chapter.

(b) *Quantities and value of donated foods.* (1) *Quantities.* Distribution of donated foods to nonresidential child care institutions shall be made on the basis of the average daily number of lunches and suppers to be served which meet the meal-type requirements prescribed in the regulations for the Child Care Food Program under Part 226 of this chapter, as evidenced by the most recent written caseload factor information which must be provided by the administering State agency or FNSRO to the distributing agency not later than June 1 each year.

(2) *Value.* For each school year, the national average value of donated foods to be made available to States for distribution to nonresidential child care institutions, or cash payments in lieu thereof, shall not be less than 11 cents for each lunch and supper and shall be adjusted on July 1, 1982, and on each July 1 thereafter, to reflect changes in the Price Index for food used in schools and institutions as prescribed by section 6(e) of the National School Lunch Act, as amended. These adjustments shall be computed to the nearest one-fourth cent and shall be made effective at the beginning of each school year.

(c) *Cash in lieu of donated foods.* In accordance with Part 240 of this chapter, State agencies may elect to receive cash payments in lieu of donated foods for use by institutions which participate in the Child Care Food Program under Part 226 of this chapter.

(d) *Types of donated foods authorized for donations.* Nonresidential child care institutions which participate in the Child Care Food Program under Part 226 of this chapter are eligible to receive donated foods under section 416, section 32, section 709, section 6 and section 14.

§ 250.50 Service institutions.

(a) *Distribution.* The distributing agency shall distribute donated foods only to those service institutions whose eligibility to receive donated foods for use in the Summer Food Service Program for Children under Part 225 of this chapter has been confirmed in writing by the State agency or FNSRO administering the program, where applicable. Lists of participating service institutions which have been prepared by the administering State agency or FNSRO may serve as written confirmation of eligibility.

(b) *Quantities and value of donated foods.* Distribution of donated foods to service institutions shall be made on the basis of the average daily number of meals by type to be served which meet the meal-type requirements prescribed in the regulations for the Summer Food Service Program for Children under Part 225 of this chapter as evidenced by the most recent written caseload factor information which must be provided by the State agency or FNSRO administering the program to the distributing agency by June 1 of each year.

(c) *Types of donated foods authorized for donation.* Service institutions which participate in the Summer Food Service Program for Children under Part 225 of this chapter are eligible to receive donated foods under section 416, section 32, section 709, and section 14.

§ 250.51 Special Supplemental Food Program for Women, Infants and Children.

(a) *Distribution.* At the request of the State agency responsible for administering the Special Supplemental Food Program for Women, Infants and Children (WIC Program) under part 246 of this chapter and with approval of the Department, donated foods may be made available for distribution to program participants. In instances when donated foods are made available, State agencies shall pay the Department using funds allocated to the State for the WIC Program for those donated foods which are provided to participants as part of the food package. Donated foods which are provided to participants in addition to the quantities authorized for the food package will be made available to the State agency free of charge.

(b) *Quantities and value of donated foods.* Distribution of donated foods to State agencies for the WIC Program shall be made on the basis of each State agency's quarterly estimate of need.

(c) *Types of donated foods authorized for donation.* State agencies participating in the WIC Program under Part 246 of this chapter are eligible to receive donated foods under section 416 and section 32.

Subpart E—Where to Obtain Information

§ 250.60 Program information.

Interested persons desiring information concerning the program may make written request to the following Regional Offices:

(a) Northeast Region, Food and Nutrition Service, USDA, 10 Causeway Street, Boston, Massachusetts 02222–1065 for the following States: Connecticut, Maine, Massachusetts, New Hampshire, New York, Rhode Island and Vermont.

(b) Mid-Atlantic Region, Food and Nutrition Service, USDA, Mercer Corporate Park, Corporate Blvd., CN 02150, Trenton, New Jersey 08650, for the following States: Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, Puerto Rico, Virginia, Virgin Islands and West Virginia.

(c) Southeast Region, Food and Nutrition Service, USDA, 1100 Spring Street, NW, Atlanta, Georgia 30367, for the following States: Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina and Tennessee.

(d) Midwest Region, Food and Nutrition Service, USDA, 50 East Washington Street, Chicago, Illinois 60602, for the following States: Illinois, Indiana, Michigan, Minnesota, Ohio and Wisconsin.

(e) Mountain Plains Region, Food and Nutrition Service, USDA, 2420 West 26th Avenue, Room 430–D, Denver, Colorado 80211, for the following States: Colorado, Iowa, Kansas, Missouri, Montana, Nebraska, North Dakota, South Dakota, Utah and Wyoming.

(f) Southwest Region, Food and Nutrition Service, USDA, 1100 Commerce Street, Room 5–C–30, Dallas, Texas 75242, for the following States: Arkansas, Louisiana, New Mexico, Oklahoma and Texas.

(g) Western Region, Food and Nutrition Service, USDA, 550 Kearney Street, Room 400, San Francisco, California 94108 for the following States: Alaska, American Samoa, Arizona, California, Guam, Hawaii, Idaho, Nevada, Oregon, Trust Territory and Washington.

Dated: May 25, 1988.

Anna Kondratas,

Administrator.

[FR Doc. 88-12220 Filed 6-2-88; 8:45 am]

BILLING CODE 3410-30-M

federal register

Friday
June 3, 1988

Part III

Department of Health and Human Services

Health Care Financing Administration

42 CFR Parts 431, 435, 440, 442, and 483
Medicaid Program; Conditions for Intermediate Care Facilities for the Mentally Retarded; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 431, 435, 440, 442, and 483

[BERC-266-F]

Medicaid Program; Conditions for Intermediate Care Facilities for the Mentally Retarded

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

ACTION: Final rule.

SUMMARY: This rule revises the format, location and content of the standards for intermediate care facilities for the mentally retarded and persons with related conditions (ICFs/MR). (The standards are those requirements that ICFs/MR must meet in order to participate in the Medicaid program). The new format will be that of "conditions of participation" and will make the regulations for ICFs/MR consistent with the organization of the Medicare and Medicaid regulations for skilled nursing facilities. The new location will be under a new Part 483, "Conditions of participation for long term care facilities". Revisions to the content of the regulations are designed to increase the focus on the provision of active treatment services for clients, clarify Federal requirements, and maintain essential client protections. The major outcome of these regulations will be to align Federal standards with contemporary care practices for residential care services for persons with mental retardation or other developmental disabilities. We also are making several technical changes and cross-references to achieve consistency with other existing regulations.

EFFECTIVE DATE: The regulations are effective on October 3, 1988.

FOR FURTHER INFORMATION CONTACT: Samuel Kidder, (301) 966-4620.

SUPPLEMENTARY INFORMATION:

I. Background

General

Section 1905(a)(15) of the Social Security Act (the Act) authorizes optional Medicaid coverage for services in intermediate care facilities (ICFs). These are facilities that provide health-related care to individuals who do not need the degree of care commonly provided in hospitals or skilled nursing facilities, but who do require care and services above the level of room and board that can only be made available to them through institutional facilities. Section 1905(d) of the Act indicates that the term "intermediate care facility services" may include services in a public institution for the mentally retarded or persons with related conditions (ICF/MR). (Private facilities may also participate as ICFs/MR.)

Fifty States and jurisdictions currently cover ICF care; 49 of these include ICF/MR care and serve over 154,000 individuals in over 3,600 ICFs/MR, ranging in size from 4 beds to almost 1,500 beds.

ICF/MR Standards—Current Regulations

Current standards for ICFs/MR are found at 42 CFR Part 442, Subpart G. These standards were published in 1974 and are based primarily on the 1971 voluntary standards of the Accreditation Council for Facilities for the Mentally Retarded (AC/FMR), now renamed the Accreditation Council on Services for People with Developmental Disabilities (ACDD). The standards are the requirements that ICFs/MR must meet in order to participate in the Medicaid program. They were developed on the assumption that they would be used for the most part in large, public institutions which served as the principal source of out of the home placement of persons with mental retardation at the time the standards were published. Since the early 1970s, litigation, legislation, research and technological advances have influenced the way in which clients are identified, assessed, and provided services. The size of institutions has steadily decreased and the provision of a broad spectrum of services to clients in community settings has expanded greatly in the last 10 years.

Despite these changes, the standards have not been significantly revised since they were originally published in 1974. On March 4, 1986, we published in the **Federal Register** (51 FR 7520) a proposed revision of the standards. The changes we proposed were designed to increase the focus on the provision of active treatment services to clients, clarify Federal requirements, maintain essential client protections, and to provide State survey agencies with a more accurate mechanism for assessing quality of care.

II. Provisions of the Proposed Regulations

We based our proposal, particularly the Active Treatment Services section of our proposed standards, primarily on the accreditation standards published in 1983 by the ACDD. We based our revisions on the following general principles:

- The standards should enable both the facility and monitoring agencies (State survey agencies and Federal reviewers) to form judgments about whether individuals needs are being properly assessed and appropriate interventions planned and delivered.
- The standards should be applicable to all of the various sizes of facilities that provide services to persons with mental retardation and should provide these facilities with greater flexibility in the administration of their programs.
- The standards should focus more on client and staff performance rather than on compliance with processes and paper requirements.
- The standards should provide for individual client protections, given the vulnerability and frequent isolation of many clients in ICFs/MR.

The major organizational and structural proposed revisions to the standards were as follows:

- We proposed to reorganize the standards into four major sections in order to eliminate duplicative language and provide the facilities and surveyors with a logical, accountable method of determining compliance. The four sections that we proposed were: administrative services; active treatment services; physical environment; and, safety and sanitation.
- We proposed revisions to much of the detailed language of the current standards to give facilities greater ability to administer their programs, while recognizing their widely varying sizes, locations and organizational structure. We proposed retaining appropriate detail in the areas of needed client protections.
- We proposed rewording much of the language contained in the current regulations to reflect contemporary terminology in the field of developmental disabilities. For example, we proposed to substitute the term "client" for "resident" throughout the standards.
- We proposed to retain necessary emphasis on health services, but included revisions that would reflect the wide diversity in health care delivery systems utilized by ICFs/MR.
- The proposed standards emphasized the development of the individual client in defining the active treatment process. We used the ACDD standards for active treatment as a guide and proposed to link professional qualifications and duties to the active treatment process.
- We proposed to clarify numerous existing standards that have created problems for providers and reviewers (for example, qualifications for the

qualified mental retardation professional, thermostatically controlled water faucets, self-administration of medications, and the application of State nursing home health and sanitation standards).

III. Discussion of Comments

We received 236 timely items of correspondence in response to the proposed notice. Comments were received from individuals, associations, State health departments and Medicaid providers of services (primarily, ICFs/MR). With few exceptions, HCFA's efforts to develop a performance based regulation were commended by commenters as a "step in the right direction". Yet, many of these same commenters offered suggestions that would have the effect of increasing the amount of prescriptive, process oriented requirements we sought to eliminate in the proposal. One commenter, representing a large number of small providers, noted that "we are particularly appreciative of efforts to offer more flexibility to service providers in the proposed rules, and it is with a sense of irony that we find we will be recommending a diminution of that flexibility * * *".

Our experiernce with the ICF/MR regulations, first published in 1974, has provided sufficient evidence of the failure of essentially prescriptive, process oriented regulations to work effectively in behalf of the developmental, health, social, and behavioral needs of clients. We remain committed to the principles on which we based the proposal and have rejected many of the suggestions that we think only "reload" prescriptive requirements that we sought to eliminate. Thus, our response to many comments in the following sections will say simply that we rejected them as being "too prescriptive". While we appreciate the thoughtfulness and sincerity of the commenters, we disagree with the rationale behind many of these suggestions. A summary of the comments and our responses to them, follows.

A. Condition of Participation Format

Comment: We requested comments on the issue of organizing these regulations into the condition of participation format. Approximately 50 commenters expressed views on the issue. Under such an approach, State agencies would survey for compliance with the conditions of participation. We note that a condition is often made up of several "standards". In order for the condition to be met, all or a majority of the standards must be met. Thus, a facility is found to meet *all* the conditions of participation, it would be eligible for Medicaid certification. If a facility meets all the conditions of participation, but has deficiencies in one or more of the standards comprising a condition of participation, it has up to 12 months to achieve compliance in conformity with a corrective plan of action (provided that the deficiencies do not immediately jeopardize the health and safety of the facility's clients, in which case the facility's certification must be terminated as set forth under § 442.117).

About two thirds of the commenters on this issue were in favor of the condition of participation format. Almost all of these commenters favored the condition format because they believed that it would lead to more enforceable requirements. However, many deplored the idea that a facility could operate for 12 months with standard level deficiencies simply by having a plan of correction in existence.

The other third of the commenters on this issue opposed the condition of participation format because they believe that the structure of the condition format is such that the change for deficiencies to result in adverse action is increased. Thus, the commenters believe the condition format would sharply increase the facility's vulnerability to adverse action. They asserted that since there is no empirical basis for establishing minimum thresholds of compliance within any of the suggested conditions, the decision of the surveyor would be no less subjective under the condition of participation than under the standards format, but the potential penalty would be greater.

Response: We have adopted the condition of participation format in these final regulations. While we appreciate the view that an empirical basis for deciding when a standard or a condition is out of compliance is conceptually possible, we believe that approach could lead to an even less desirable circumstance. If minimum requirements for taking adverse action were established, very little professional judgment would be necessary and compliance decisions could be made without regard to the human factors or circumstances of the clients. For example, a requirement that 25 percent of the clients meet 40 percent of the objectives established in their individual plans of care, does not take into consideration the fact that the failed objectives may not have been the most important for those clients. Judgment of the quality of human services will always be to some extent subjective. While we will continue to strive to develop clear and precise regulations and survey techniques, we always will need to rely heavily upon surveyors who can make judgments about the human factors or circumstances relative to a consensus standard established as administrative law.

The condition of participation format, which originated in the Medicare program, is a format structured to assure that facilities that do not meet at least minimum requirements do not participate in the program. The condition of participation format enables us to define the critical major requirements for participation. If the facility is performing so poorly as to warrant a determination that one or more conditions of participation are not met, then we believe the facility does not meet the requirements for participation in the ICF/MR program, namely that the facility is providing needed services in a safe and healthful environment.

In developing the conditions of participation format, we decided that the conditions for ICFs/MR would be located most appropriately in 42 CFR Subchapter E, "Standards and Certification". Subchapter E currently includes the conditions of participation for hospitals and specialized providers. In this final rule, we have established under Subchapter E a new Part 483, "Conditions of Participation for Long Term Care Facilities". The outline of the condition of participation format that we have adopted in this final rule follows. In the outline, we have indicated which sections of the proposed rule were used in establishing the conditions.

§ 483.400 Basis and purpose.
§ 483.410 Condition of Participation: Governing body and management
(a) Standard: Governing body (proposed § 442.412)
(b) Standard: Compliance with Federal, State and local laws (proposed § 442.416)
(c) Standard: Client records (proposed § 442.432)
(d) Standard: Provision of needed services (proposed § 442.418)
§ 483.420 Condition of Participation: Client protections
(a) Standard: Protection of clients' rights (proposed § 442.401)
(b) Standard: Client finances (proposed § 442.410)
(c) Standard: Communication with clients, parents and guardians (proposed 442.414)
(d) Standard: Staff treatment of clients (proposed § 442.424)
§ 483.430 Condition of Participation: Facility staffing
(a) Standard: Qualified mental retardation professional (proposed § 442.450(a))
(b) Standard: Professional program services (proposed § 442.460)

(c) Standard: Facility staffing (proposed § 442.426)
(d) Standard: Direct care staff (proposed § 442.428)
(e) Standard: Staff training program (proposed § 442.430)
§ 483.440 Condition of Participation: Active treatment services
(a) Standard: Active treatment (proposed § 442.440)
(b) Standard: Admissions, transfers and discharge (proposed § 442.442)
(c) Standard: Individual program plan (proposed § 442.444)
(d) Standard: Program implementation (proposed § 442.446)
(e) Standard: Program documentation (proposed § 442.448)
(f) Standard: Program monitoring and change (proposed § 442.450(b), (c), (d) and (e))
§ 483.450 Condition of Participation: Client behavior and facility practices
(a) Standard: Facility practices—conduct toward clients (proposed § 442.452 Behavior management policies and procedures)
(b) Standard: Management of inappropriate client behavior (proposed § 442.454 Behavior modification programs)
(c) Standard: Time-out rooms (parts of proposed § 442.452, Behavior management, and proposed § 442.454, Behavior modification)
(d) Standard: Physical restraints (proposed § 442.456)
(e) Standard: Drug usage (proposed § 442.458)
§ 483.460 Condition of Participation: Health Care Services
(a) Standard: Physician services (proposed § 442.462)
(b) Standard: Physician participation in the individual program plan (proposed §§ 442.464 and 442.466)
(c) Standard: Nursing services (proposed § 442.468)
(d) Standard: Nursing staff (proposed § 442.470)
(e) Standard: Dental services (proposed § 442.472)
(f) Standard: Comprehensive dental diagnostic services (proposed § 442.474)
(g) Standard: Comprehensive dental treatment (proposed § 442.476)
(h) Standard: Documentation of dental services (proposed § 442.478)
(i) Standard: Pharmacy services (proposed § 442.480)
(j) Standard: Drug regimen review (proposed § 442.482)
(k) Standard: Drug administration (proposed § 442.484)
(l) Standard: Storage and recordkeeping (proposed § 442.486)
(m) Standard: Labeling (proposed § 442.488)
(n) Standard: Laboratory services (proposed § 442.489)
§ 483.470 Condition of Participation: Physical environment
(a) Standard: Client living environment (proposed § 442.500)
(b) Standard: Client bedrooms (proposed § 442.502)
(c) Standard: Storage space in bedrooms (proposed § 442.504)
(d) Standard: Client bathrooms (proposed § 442.506)
(e) Standard: Heating and ventilation (proposed § 442.508)
(f) Standard: Floors (proposed § 442.510)
(g) Standard: Space and equipment (proposed § 442.512)
(h) Standard: Emergency plans and procedure (proposed § 442.550)
(i) Standard: Evacuation drills (proposed § 442.552)
(j) Standard: Fire protection (proposed § 442.554)
(k) Standard: Paint (proposed § 442.556)
(l) Standard: Infection control (proposed § 442.436)
§ 483.480 Condition of Participation: Dietetic services
(a) Standard: Food and nutrition services (proposed § 442.558)
(b) Standard: Meal services (proposed § 442.560)
(c) Standard: Menus (proposed § 442.562)
(d) Standard: Dining areas and services (proposed § 442.564)

B. Basis and Purpose (Proposed § 442.400; Final § 483.400)

Comment: One commenter objected to the word "facility" in the statement that describes the Secretary's authority to prescribe standards for "intermediate care facility services". The commenter thought the word facility focused too much on physical plant issues rather than on client services.

Response: In this context, the word facility is used as it appears in the statute (section 1905(d) of the Act) that establishes the ICF/MR benefit under the Medicaid program. The context in which it appears makes it clear that it is "facility services" that are covered, and it is clearly services that are emphasized in these regulations.

Comment: Several commenters wanted to maintain the provisions of the current regulations at § 442.402 that require a facility to establish philosophy, objectives and goals, and § 442.407 that requires a facility to have policy and procedure manuals.

Response: In the proposal and in these final regulations, we have emphasized the outcomes of care for the client. The facility's philosophy, policies, and procedures are essential to its successful operation. However, we intend to measure facility performance, and this is what we expect to see reflected in client outcomes.

C. Protection of Clients Rights (Proposed § 442.401; Final § 483.420(a))

Comment: Several commenters recommended that paragraphs (i), (j) and (k) of the proposed § 442.401 concerning the protection of client rights be modified by replacing the word "permit" with the phrase "ensure that". The commenters believed that this would emphasize that the rights discussed in these paragraphs are basic and that the facility does not have the right to deny them as the word "permit" suggests.

Response: We accept this recommendation and have revised the regulations accordingly.

Comment: Commenters expressed a variety of opinions regarding the absence in the proposed regulations of the existing requirement at § 442.405 that states that a qualified mental retardation professional may determine if a client is incapable of understanding his or her rights. Many commenters also suggested that the proposed § 442.401(a) that lists the individuals a facility must inform of clients' rights, be amended to include a legal advocate as one who must be informed. Similarly, others stated that it should be mandated that when a client is adjudicated incompetent, a legal guardian be appointed. Still others wanted to expand the proposed section by adding a new subsection detailing clients' rights in obtaining a legal advocate.

Response: The reason that the proposal and this final rule delete the authorization for a qualified mental retardation professional to determine a client's competency is that this determination involves a judicial process that goes beyond a clinical process. With respect to the issue of informing a legal advocate of a client's rights, there is nothing in the proposal or the final rule to preclude notification. Regarding the mandating of a legal guardian in the case of incompetency, this is a matter traditionally regulated under State laws. Finally, neither the proposal nor the final rule preclude a facility from obtaining a legal advocate for a client, but we have no authority to mandate his or her appointment.

Comment: Several commenters asked whether the proposed § 442.4019b), which would require a facility to inform each client, parent or guardian of the attendant risks of treatment, referred to medical treatment exclusively or other modalities as well.

Response: The term "attendant risks of treatment" refers to all treatment.

Comment: Two commenters asked if there was conflict between the proposed § 442.401(b), which would establish a client's right to refuse treatment, and the facility's mandate to provide active treatment.

Response: We will explain in interpretive guidelines that a client refusing a particular treatment must be offered acceptable alternatives to the treatment being refused if acceptable alternatives are available (for example,

drug therapy). If the client refuses the alternative treatment as well, or if no alternative exists to the treatment that was refused, the facility must consider whether it can continue to treat the client consistent with these regulations.

Comment: Commenters suggested that the proposed § 442.401(i) that would establish a client's right to send and receive mail be modified to indicate that a client has a right to send and receive unopened mail.

Response: We agree and have modified the regulations to indicate that a client has this right.

Comment: One commenter suggested that the proposed § 442.401(g) that would require a facility to provide each client with the opportunity for personal privacy be expanded to indicate the locations where privacy is a client right.

Response: We believe this is conceptually self-evident. We cannot enumerate all of the types of living environments that lend themselves to client privacy, so we cannot practically comply with this recommendation. However, we have modified the regulations to emphasize the need for privacy during treatment procedures and care of the personal needs of the client.

D. Client Finances (Proposed § 442.410; Final § 483.420(b))

Comment: Most commenters on the requirement to keep a full and complete accounting of clients personal funds were concerned that a minutely detailed accounting by the facility should not be required. Clients' personal funds include funds for "incidental" expenses (such as ice cream and bus fares), funds that a capable client handles without assistance, funds dispensed to a client under a program to train the client in money management, and funds that are not entrusted to the facility (for example, that are paid directly to the client's representative payee).

Response: The Conference Report (H.R. Rep. No. 673, 95th Cong., 1st Sess. 49 (1977)) on the bill that enacted section 1861(j)(14) of the Act, the provision that requires skilled nursing facilities to account for patients' funds, states that: 'Such system must provide for separate and discrete accounting for each patient with a complete accounting of income and expenditures.' The requirement for ICFs to account for patients' funds was incorporated into the Medicaid statute at section 1905(c) of the Act, by section 8(a) of Pub. L. 95–292.

However, we agree with the commenters who maintain that the facility should not be held responsible for personal funds used for incidental expenses or "pocket money". Consequently, we have restated the requirement, now at § 483.420(b)(1)(i) to clarify that the facility is only responsible for the personal funds of which it has custody on behalf of the client.

Comment: Some commenters suggested that specific emphasis be placed on the facility's responsibility to encourage and teach clients to manage their own funds to the extent possible.

Response: We believe that the need to encourage and train clients in managing their own funds to the extent possible was reflected in the proposed § 442.401(d) that would require the facility to allow each client to manage his or her own financial affairs and to teach him or her to do so to the extent of the client's capabilities. Consequently, we have made no change to the proposed requirement in this final rule. We note that the requirement is located at § 483.420(a)(4) in this final rule.

Comment: Other commenters recommended that we retain the requirement in current regulations at § 442.404(a)(4) that the facility inform the client in writing of available services and any applicable charges.

Response: The ICF/MR is required to provide its clients with the package of services specified in these regulations. Further, Medicaid regulations at § 447.15 provide that, except for any recipient cost-sharing requirements specified by the State plan, a Medicaid provider must accept the amount paid by the State Medicaid program as payment in full. Thus, the facility is effectively precluded from charging the client for services that it provides as part of the required ICF/MR package, making a list of applicable charges unnecessary.

Comment: Concerning the proposed § 442.410(a), which would preclude the commingling of a client's funds with any funds other than those of another client, two commenters suggested the commingling of clients' funds in a shared trust fund, noting that small, individual client savings accounts can be depleted by bank charges. However, they added that it would be impossible to maintain individual running accounts of interest accrued to each client in a shared account.

Response: The proposed rule that would prohibit the commingling of clients' funds with facility funds is required by section 1905(c)(4) of the Act, which incorporates section 1861(j)(14) of the Act. Section 1861(j)(14) of the Act precludes the commingling of clients' funds in skilled nursing facilities that are approved for Medicare participation. Thus, under section 1905(c)(4), this provision applies to ICFs. There is nothing in the Act that requires the facility to maintain clients' personal funds in financial institutions in accounts separate from other client accounts, or to maintain these funds in interest bearing accounts (although it would ordinarily be prudent to do so). However, if the facility elects to pool clients' funds in an interest bearing account, it is expected to know the interest separately accrued by each client, as part of its required accounting of funds.

Comment: One commenter questioned the need for any commingling of clients' funds, and opposed any system that could allow personal funds to lose their individual identity, or allow access to them without consent of the client or guardian. Another suggested allowing combined funds within a shared bank account but mandatory, separate accounting cost centers for each client. Still another commenter noted a potential conflict between Federal law and a particular State's law requiring interest from a patient's trust account to be deposited into a common recreational fund account.

Response: Section 1905(c)(4) of the Act, the proposed regulations, and these final regulations neither require nor prohibit the commingling of a client's funds with those of other clients in accounts in financial institutions, nor do they require that funds, when deposited, be deposited in interest bearing accounts. With regard to the potential conflict between State and Federal law, we would have to examine the specifics of the State law to determine whether, in fact, it conflicts with the Federal Medicaid statute.

Comment: In regard to the proposed § 442.410(b), which would require a written financial record that includes management of all funds handled by the facility on the client's behalf, one commenter suggested including a signed statement that the facility management of funds is done at the client's option, and another expressed support for the requirement for a written financial record.

Response: We believe the issue of a client authorizing the facility to manage his or her funds was already adequately addressed in the proposed § 442.401(d) concerning clients' rights. That section would require that the client be allowed to manage his or her own financial affairs as much as possible, and implied that facility management of the client's funds is possible only if the client elects it. We have made no changes to this provision that now is located at § 483.420(a)(4). We believe that the requirement in the introductory

paragraph of the proposed § 442.410, for a full and complete accounting of funds, by its nature necessitates maintenance of a written record. Therefore, we believe that the language in the proposed § 442.410(b) that would specifically require a written record is unnecessary, and we have deleted it.

Comment: With respect to the proposed provision regarding availability of the financial record (§ 442.410(c) of the proposal), eight commenters recommended that the word "and" in the phrase "to the client and his or her parents or guardian" be changed to "or", noting that a parent or guardian should not have automatic access to the financial record of an adult client who can manage his or her own finances. Several additional commenters suggested that instead of changing "and" to "or", the words "as appropriate" be added to the end of the sentence. It was noted that even a client who has been adjudicated as incompetent should have the opportunity to examine his or her own financial record. Requiring the record to be made available to the client "or" the parent or guardian might be interpreted as precluding this opportunity.

Response: We agree with the commenters who point out that parents should not have automatic access to the financial records of adult clients who can manage their own finances. Therefore, we are revising the last part of the sentence to read " * * * client, parents (if the client is a minor), or legal guardian". This wording adequately addresses the general issue of access to the client's financial records.

Comment: Some commenters suggested requiring the facility to furnish the client and family with an annual financial statement.

Response: We do not believe it is necessary to require a facility to furnish an annual financial statement to the client or the client's family, since the facility is already required to make the financial record available at any time upon request. Requiring an annual statement could create the erroneous impression that the facility need only make the record available once a year and may impose, as well, a reporting burden not desired by family members or guardians.

Comment: Other commenters recommended requiring the financial record to be available, at the client's request, to a designated advocate and requiring that financial records be made available to those with a legal right to the information (which would not necessarily include the parent or guardian) and to the client "unless contraindicated".

Response: We do not believe that it is necessary to make explicit reference to third parties designated by clients to represent them, such as advocates. The facility already is required to make the record available to the client who, in turn, can elect to make it available to any other individual of the client's choice. This election also can be made by the client's parents (if the client is a minor) or legal guardian on the client's behalf.

E. Governing Body (Proposed § 442.412; Final § 483.410(a))

Comment: Most of the comments on this section concerned the provision in the proposed paragraph § 442.412(b) that would require "knowledge in the field of developmental disabilities" as one of the qualifications of the facility administrator. Many commenters requested clarification on how possession of this knowledge can be established (degree, years of experience, etc.). Some questioned the need for this requirement and expressed the belief that organizational skills, as well as managerial/administrative experience and training, are the most important qualifications for the administrator.

Response: After reviewing the comments regarding this requirement, we have decided to delete it. It would be difficult to formulate definitive, all-inclusive criteria for demonstrating this type of knowledge and experience. We believe that the presence of sufficient knowledge, experience and managerial skills in the field of developmental disabilities will be reflected in the quality of care furnished to clients in the facility. Therefore, the most appropriate indicators in assessing this factor will be outcome-oriented; that is, the quality of care that the clients actually receive.

Comment: One commenter requested that we revise the regulations to clarify that it is permissible for more than one facility to share a common administrator or governing body.

Response: Neither the proposed nor these final regulations preclude such an arrangement as long as the administrator adequately fulfills the functions and responsibilities required to manage each facility (or, in the case of a governing body, as long as the governing body meets the specific requirements set out in the standard for governing bodies at § 483.410(a) for each of the facilities involved).

Comment: One commenter requested that we keep the requirement in current regulations at § 442.408 for a management audit plan.

Response: We did not include the requirement for a management audit plan in the proposal or in this final rule. The reason is that we believe that the existence of a plan is not an appropriate measure of whether its function has been fulfilled and that each facility should determine for itself, either in advance or continously, the manner in which it monitors its own performance.

F. Communications With Clients, Parents, and Guardians (Proposed § 442.412; Final § 483.420(c))

Comment: Several commenters suggested that we maintain the provision in current regulations at § 442.414(a)(1) that requires a facility to notify parents or guardians of any significant in the client's condition.

Response: This requirement was addressed in the proposed § 442.434 that would require the facility to notify the client's parents or guardian promptly of any significant incidents. In the final regulations, this provision is located at § 483.420(c)(6). It requires facilities to notify promptly the client's parents or guardian of any significant incidents or changes in the client's condition. For a further discussion of the provision, see section III.P. of this preamble.

Comment: The proposed § 442.414 included an introductory statement that would require the facility to have an active program of communication with the client, parents, and guardian. Some commenters suggested that the word "and" be change to "or", to allow for direct communication between the facility and a competent adult client rather than through the client's parents.

Response: The proposed introductory statement was not intended to establish an explicit requirement, but rather to set the general tone of the requirements that follow it. Since it causes confusion as to its intent, we have revised it to say simply, "The facility must—". As in the proposed rule, the introductory statement of this final rule is followed by specific requirements.

Comment: Other commenters suggested that we replace the word "permit" as used in this section with "promote," to indicate a more active facility role in enabling clients to exercise their basic rights.

Response: We agreed with the commenters and, in this standard, have replaced the word "permit" with "promote" to emphasize the facility's active role in the communications process. We plan to issue interpretive guidelines that will clarify that this revised wording places a higher degree of responsibility on the facility in this area.

Comment: The proposed § 442.414(a) would require the facility to permit participation of parents and guardians

in the active treatment process specified in the proposed § 442.440, unless that participation is unobtainable or inappropriate. Many commenters requested clarification of the term "inappropriate" and of the process by which parental or guardian participation in the client's active treatment plan would be determined to be inappropriate or unobtainable. Additional commenters asked whether the term "active treatment" in this context is synonymous with "individual program plan".

Response: In this final rule, we have deleted the cross-reference to § 442.440 concerning active treatment, and have revised the language to refer to "the process of providing active treatment to a client". This is to clarify that the facility must promote parent/guardian participation in the entire range of activities connected with the provision of active treatment, from client assessment through delivery. Regarding the terms "inappropriate" and "unobtainable", we plan to issue interpretive guidelines to clarify that, for example, it would be inappropriate for an individual to attend interdisciplinary team meetings if his or her behavior is so disruptive or uncooperative as to preclude effective participation by anyone else. Similarly, the term "unobtainable," as used in this standard, means that the facility had made a bona fide effort to *seek* parental participation in the client's active treatment process, even though the effort may ultimately be unsuccessful (for example, the parent may be impossible to locate, or may prove unwilling or unable to participate).

Comment: Several commenters expressed concern that unannounced visits to the client (proposed at § 442.414(c)) or to areas of the facility that provide direct client care services (proposed at § 442.414(d)) should not be allowed to interfere with or disturb the privacy and rights of that or any other client.

Response: We share this concern, and have amended the language to provide for visits "consistent with the right of that client's and other client's privacy".

Comment: Over half the commenters addressing the proposed § 442.414(e) noted that, although the proposed regulations would require facilities to permit frequent and informal leaves of absence, State Medicaid programs often make no or very limited payment to reserve the client's bed in the facility during the leave of absence.

Response: Under the Medicaid program, payment during a leave of absence is a matter for each State to decide. The Medicaid regulations governing payment during leaves of absence (at § 447.40) provide that each State is free to determine whether and to what extent it will make payment in these situations. Of course, Federal matching funds are available whenever a State decides to make such payments under the regulations.

Comment: Other commenters suggested that a leave of absence should not be permitted in situations in which the interdisciplinary team determines that it would be inconsistent with the client's program goals (such as when a home visit would be potentially harmful).

Response: The proposed regulations would and these final regulations do require the facility to permit clients to go on visits and trips. A facility is not required to sponsor such trips or to allow the client to take a particular type of trip that is contraindicated. If a specific type of trip is contraindicated by a particular circumstance (for example, child abuse by a parent), then the facility is not required to permit such trips. However, as with any right that may need to be modified or limited, the client should be provided with the least restrictive and most appropriate alternative available. We note that in the final rule under the standard concerning the protection of clients' rights at § 483.420(a)(3), we have clarified the proposed requirements on a client's exercise of rights, by including the example of a client's right to due process.

Comment: Some commenters suggested deletion of the word "frequent" with reference to leaves of absence, to make clear that the regulations do not apply to facilities that provide only part-time, non-residential care.

Response: We are retaining the word "frequent", since these regulations apply only to inpatient facilities and, therefore, clearly do not include those facilities which provide only part-time care.

G. Compliance With Federal, State, and Local Laws (Proposed § 442.416; Final § 483.410(b))

Comment: A number of commenters expressed approval of the inclusion of civil rights requirements in this provision. However, there were also questions as to whether the applicability of civil rights requirements included accessibility for the handicapped under section 504 of the Rehabilitation Act of 1973.

Response: The provisions of section 504 of the Rehabilitation Act of 1973, including accessibility for the physically handicapped, apply to all programs receiving Federal funds. The Office for Civil Rights of the Department of Health and Human Services administers the regulations implementing section 504 relative to building accessibility for the physically handicapped and is routinely involved in the certification process for ICFs/MR. Because the proposed regulations text at § 442.416 gave the appearance that HCFA would be enforcing civil rights and research requirements, we have deleted these requirements from the text. However, we have added a new § 483.405 which describes the relationships between these regulations and those administered by other HHS agencies (for example, nondiscrimination on the basis of age administered by the Office of Civil Rights). Violations of these regulations, while not a condition of participation, may result in the termination or suspension of, or refusal to grant or continue, Federal financial assistance.

Comment: One commenter believes that there is an inconsistency between the proposed standard at § 442.416, which would require that the facility comply with all applicable Federal, State and local laws, and the proposed revision in the regulations at § 442.252 that would exempt ICFs/MR from meeting State nursing home regulations.

Response: The current § 442.252 requires all ICFs to meet State imposed safety and sanitation standards for nursing homes. These State-imposed nursing home requirements are not always appropriate to ICFs that serve the mentally retarded. Thus, we proposed to limit the applicability of § 442.252 to ICFs other than ICFs/MR. We see no inconsistency between the proposed amendments to § 442.252 and the proposed § 442.416 that would require facility compliance with Federal, State and local laws that are "applicable" to ICFs/MR. In order to further clarify that these regulations do not require State-imposed safety and sanitation standards for nursing homes to be applied to ICFs/MR, we considered moving § 442.252 from Part 442, Subpart E that applies to all facilities, to Subpart F that applies only to ICFs other than ICFs/MR. However, the current rules under Subpart F already address safety and sanitation laws at § 442.315(c). Therefore, in this final rule, we are deleting § 442.252. Thus, these regulations do not require States to apply State nursing home requirements with regard to safety and sanitation standards to ICFs/MR. However, a State continues to be free to apply State ICF/MR standards and, if it does, the facility is required by § 483.410(b) of these regulations to

comply with those State requirements. These regulations impose Federal safety and sanitation requirements on ICFs/MR at § 483.470 and elsewhere.

Comment: One commenter asked how to determine which provision would be controlling in situations where two or more applicable requirements conflict.

Response: We believe the commenters may be referring to a perceived conflict between the proposed § 442.416, which requires compliance with Federal, State and local laws, and the proposed § 442.460, which describes personnel qualifications. It is possible that a State may require one level of qualification for personnel (for example, doctoral) and the Federal regulations require a lower level (for example, bachelors). In fact, this does not represent a conflict because the regulations represent the basic minimum participation requirements. If a State permits licensure with lower requirements, these Federal regulations control for purposes of Medicaid certification. If, on the other hand, a State imposes higher requirements, the facility must in effect meet the higher of the two requirements.

H. Provision of Needed Services (Proposed § 442.418; Final § 483.410(d))

Comment: Approximately 45 commenters expressed views about the provision in this section that would require the facility to provide the following services directly through its own staff: the services of a qualified mental retardation professional; direct care services; nursing services; development and monitoring of active treatment programs; and living quarters. The majority of the commenters objected to the provision because it would require the facility to employ staff directly and prohibited them from "arranging for" staff on an as needed basis. The most frequent objection dealt with the employment of nursing staff for clients with medical care plans. Many commenters believe it is unreasonable to require a facility to employ directly a nurse for clients with medical care plans when a client may have such a plan infrequently and then, only for a short period of time. They felt that employment of nurses on a temporary basis, perhaps through a home health agency, would be a better alternative.

Other objections came from a State which by law requires case management and assessment to be conducted by county government and not the facility. The proposed requirement for providing active treatment monitoring services "directly" would seriously conflict with this local law. Another State provides the qualified mental retardation professional function, nursing services and the development and monitoring of active treatment programs through a centralized client services management agency. This arrangement has allowed for the development and support of small community-based facilities that could not exist without it.

Another commenter objected to requiring direct provision of living quarters because it precluded the facility from leasing space to provide services in small community-based facilities.

Response: The basic objective in specifying which services had to be provided directly by the facility was to assure that a facility would not create an ICF/MR "on paper" and contract out all the essential services, thereby escaping any real responsibility for their quality. The commenters on this requirement have pointed out the considerable difficulty this would cause for existing arrangements and for initiatives to establish more community based facilities. The commenters also pointed out how this requirement conflicts with our stated objective of providing more flexibility with greater emphasis on the outcome. As a consequence, we have deleted the requirement for direct provision of these services while retaining the requirements a facility must meet when it arranges to obtain a service from an outside resource. These requirements are: (1) For a written agreement specifying the conditions under which the services are provided and that the facility is responsible for assuring that the outside services meet Federal standards for quality; and (2) that the facility, itself, assure that the services meet client needs. If a facility fails to meet any of these requirements (for example, if the facility fails to assure the quality of the services provided under an arrangement), it is subject to the same sanctions as if it had provided the services directly.

I. Personnel Policies (Proposed § 442.420; Final § 483.420(d))

Comment: A significant number of commenters raised objections about the proposal to require facilities to develop and implement personnel policies. Some insisted that to be meaningful these policies should be in writing. Others wanted personnel policies to be reviewed annually. Another commenter wanted to distinguish the term "job description" from "job classification".

Response: Because of the significant interpretive problems raised by commenters, because we do not view the availability of job descriptions and written personnel policies as a significant client care issue, and because written job description and personnel policies are regulated by State law, especially for the small provider, we have withdrawn the proposed requirements at § 442.420(a) for personnel policies and § 442.420(b) for job descriptions. We note that the remaining provisions of this proposed section have been moved. The proposed § 442.420(c) dealing with communicable disease has been modified as indicated in the following comment and response, and incorporated into the provisions relating to infection control (§ 483.470(1)(4) of this final rule). The proposed § 442.420(d) that would prohibit employment of individuals with a history of child abuse has been incorporated into the provisions relating to staff treatment of clients at § 483.420(d) of this final rule.

Comment: Many commenters were concerned about the proposed regulations that would prohibit employees with signs and symptoms of communicable disease from working. They were concerned about the definition of the phrase "communicable disease" and suggested the requirement be changed to apply only to those employees who have contact with clients.

Response: We agree and have changed the regulations to prohibit employees with symptoms or signs of a communicable disease from "direct contact" with clients and their food (§ 483.470(1)(4) of this final rule).

Comment: Many commenters expressed concern about the problem of employing those with a history of child abuse, neglect or exploitation, indicating that a "history" of abuse was vague and nonspecific. Several of these commenters suggested that the proposed requirement be modified to prohibit employment by those convicted of child abuse, neglect or exploitation.

Response: We agree in part and have modified the requirement to prohibit employment of individuals who have been "convicted" of one of the mentioned abuses. However, we have retained the proposed prohibition against the employment of individuals with a "history" of such abuses but have defined "history" as "prior employment history". We do not believe that it would be an unreasonable task for the facility to obtain references from previous employers to determine if a prior history of child abuse, neglect or exploitation exists.

J. Licensure and Professional Standards (Proposed § 442.422; Deleted in Final)

Comment: Seven commenters objected to the provision that would

require the facility to meet the same professional licensure requirements that the State has established for comparable positions in the community. Commenters stated that this requirement would have the effect of superseding State laws that specifically allow less qualified individuals to practice in State institutions (that is, ICFs/MR) than in community facilities. Three of the commenters asked us to amend the regulations so that it would not supersede State law in those States that allow a lower standard in State institutions. One commenter specifically asked that we add the words "unless specifically provided for under State law and regulation".

Two commenters suggested that we clarify the regulations because the proposed § 442.460(e)(5) would allow a masters level psychologist, but the proposed § 442.422 would require a doctoral level if the facility was in a State that required the doctoral level degree for community practice.

Response: We agree with the commenters who would like to amend this section so that these regulations would not supersede State laws that specifically allow lower personnel requirements in public institutions (that is, ICFs/MR). These laws are usually based on the theory that the setting of larger State institutions imposes a level of supervision that is not present in independent practice. To amend this section as commenters wish would be to require the facility to meet the personnel credentialling requirements of State law. We have deleted the proposed § 442.422 from the final rule because the proposed § 442.416 (§ 483.410(b) of this final rule) that would require the facility to meet applicable State laws meets their concerns on this issue.

The deletion of § 442.422 answers the concerns that the proposed personnel requirements for psychologists at § 442.422 were inconsistent with the proposed requirements under the standard for professional program services (§ 442.460(e)(5) of the proposed, § 483.430(b)(5) of the final).

K. Staff Treatment of Clients (Proposed § 442.424; Final § 483.420(d))

Comment: Many commenters suggested that to be useful the policies and procedures that prohibit mistreatment, neglect and abuse should be in writing.

Response: We agree that policies and procedures on prohibition of mistreatment, neglect and abuse should be in writing and have amended the regulations accordingly. Since these policies and procedures are directly related to the protection of clients' rights, health and safety, we want everyone in a facility to know exactly what policies and procedures exist in this regard.

Comment: Many commenters objected to the five day time frame for investigations of alleged incidents of mistreatment, neglect or abuse. Some commenters indicated that five days is too short a period to conduct an investigation while others said that five days is an excessive amount.

Response: The current regulations at § 442.430(c)(2) allow 24 hours for this reporting. In the proposed rule, we increased this reporting time to five working days because we wanted to allow sufficient time for a reasonably thorough investigation. While incidents of this nature will vary widely in their degree of severity, and thus require a wide variation in time necessary to investigate them, we believe that five working days is a good balance for most cases. Further, we do not preclude the facility from conducting such investigations in a shorter period of time.

Comment: One commenter stated that the regulations should state the specific kinds of reporting mechanisms that are acceptable to meet the proposed requirements for reporting mistreatment, abuse or neglect of clients.

Response: We believe that the proposed regulations adequately address the broad objective the facility much achieve. We do not believe it necessary to specify detailed reporting mechanisms. We also believe that a facility should be free to develop its own specific procedures as long as documentation exists that shows that alleged violations are investigated and appropriate action taken.

Comment: One commenter suggested that this section be expanded to prohibit client exploitation as well as mistreatment, neglect and abuse.

Response: We do not agree with this suggestion because we believe that "mistreatment" would include the exploitation of a client. We will explain in interpretive guidelines that mistreatment includes exploitation.

Comment: One commenter suggested clarification of the term "appropriate corrective action" as it pertains to the actions of the administrator once an alleged violation has been verified.

Response: We can not attempt to describe all the potential abuses and the degrees to which they may occur. Thus we cannot attempt to define "appropriate corrective action". The facts of the situation will have to be evaluated by the surveyor and a judgment made about appropriateness.

Comment: Several commenters suggested that this section could be strengthened by clearly stating that the facility's immediate responsibility in the event of an allegation of abuse or neglect is to ensure no further harm to the client.

Response: We agree and have modified the regulations to require the facility to take steps to prevent any further potential abuse while alleged abuses are being investigated.

Comment: Several commenters suggested that the facility should be required to investigate abuse or injuries caused by another client, self-abuse, or incidents by an unknown source.

Response: We have accepted this comment and, at § 483.420(d)(1) of this final rule, have changed the proposed provisions to require the facility to prohibit neglect or abuse by any individual. We also have modified the proposed provisions to include a requirement that the facility investigate injuries of unknown sources regardless of the source.

Comment: One commenter suggested that the report of an investigation into alleged violations of mistreatment, abuse and neglect should be a preliminary report.

Response: We do not agree with this suggestion. We have already extended the period in which a report may be prepared from 24 hours to five working days. To allow the report to be preliminary would unnecessarily weaken the requirement.

Comment: Several commenters suggested that the proposed regulations be modified so that "alleged violations of policies are reported" is changed to "alleged violations of abuse and neglect are reported". Other commenters asked that we simply delete the words "of policies" so that the focus would be on the violation, not on policy.

Response: We agree with the commenters that the focus of the requirement is the reporting of mistreatment, abuse and neglect. Therefore, we have changed the regulations accordingly.

Comment: One commenter requested that we define "working days" as it is used in the proposal requiring a facility to report investigations of alleged violations of mistreatment, abuse and neglect within five working days.

Response: We will define this term in intepretive guidelines by stating that it refers to Monday through Friday excluding State and Federal holidays.

Comment: One commenter indicated that there should be a way to bypass the administrator if he or she is the abuser.

Response: We agree with this commenter and have modified the regulations so that the results of an investigation may be reported to the administrator or to "other officials". (The interpretive guidelines will expalin that when a report of known or suspected abuse or neglect involves the acts or omissions of the administrator, a different properly constituted authority outside of the facility must receive and investigate the report and take appropriate protective and corrective action.)

Comment: One commenter noted that it would be appropriate to incorporate into this standard the prohibition of verbal, physical and sexual abuse proposed under the standard "Behavior Management—policies and procedures" at § 442.452(c).

Response: We have deleted the reference to verbal, physical or sexual abuse from the standard concerning behavior management and will explain in interpretive guidelines that the prohibition of these forms of abuse are encompassed under the standard concerning staff treatment of clients.

Comment: One commenter stated that this section also should mandate that facilities have an appropriate procedure to deal with situations when clients are missing.

Response: We agree with this commenter. However, provision already was made for addressing the issue of missing clients under the proposed § 442.550 that concerns emergency plans and procedures and that would require the facility to develop and implement written plans and procedures to deal with missing clients. This provision has been incorporated into the final rule at § 483.470(h).

Comment: One commenter expressed concern that measures be taken to protect the rights of employees as well as clients.

Response: While it is true that employee rights are a significant issue in allegations of client abuse, these regulations are designed to protect and treat clients of the facility. We expect State and local law, employment contracts, and union contracts to address issues of employee protections.

L. Facility Staffing (Proposed § 442.426; Final § 483.430(c))

Comment: One commenter expressed an opinion on the proposed requirement at § 442.426(a) that the facility must not depend upon clients or volunteers to perform direct care services for the facility. In their view, the phrase "must not depend" is unclear. They asked whether this means that clients or volunteers cannot perform client care services and whether this would eliminate forster grandparents.

Response: The intent of the regulations is that the facility may not entirely rely upon volunteers for routine staffing. The interpretive guidelines for these regulations will explain that volunteers may provide supplementary services but that the facility may not rely exclusively upon them to perform direct care services. Facilities cannot depend on volunteers to fill required staff positions.

Comment: There are fifteen comments on § 442.426 (b) and (e) of the proposed regulations. The intent of both these sections is that direct care staff are not required to perform support services to the extent that these duties interfere with the exercise of their primary direct client care duties. Most of the commenters felt that the wording in the proposed paragraph (b) (which states that direct care staff must not be required to provide housekeeping, laundry or other support services to the extent that these duties interfere with the exercise of their primary direct client care duties) precluded any flexibility in management. In their view, there are, at times, legitimate reasons for direct care staff to perform such duties. For example, at times, staff in group homes do housework while training residents. The commenters preferred the wording in the proposed paragraph (e) that states, "The facility must provide sufficient support staff so that direct care staff are not required to perform support services to the extent that these duties interfere with the exercise of their primary direct client care duties.

Response: We have accepted the comments, recognizing that the proposed paragraphs (b) and (e) of § 442.426 are duplicative. Since the commenters preferred the wording of paragraph (e), we have deleted the proposed paragraph (b) and retained the language of the proposed paragraph (e).

Comment: There were seventeen commenters on the proposed requirement at § 442.426(c) that in each residential living unit housing clients for whom a physician has ordered a medical care plan, or clients who are aggressive, assaultive or security risks, or one that houses more than 16 persons, there must be responsible direct care staff on duty and awake when clients are present to take prompt, appropriate action in case of injury, illness, fire or other emergency. Many of the commenters felt that the term medical care plan was unclear and needed to be defined. Several commenters also questioned whether or not the proposed requirement meant that there must be responsible direct care staff on duty and awake when clients are present in group homes with live-in houseparents.

Response: We have accepted the comments requesting clarification of the term "medical care plan". This also was a significant issue in the comments on the proposed § 442.464, Physician Participation (see Section III.AA. of this preamble). Thus, we have clarified under § 483.460(a) concerning physician services that a physician must develop, in coordination with licensed nursing personnel, a medical care plan of treatment for a client whose health needs are so severe as to require 24-hour licensed nursing supervision. With regard to group homes with live-in houseparents, the proposed regulations would require and the final regulations require responsible direct care staff on duty and awake when clients are present in each of the situations stated in the proposed regulation; that is, when the residential building houses more than 16 clients or when the residential living unit houses clients for whom a physician has ordered a medical care plan, or clients who are aggressive, assaultive or security risks. In these situations, clients are high risk individuals in terms of their vulnerability to emergency situations such as fires, injuries or health emergencies (for example, aspiration, cardiac or respiratory failure, seizures). Such vulnerability also increases as the number of clients in a facility increase. Thus, in these situations, a responsible direct care staff person on duty and awake has been retained as a requirement.

Comment: There were five comments on the proposed requirement at § 442.426(d) that in each defined residential living unit housing clients for whom a physician has not ordered a medical care plan and that houses 16 or fewer clients, there must be a responsible direct care staff person immediately accessible to clients on a 24-hour basis. The majority of the commenters felt that the term "immediately accessible" should be defined. One commenter felt that the regulation should read, "there must be a responsible direct care staff person on the premises and immediately accessible".

Response: We have revised the regulations to read that staff must be "on duty" rather than immediately accessible. Interpretive guidelines will explain that the intent of the regulation is that at all times a staff person is in a position to help if client need arises. We will explain that on-duty staff, for purposes of this provision, need not be

awake. We also will explain that the provision (located in the final rule at § 483.430(c)(2)) has been modified to assure that 16 or fewer clients located in units of multi-unit buildings must have staff on duty and "awake". This provision is necessary because multi-unit buildings are usually of such size and configuration that the opportunity for staff to detect and react to client problems is excessively limited.

Comment: Commenters felt that the term "support staff" was unclear in the proposal at § 442.426(e) that would require the facility to provide sufficient support staff so that direct care staff are not required to perform support services to the extent that those duties interfere with the exercise of their primary direct client care duties.

Response: We have accepted these comments and will include the following definitions in the interpretive guidelines for the regulation: Support staff include all personnel hired by the facility that are not either direct care staff or professional staff. For example, support staff include, but are not limited to, housekeepers, maintenance and laundry personnel. Direct care staff are those personnel managing and supervising the daily needs of clients in their living quarters.

Comment: Thirty-one comments were received on the proposed requirement at § 442.426(f) that the facility must employ a qualified dietitian, who is registered or eligible for registration by the American Dietetic Association, either on a full-time, part-time or on a consultant basis. The majority of the comments suggested that the regulation should be more specific with regard to the number of hours a qualified dietitian should be employed by the facility. Most of the commenters felt that the number of hours should depend on facility size. There was no consensus among the commenters, however, as to how specific guidelines could relate facility size to the number of hours needed from a qualified dietitian. Several commenters felt that the regulations should allow more flexibility by stating that the facility should employ a qualified dietitian for sufficient time to meet the needs of residents. Some of the commenters also believed that the requirements regarding dietitian personnel in the proposed § 442.426 (f) and (g) should be moved to the proposed standard at § 442.558, concerning food and nutrition services.

Response: We have accepted the comments suggesting that the regulations be flexible enough to allow facilities to employ a qualified dietitian for sufficient time to meet the needs of residents. We also have accepted the comments suggesting that facility requirements for employing a dietitian should be moved from the standard concerning facility staffing to the standard concerning food and nutrition services. Additionally, to ensure that all professional qualifications are consolidated, we have moved the qualifications for a professional dietitian to the professional program services standard. Thus, in this final rule, the standard for food and nutrition services at § 483.480(a)(2) will state that "A qualified dietitian must be employed either full-time, part-time, or on a consultant basis at the facility's discretion."

Comment: Twenty-one comments were received concerning the proposed requirement that if a qualified dietitian is not employed full-time, the facility must designate a person to serve as the director of food services. Many of the commenters felt that qualifications for a non-dietitian food service director need to be added. Additionally, several commenters believed that the regulations should be expanded to specify the duties of the food service supervisor.

Response: We have not accepted the comments requesting that the qualifications and duties of the designated director of food services who is not a qualified dietitian be added to the regulations. The outcomes of good food and nutrition services were outlined under the proposed standards at § 442.460 Meal Services, § 442.562 Menus, and § 442.564 Dining Areas and Service, and have been adopted into this final rule under the condition of participation concerning dietetic services at § 483.480. An example of an outcome is nutritional foods served in appropriate quantities and at appropriate temperatures. The intent of the regulations is that the specified outcomes be met. If the outcomes are achieved, the qualifications and duties of the person performing the services do not need to be specified in regulations.

M. Direct Care Staff (Proposed § 442.428; Final § 483.430(d))

Comment: Approximately 60 commenters expressed views on the proposal to prescribe various staff to client ratios depending on the needs of the clients (for example, one staff member to 3.2 clients with severe disabilities; one staff member to four clients with moderate disabilities; and one staff member to six clients with mild disabilities).

In essence, the commenters had two clear reactions to the proposal: (1) They uniformly thought that the ratios were inadequate to provide active treatment and barely adequate to provide custodial care, and many commenters thought that we needed a requirement for "sufficient" direct care staff to supplement the ratios as they were proposed; and (2) the commenters thought the ratios needed clarification. Commenters asked for clarification of the following: what staff are included in calculating the ratios; was it permissible to have part-time staff serve when the number of clients dictated less than a full-time staff; and, are staff necessary when there are no clients in the living unit such as when all clients are at workshops or school. Finally, commenters expressed a preference for ratios based on shifts, as described in the preamble to the proposed rule, rather than on a 24-hour basis as proposed in the regulations text.

Response: We have retained the ratios as proposed, which would require staffing levels comparable to those in existing regulations at § 442.445(c), but in accordance with public comments, we have made the following changes in order to strengthen and clarify the regulations.

1. We have decided to retain the proposed ratios, which are based on a 24-hour time frame, in order to provide the facility as much flexibility in staffing as possible.

2. We have added a requirement that the facility provide "sufficient direct care staff to manage and supervise clients in accordance with the individual program plans". This standard clearly establishes "sufficient staff" as the optimal requirement and subsumes the ratios as the minimal standard. We believe the addition of the "sufficient direct care staff" provision is an effective means of addressing the commenters' opinions that the stated ratios are inadequate, since the new provision is tied to implementation of client objectives and therefore assessable in an outcome oriented survey process.

3. We will define in interpretive guidelines that direct care staff are those staff who manage, supervise and provide direct care to clients in their residential living units. This staff could include professional staff (for example, registered nurses, social workers) or other support staff if their primary assigned, daily shift function is to provide management, supervision and direct care of clients' daily needs (for example, bathing, dressing, feeding, toileting, recreation, and support and reinforcement of active treatment objectives) in their living units. However, professional staff who simply work with clients in a living unit on a periodic basis cannot be included. Also, supervisors of client care staff can be

counted only if they share in the actual work of the direct care of clients. Supervisors whose principal assigned function is to supervise other staff cannot be included.

4. We have added a provision that stipulates that when no client is present in the living unit, no staff need to be present. This will satisfy commenters who objected to staffing a facility when all the clients were away at workshops or school. However, we have included a requirement for a responsible staff person to be available by telephone in case one of the clients needs to return to the living unit (§ 483.430(d)(4)).

5. We will make it clear in interpretive guidelines that when only one client is in a living unit, there must be at least one staff person on-duty. As did the proposed regulations, the final regulations require a minimum of one staff person to be on duty when clients are present in a facility housing 16 or fewer clients (§ 483.430(c)(3)), and a minimum of one staff person to be on-duty and awake when clients are present in a facility housing more than 16 clients (§ 483.430(c)(2)).

N. Staff Training Program (Proposed § 442.430; Final § 483.430(e))

Comment: Many commenters expressed support for the proposed changes regarding staff training since we emphasized performance rather than meeting paper requirements. However, other commenters indicated that the proposed standard was too general and that a greater degree of specificity was needed indicating the kinds of training required, the number of hours required for training, documentation of inservice curricula, etc.

Response: We believe that the proposed standard would allow a degree of flexibility to a staff training program that would be lost by establishing specific criteria. The training needs of facilities vary from facility to facility, with such factors of facility size and staff experience being important elements in determining training needs. We believe that specific criteria would be counterproductive to the intent of the standard.

Comment: Several commenters expressed concern about the requirement in the proposed § 442.430(c) that states that staff must be able to demonstrate the skills and techniques needed in client care. Concern was focused on the means of establishing that the requisite skills have been learned. It was suggested that interpretive guidelines be issued that would define more clearly the expectations of achieving this requirement.

Response: We believe the standard is clearly stated. Essentially, staff must know how to do what the facility has committed itself to do in behalf of each client's active treatment objective. This is the essence of an outcome oriented requirement. If staff do not know how to do their jobs, clients cannot achieve stated objectives in their plans. We will assess in surveys whether staff can show us how to implement active treatment programs and to treat clients.

Although not in response to a particular comment, we have made one clarifying change to the standard. We have changed the provision of the proposed § 442.430(c) from, "Staff must be able to demonstrate skills and techniques necessary to implement the individual program plans for each client under their care," to "each client for whom they are responsible".

O. Client Records (Proposed § 442.432; Final § 483.410(c))

Comment: There were several comments on the proposed regulation at § 442.432(a) that would require the facility to develop and maintain a recordkeeping system. Most of the commenters suggested that the current regulations found at § 442.501(b) requiring specific client data and § 442.501(c) requiring a discharge summary be added.

Response: Necessary elements of the current regulations at § 442.501 (b) and (c) were included in the proposed regulations. The requirement for specific client data was included at the proposed § 442.448(a) (§ 483.440(e)(1) of this final rule); the requirement for a discharge summary was included at the proposed § 442.442(c)(4) (§ 483.440(b)(5)(ii) of this final rule); relevant health-related information was included at the proposed § 442.448(b) (§ 483.420(c)(1) of the final rule); relevant restraint information was included at the proposed § 442.456 (c), (e) and (h) (§ 483.420(c)(2) and § 483.450 (c)(4) and (d)(2), (4) and (6) of the final rule); relevant behavioral and family-related information was included at the proposed § 442.448(a) (§ 483.440(e) (1) and (2) of the final rule); and relevant social and legal information was included at the proposed § 442.432 (a) and (c) (§ 483.420(c) (1) and (3) of the final rule).

Comment: There were 11 commenters on the proposed regulations at § 442.432 (b) and (c) that deal with the confidentiality and release of information in clients' records. All of the commenters believed that the regulations should specify that confidentiality and release of information does not apply to government agencies and advocacy groups.

Response: We agree with the thrust of the commenters suggestions that government agencies and advocacy groups be allowed to review client records when appropriately trying to evaluate the information that such records contain. However, we have not revised the regulations. To state in the regulations that advocacy groups have access to information without receiving the necessary consent from a client or his or her parents or legal guardian violates the rights of the client.

Comment: There were three comments on the proposed requirement at § 442.432(d) that any individual who makes an entry in a client's record must make it legibly, date it, and sign it. All of the commenters believed that the requirement that each record be signed is obsolete in the days of automated data systems.

Response: We have not accepted these comments. Even though computerization is routine in many areas of client records, the purpose of any routinization of information that is involved is to save the time of professionals. The signature on the client's record however, indicates that the information in the record has been individualized and the professionals take responsibility for the information it contains. However, interpretive guidelines will permit the use of electronic signatures in cases in which the facility has created the option for medical records to be maintained by computer rather than in hard copy.

Comment: There were five comments on the proposed requirement at § 442.432(f) that the facility must provide each identified residential living unit with appropriate aspects of each client's record. All of the commenters believed that the regulation was too vague and that the terms "appropriate aspects" should be clarified.

Response: We will define the term "appropriate aspects" in interpretive guidelines as meaning the active treatment, social as well as health aspects of the plan.

P. Emergencies or Death of a Client (Proposed § 442.434; Final § 483.420(c)(6))

Comment: There were eleven comments on the proposal to require facilities to notify promptly the client's parent or guardian of any significant incidents including serious illness, accident or death, and autopsy findings if requested. Many of the commenters felt that examples of significant incidents, in addition to serious illness,

accident or death, should be included. Some of their suggestions were unauthorized absence from the facility and allegations of abuse. An additional group of commenters thought that autopsy findings should not be included because many facilities do not do autopsies or receive autopsy reports.

Response: In this final rule, we have included abuse and unauthorized absences as examples of significant incidents. Also, we will issue interpretive guidelines that will state other examples, including those the commenters suggested.

We note that we have moved this standard into the standard concerning communications with clients, parents, and guardians. Thus, in the final regulations, it is located at § 483.420(c)(6). Additionally, we have accepted the comments requesting that autopsy findings be removed from the regulations.

Q. Infection Control (Proposed § 442.436; Final § 483.470(l))

Comment: Three commenters recommended that we define in the regulation the term "active program" as it was used in the proposed provision to require an active program for the prevention, control, and investigation of infection and communicable diseases.

Response: We have not accepted these comments to include this level of specificity in the regulations. However, interpretive guidelines will define an active program as one that includes the direct care staff routinely washing their hands after working with a client who has an infectious disease, the continuous use of aspectic technique when appropriate, an on-going program of communicable disease control and investigation of infections.

Comment: Five commenters expressed an opinion on the proposal to require facilities to maintain a log of incidents and corrective actions related to infections. Several of the commenters believed that the maintenance of a log could be burdensome and would be of no use to the facility. Additionally, some commenters felt that the term "record" should replace the term "log".

Response: We have changed the word "log" to "record". However, we have not removed the requirement to maintain such records. Without such records, public health officials have no evidence with which to conduct epidemiological investigations. Such investigations are necessary to establish the causation upon which corrective action must be based.

R. Active Treatment (Proposed §§ 435.1009 and 442.440; final §§ 435.1009 and 483.440(a))

Comment: Forty-three commenters submitted their opinions about the proposed definition of active treatment provided at §§ 442.440 and 435.1009. In general, commenters expressed clear support for the concept underlying the proposed defintion. Twenty-one commenters expressed specific support that active treatment explicitly include those services intended to prevent client regression. However, commenters stated that in their opinion, the language of the proposed definition was still unclear. Objections expressed by the majority of commenters focused on four issues: (1) The definition of active treatment included the term "active treatment", thus active treatment was defined as being an "active treatment program"; (2) the difference in meaning of the terms "behavioral", "developmental" and "social" skills, as used in the definition, was insignificant, and technically imprecise; (3) services intended to "decelerate" the rate of regression of clients who have degenerative conditions (for example Muscular dystrophy, or Alzheimer's disease) were not included as "active treatment"; and (4) the phrase, "For dependent clients where no further positive growth is demonstrable", as used in the proposed definition, was perceived to be stigmatizing, did not identify criteria useful in making such determinations, and authorized a facility unintentionally, to provide "custodial care" if client potential for growth was uncertain, or not easily measurable. Commenters submitted suggested revisions to the proposed language to be considered for inclusion.

Response: We found the comments pertaining to active treatment to be helpful, and agree that the proposed definition (at § 435.1009) and requirements (at § 442.440) could be strengthen with some of the modifications suggested. Therefore, we have made several revisions. First, in § 435.1009, of this final rule we stated that active treatment is treatment that meets the requirements specified in the standard concerning active treatment at § 483.440(a). Second, we have revised the regulations to include at § 483.440 a condition of participation entitled "Active treatment services". The standard at § 483.440(a) now specifies that active treatment is the aggressive, consistent implementation of a program of specialized and generic training, treatment, health and related services, as described in 42 CFR Part 483, Subpart D. Third, since the use of the terms "behavioral", "developmental", and "social" to modify the word "skills" was technically imprecise, we have revised the standard concerning active treatment to require that each client's program must be directed toward the acquisition of the behaviors necessary for the client to function with as much self-determination and independence as possible. Fourth, although the proposal had been intended to include services to decelerate the regression of clients with degenerative conditions, we have revised the regulations (now at § 483.440(a)(1)(ii)) to include this statement as an explicit requirement. Lastly, we have deleted the qualifier phrase, "For dependent clients where no further positive growth is reasonably considered possible", since the language of the regulation, "active treatment includes services to prevent or decelerate regression or loss of current optimal status" embodies our original intent.

Comment: One commenter criticized the proposed definition of active treatment because it did not mandate that clients be placed in the "least restrictive alternative" available. This commenter stated that, for the definition of active treatment to be consistent with accepted standards in the field of mental retardation and developmental disabilities, it should include this requirement at §§ 435.1009(a)(1) and 442.440(a)(1).

Response: We appreciate the suggestion of the commenter, and agree that placing clients in the "least restrictive alternative" available is an important principle in the field of mental retardation and developmental disabilities. It is our belief, however, that requiring this as a part of the active treatment program, and thus making it a requirement for FFP, would go beyond the statutory intent of Congress in authorizing ICF/MR services. There is nothing in the statutory language at 1905(d) of the Act, which authorizes ICF/MR services, that suggests that the size or the location of a facility, or whether a facility is the least restrictive alternative, should determine whether or not a facility qualifies for FFP. The only statutory requirement is that a client receive active treatment at the facility. Therefore, we have not accepted this suggestion for change. However, we have revised these regulations to include the application of this concept to other provisions, especially with regard to imposition of restrictive or intrusive techniques to change client behavior as discussed in § 483.450(b)(1)(iii) of this final rule.

Comment: A few commenters criticized the proposed definition, because in their opinion it implies that only "some" clients can benefit from active treatment. These commenters stated that all individuals can benefit from active treatment, since it means training or education.

Response: We agree that the term "active treatment" is defined by many professionals in the field of mental retardation and developmental disabilities, to mean habilitation, education and training services. Also, active treatment is often considered to be synonymous with life-long learning. However, the purpose of the proposed definition of active treatment was not to include all the meanings that may be given to the term, but to provide a definition of active treatment that specifically encompasses those services that clients must require and receive, in order to be certified as needing ICF/MR care under the Medicaid benefit. We believe the definition of active treatment included in the final rule achieves that purpose. Nevertheless, we recognize that there are other definitions of active treatment. As we noted, we have set forth a definition of active treatment in the final rule at § 435.1009 that cross-refers the reader to the standard for active treatment at § 483.440(a).

Comment: A few commenters criticized the proposed definition of active treatment because in their opinion it did not identify the specific "outcomes" toward which active treatment is to be directed. Other commenters suggested that we amend the definition to require that clients must not only receive active treatment, but that they also must benefit from active treatment, as well.

Response: We agree that active treatment should be outcome oriented. But, we do not agree that we should include this additional requirement. We believe the state-of-the-art is such that we can hold providers accountable to implement, review and continually modify the strategies they use to impove client functional abilities. However, we recognize that there are legitimate reasons why a client may not gain a desired objective. Thus, active treatment is measured more in terms of how aggressively, competently and consistently the ICF/MR pursues objectives in behalf of clients.

Comment: Several commenters stated that the provision of habilitation services is the cornerstone of active treatment. Therefore, they recommended specifically that the proposed definition be amended to include the term "habilitation", as it is used in the context of the Home and Community-Based Services Waiver program (as provided in section 1915(c)(5) of the Act, that was added by section 9502(a) of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), Public Law 99-272).

Response: We do not agree that the term habilitation, as defined for purposes of the home and community-based waiver program, should be included in the definition of active treatment at § 435.1009. Although Congress provided a definition of habilitation services in section 1915(c)(5) of the Act, that definition focuses on clients who otherwise would have been institutionalized rather than strictly those currently in an ICF/MR. By its own terms, it refers to "individuals who receive such services after discharge from a skilled nursing facility or intermediate care facility," and not to inpatients. While active treatment may include some services that are defined as being habilitative, we do not believe that it is feasible to attempt to identify in our definition of active treatment every type of service that must be provided to ICF/MR residents to assist them to reach maximum possible independence. Nevertheless, we believe our definition of active treatment is sufficient in scope to encompass the whole range of services necessary for clients to achieve maximum possible independence.

Comment: Conversely, other commenters objected to the proposed definition of active treatment, because in their opinion it meant that active treatment was limited only to habilitation services. Twenty-two commenters suggested that the definition of active treatment also should include vocational, educational, rehabilitational, medical, behavioral, social, and personal care services; and any other services necessary to meet the client's needs as identified by the comprehensive functional assessment. These commenters recommended that clients should be provided with any of these services that are needed to help them achieve a developmental goal related to their individual program plans (IPPs).

Response: Such services may be among those embraced by some within the term "active treatment". However, as stated before, we do not agree with the commenters that we should attempt to identify specifically in the regulations all the various services that can be considered to be active treatment. We do not believe that this would be feasible because there are many contingencies that may effect whether or not a specific service constitutes active treatment for a particular client. However, we believe the definition of and standard for active treatment in this final rule does encompass the whole range of services necessary for the client to achieve as much individual independence as possible.

Comment: Several commenters recommended that we identify within the definition of active treatment, those active treatment services that are reimbursable by Medicaid. These commenters stated that the regulations should provide a clear distinction between those services for which FFP is available, and those vocational and educational services that are not covered by Medicaid. Also, commenters believed that interested groups and citizens should be given the opportunity to offer comments and suggestions on how these distinctions would be made. Although HCFA has used guidelines for this purpose, the commenters asserted that regulations are preferable.

Response: We disagree. First, the source of payment for services a facility provides does not govern the requirements relating to the provision of services. Thus, all "active treatment" services, although necessary as a condition of participation, may not be reimbursable as medical assistance or rehabilitative services under Medicaid. A facility must meet the requirements of these regulations to participate in the Medicaid program regardless of the payment status of individual services. Also, the distinction between payors is often as much a function of Federal and State education and vocational training laws as it is related to the nature of the services themselves. Thus substantive distinctions between types of services are not within the purview of this regulation. Regulations addressing the exclusion of FFP for vocational training and educational activities in ICFs/MR already are contained at § 441.13(b).

With respect to the commenters' concern about HCFA guidelines used to interpret § 441.13(b), we note that the State Medicaid Manual (SMM) is the official medium by which HCFA interprets or clarifies issues and sets forth procedures that States are required to follow in implementing the regulations. Guidelines that are issued as part of the SMM are official interpretations of the law and regulations. Thus, these guidelines are not a substitute for the regulations, but a guide to States on compliance with the requirements in the regulations.

Comment: Several commenters stated that we should revise the requirements for active treatment to encompass directly all of the services described in §§ 442.442 through 442.460 of the

proposed regulations, since these sections more clearly describe the whole active treatment process than our proposed definition does.

Response: We agree in part with the commenter. In restructuring the regulations in the condition format, we have established a condition of participation concerning active treatment services (§ 483.440). Under that condition, we have included as standards (a) through (f) the standards that we had proposed as § § 442.440 through 442.450:

(a) Standard: Active treatment (proposed as § 442.440).
(b) Standard: Admissions, transfers and discharges (proposed as § 442.442).
(c) Standard: Individual program plan (proposed as § 442.444).
(d) Standard: Program implementation (proposed as § 442.446).
(e) Standard: Program documentation (proposed as § 442.448).
(f) Standard: Program monitoring and change (proposed as § 442.450 (b), (c), (d), and (e).

We have not included the proposed standards at §§ 442.452 through 442.460 under the condition of participation concerning active treatment. We believe that the proposed standards at §§ 442.452 through 442.458 are grouped more appropriately under the condition concerning client behavior and facility practices (§ 483.450 of this final rule), and the proposed standard at § 442.460 concerning professional program services is placed more appropriately under the condition for facility staffing (§ 483.430 of this final rule).

Comment: Some commenters requested that we clarify the meaning of the proposed rule at §§ 442.440(b) and 435.1009(b) that state that "Active treatment does not include maintenance of generally independent clients who are able to function with little supervision or who require few if any of the significant active treatment services described in 42 CFR Part 442." Commenters suggested that either we define what we mean by the phrases "generally independent clients", "significant active treatment services", "little supervision", and "few if any"; substitute other terms; or specify the amount and intensity of services necessary to qualify a client as being eligible for ICF/MR level of care.

Response: A determination that a particular client does not need active treatment, because he or she is sufficiently independent, is a decision that has to be made on an individual basis. Therefore, to allow room for professional judgment on the part of surveyors and providers, and because of the limitations of the current state-of-the-art, we believe it is necessary to describe the requirement in general terms. However, for purposes of clarity, we have revised the proposed rule, so that the regulations now describe these clients as being "able to function with little supervision or in the absence of a continuous active treatment program". We will issue interpretive guidelines that will describe the characteristics of clients who should be reviewed closely by surveyors for inappropriate placement in an ICF/MR setting. Generally, inappropriately placed clients are those clients who can become increasingly more independent without aggressive and consistent training. These clients are usually able to apply skills learned in training situations to other settings and environments. These clients would generally be able to take care of most of their personal care needs, to make known to others their basic needs and wants, and to understand simple commands. They generally would be capable of working at a productive wage level, and, to some extent, would be able to engage appropriately in social interactions. Also, usually they would be able to conduct themselves appropriately when allowed to have time away from the facilities' premises. Facilities serving these types of clients, who are by definition inappropriately placed, will be carefully evaluated for inappropriate certification as an ICF/MR.

Comment: Ten commenters objected to the active treatment program described in the proposed § 442.440(d), because it did not include the maintenance of generally independent clients. Commenters objected to this exclusion because they believe that without the programmatic structure provided in an ICF/MR, some of these clients would not be able to continue to function independently and would regress rapidly.

Response: We believe that some clients need the help of an ICF/MR to continue to function independently because they have learned to depend upon the programmatic structure it provides. We believe these clients should be trained to overcome this learned "dependency" through a carefully designed active treatment program aimed at its elimination. Active treatment for such a client should be directed toward the client acquiring skills that are self-initiated and increasingly more self-directed. It should not include the "maintenance programming" of skills already developed or providing the client with mere protective oversight. Therefore, we do not agree that the prohibition against "maintenance programming" should be deleted. On the other hand, we also believe that the commenters may be misinterpreting our intentions. If "independence" may only be maintained by means of constant interventions by ICF/MR staff through a program of active treatment, then under the terms of this regulation, the client is not independent.

Comment: One commenter inquired whether planned activities that allow a client to use a newly acquired skill for the purpose of maintaining the client's skill level, could be considered to be active treatment. The commenter suggested that to enhance and support a client's progress, active treatment should include maintaining the client's use of a newly acquired skill for a period of time in order to maximize independence as much as possible.

Response: We agree that in addition to helping a client acquire a new skill, a training program must also include a period of time during which the client has the opportunity to demonstrate that the new skill has been acquired. Assisting a client in using and improving an acquired skill is part of providing active treatment on a continuous basis, as required by § 483.440(d)(1), which is the standard relating to program implementation.

Comment: One commenter expressed concern about the proposed definition of active treatment because it includes services to prevent regression. The commenter believes that this will inappropriately allow facilities to provide, as active treatment, services to clients who function at the "brain stem" level, or whose care is geared primarily towards prevention of physical regression.

Response: We disagree. It would not be acceptable to establish an active treatment program in such a way as to preclude services from being provided to certain individuals because they have certain diagnostic labels. Moreover, current knowledge is not sufficiently advanced to allow us to preclude automatically clients with certain diagnoses from receiving active treatment because they have very severe physical or medical disabling conditions that limit their ability to understand, perceive, or to respond to their surroundings.

Comment: A few commenters did not understand how the proposed rule could allow FFP for services to "prevent regression", and yet deny FFP for services to "maintain generally independent clients". Commenters requested us to explain this apparent inconsistency.

Response: These regulations describe the types of services that constitute active treatment programs that an ICF/MR must furnish. Thus, it establishes the bases for determinations of whether or not a facility can be certified as an ICF/MF and qualify for FFP. The purpose of active treatment is to build continuously on skills already acquired and to teach new skills that will assist the client to function at higher levels of independence. This requires an active process of intervention. Since maintenance services essentially constitute a passive process, we proposed to exclude from the standard for active treatment those maintenance services which are for the purpose of providing generally independent clients with mere protective oversight (see § 442.440(b) of the proposal). As the presence of mere maintenance services increases and goal-directed learning for clients decreases, the overall nature of the facility shifts from an ICF/MR to a custodial care facility. Therefore, to be consistent with statutory intent, those facilities predominantly providing the services that we consider to be maintenance services and that are described at § 483.440(a)(2) of this final rule will not be considered to be providing active treatment and will not qualify, therefore, as an ICF/MR.

In recognition of the potential impact severe physical or medical disabilities can have on a client's ability to learn new skills, we proposed at § 442.440(a)(2) (§ 483.440(a)(1)(ii) in the final rule) to include those active interventions necessary to prevent or decelerate regression in the requirements for active treatment. An example of this is the application of specific stimulation techniques to the area of the mouth of a client with severe physical and medical disabilities. If this active intervention helps the client retain the ability to take food by mouth and decelerates the client's rate of reliance on tube feedings, then we will consider this a component of the active treatment program as described under these regulations.

Comment: Eleven commenters requested that we publish, in a timely manner, interpretive guidelines to explain how these regulations will be implemented. Also, they requested that we give greater emphasis to training both providers, and State and Federal surveyors. These commenters, although they supported the intent of the proposed rule, expressed concern that unless we provided needed training on the regulations, an acceptable balance would not be achieved between holding providers accountable for the program, and at the same time, allowing them the flexibility afforded by the new rule.

Response: We agree that training on the new regulations is essential for surveyors, and this is planned. Surveyors will need more detailed instructions concerning the meaning of the new rules and how they affect the survey process. Also, we plan to issue interpretive guidelines and surveyor procedures pertaining to these regulations.

Comment: One commenter objected to the proposed definition of active treatment because it did not include the terms "prognosis" or "professionally developed and supervised activities, experiences, or therapies". These terms are a part of the definition of active treatment that is used in the current rule at § 435.1009. The commenter stated that the use of these terms in the definition of active treatment would ensure that the development of active treatment programs would be based on state-of-the-art input, and would make clearer that professional staff are expected to participate in the treatment of clients.

Response: We did not use the term "prognosis" in the new standard for active treatment (at § 483.440(a)), because it is directly related to the medical model. We wanted to emphasize the developmental model and the importance of stressing client outcomes.

The phrase "professionally developed and supervised activities, experiences, or therapies" was not used verbatim in the new rule. However, the same requirement, in different language, is contained within the standards of this final rule relating to active treatment (§ 483.440(a)), individual program plans (§ 483.440(c)), program implementation (§ 483.440(d)), program and monitoring and change (§ 483.440(f)), and physician services (§ 483.460(a)).

Comment: One commenter asked for clarification concerning what was expected of a facility, in terms of the resources it would have to expend, in meeting the proposed requirement to assist clients in reaching their "maximum possible independence". The commenter wished to know if there was a limit on the amount of resources that a facility would have to expend in assisting a client to reach his or her maximum potential.

Response: A facility must meet all the requirements of the regulations. If a facility admits a particular client, it makes a commitment to meet that client's needs as determined by that client's assessment and IPP.

Comment: One commenter asked whether the certification survey that is conducted for an ICF/MR, also would include an evaluation of the programs provided to clients during the day if the programs were obtained by the facility from another agency. The commenter suggested that it would be fairer to the ICFs/MR if the day programs that they obtain from other agencies, are certified separately.

Response: We disagree. A facility is afforded flexibility by the regulations in determining the sources it will use to provide active treatment. It can provide services directly or obtain them from other qualified resources that are available in the community. If the facility obtains services from an outside source, the regulations require that it ensure that these services are effective and consistent with the client's overall plan. Therefore, services provided by outside sources must be coordinated by the ICF/MR to ensure that they are supportive of and consistent with services provided in the facility. Thus, the facility, as the discrete unit to be certified, will be held responsible for ensuring that all the services provided to its clients, including services such as day programs, provided by outside sources, meet the conditions specified in these regulations.

Comment: One commenter could not determine, from the proposed definition of active treatment, whether services, not included in the IPP, but which are needed to treat unforeseen or emergency health problems or behavioral disorders that interrupt or alter the IPP, could be considered to be active treatment.

Response: If an emergency occurs that affects the client's behavior or medical condition and a client's usual active treatment program cannot be implemented, the services that a facility must provide to address that emergency could be considered to be active treatment.

Comment: One commenter inquired how compliance with the proposed active treatment definition would be assessed in the following situations: (1) Clients are so severely disabled that they "seem" to be relatively inactive in their treatment; (2) clients are too active, and initiate too much in their treatment; or (3) clients participate actively in unacceptable day programs. This commenter expressed concern that the proposed definition of active treatment would result in providers devoting an extraordinary amount of energy to making worthwhile services "look right" in order to satisfy surveyors and maintain a viable funding source.

Response: Compliance with active treatment is not assessed in a vacuum. It can only be done as part of a process

that considers every aspect of the client's behavior from the functional assessment phase, up to and including, on-site observations of the client in structured and unstructured environments. Therefore, to address adequately the specific situations that the commenter describes, we would have to study a client's assessment and other relevant circumstances affecting the client's behavior.

We believe the regulations clearly require facilities to use resources to improve the skill levels of their clients and not merely to make services "look right". Throughout the regulations, we have emphasized the importance of results and outcomes, and have placed minimal importance on required processes.

S. Admissions, Transfers and Discharges (Proposed § 442.442; Final § 483.450(b))

Comment: Twenty-two commenters objected to the proposed requirement to allow a facility to admit only those clients for whom it can provide needed active treatment services. Several commenters expressed concern that the proposed standard could cause an adverse effect on clients in the following situations: court ordered commitments, emergency admissions, emergency respite cases, and delayed discharges due to lack of available alternative placements. Some suggested that the existing standard at § 442.418(c) that allows inappropriate admissions on a temporary basis should be retained. Others suggested that exceptions to the proposed standard should be allowed for up to 90 days.

Response: The statute at 1905(d)(2) of the Act stipulates that for FFP to be available for services provided to a client in an ICF/MR, the client must be receiving active treatment. Therefore, we are retaining in this final rule the proposed requirement that a facility must admit only those clients for whom it can privide needed active treatment services. We recognize that a facility may be required to admit individuals based on the order of a court. Although we do not have the jurisdiction to prevent the courts from ordering placements of clients who do not need active treatment in ICFs/MR, there is no implication that these clients automatically must be classified by Medicaid as being eligible for the ICF/MR benefit.

We must emphasize that the presence of any group of clients could call into question the overall nature of the services provided. If the primary purpose of the facility is no longer to provide services to the persons with mental retardation or related conditions, the facility would no longer qualify as an ICF/MR.

Comment: Several commenters recommended that the rule allow facilities to provide clients with active treatment services either directly or through administrative arrangements.

Response: We agree. Therefore, we have deleted the reference to clients "for whom the facility can provide needed services" that appeared in the proposed rule at § 442.440(b) so that the final rule at § 483.410(d) allows facilities the flexibility to provide or arrange for the provision of needed active treatment services. However, the facility remains responsible for all services furnished to its clients.

Comment: Eight commenters objected to the proposal to require that the preadmission evaluation must be completed or updated no more than 90 days before admission. Some of these commenters suggested alternative time frames such as: 365 days for developmental assessments, and 180 days for any assessment conducted on a severely or profoundly retarded individual. Others recommended that we eliminate any specific time frame, and only require that the facility use current assessment data.

Response: The intent of the proposed standard was to ensure that admission decisions were based on current and valid information. However, we recognize that to require that this information be updated or completed no more than 90 days before admission is somewhat arbitrary. Therefore, in accordance with our commitment to stress result-oriented standards, we have deleted the 90 day timeframe and have modified the rule, so that the final regulations require that admission decisions be based on currently valid assessments.

Comment: A few commenters expressed concern because the proposed rule did not specifically mention nutritional status as one of the items that must be evaluated as part of the client's comprehensive assessment. In their opinion, an evaluation of nutritional status should be included because it is essential to understanding the client's physical status.

Response: It was our intent that an evaluation of the client's nutritional status would be included as part of the comprehensive assessments. However, we agree that unless nutritional status is specifically mentioned in the rule, it may not be included as part of the client's assessment. Therefore, we have revised the regulations to state explicitly that nutritional status is one of the items that must be evaluated as part of the client's assessment that is used by the facility in making admission decisions. We note that in the final rule, we refer to this assessment as a "preliminary", not a "comprehensive", assessment since it is completed before the client's admission to a facility. Also, in the final rule, we have referred to the assessments conducted after admissions by the interdisciplinary team (proposed in § 442.444(c)) as comprehensive assessments.

Comment: About one-third of the commenters objected to the proposed rule at § 442.442(b)(3) and § 442.464(a)(1) because it would require that a physician be involved in the development of each client's IPP. Some of these commenters stated that physician involvement in the development of a client's IPP should be required only if it is determined that it is "appropriate" or "needed". Other commenters thought a nurse should be able to serve as a representative for the physician. Several commenters stated that physicians should be able to participate by means of a written report, or through the review and approval of the IPP within 7 days of its development. Finally, some commenters felt that this requirement was too aligned to the medical model and would increase the costs of the program without providing any significant benefit to the client.

Response: Section 1903(g)(1)(B) of the Act requires, in part, that services provided to Medicaid recipients in ICFs must be furnished under a plan established and periodically reviewed and evaluated by a physician. The regulations implementing the statute are at § 456.380. This section specifically requires a physician to establish a written plan of care for each applicant or recipient before he or she is admitted or before payment may be authorized. Consistent with the statute and § 456.380, this rule requires that a physician must participate in the establishment of a client's IPP.

In developing an IPP, the team must study all of the client's needs, both medical and non-medical, and how these needs are interrelated. Therefore, participation by a physician is required to ensure that an assessment of the client's medical status is thoroughly considered and addressed by the team as it develops the IPP. Thus, the intent of the rule is to require that a physician must have input into the development of the IPP, rather than merely review or approve the IPP. This input may be by means of written reports, evaluations, and recommendations. However, the input must be from the physician, and not from a person, such as a nurse, who

is serving as the physician's representative.

As the commenters pointed out, the requirement that a physician be involved in the development of each client's IPP appeared in two of the proposed standards. In order to eliminate duplication, we have deleted this provision under the standard concerning admissions, transfers and discharges and retained it under the standard concerning physician participation (§ 483.460(b)).

Comment: Thirty-one commenters requested clarification concerning how many days the facility has to develop the client's initial IPP. Twenty-eight commenters said it was unclear because the proposed standard at § 442.442(b)(3) would require that at the time of admission, a physician must be involved in the development of the initial IPP and seemed to conflict with the proposed rule at §442.444(d) that would allow up to 30 days after admission for the interdisciplinary team to develop the IPP.

Response: "At the time of admission" means during the admission process which extends from when the client is admitted to the time the initial IPP is completed.

Comment: Several commenters requested clarification of the meaning of the terms "transfers", "discharges" and "good cause".

Response: Interpretive guidelines will explain that transfer means the temporary movement between facilities or permanent movement between living units of the same facility. Discharge means the permanent movement of a client to another residence that is not under the jurisdiction of the facility's governing body.

Moving a client for "good cause" means for any reason that is in the best interest of the client. Also, we believe the client, family, or guardian should be provided with sufficient time to prepare for any move (except in emergencies). The exact amount of time cannot be specified, since it will depend upon the reasons for the move, the effect it will have on the client and the client's family or guardian, and the type of adjustments that will have to be made to prepare for the change. Moreover, the family and client usually should be involved in the initial stages of any decision to move a client, since these decisions generally should be part of a team process that includes the client and his or her family or guardian. Also, if a client has an advocate, the advocate should participate in the decision making process. We recognize that the decision to move a client often results in disagreements, uncertainties and conflicting interests. Therefore, we believe that it is important to require that there must be a good reason for deciding to move a client, and that the decision takes into consideration what best serves the interests and the needs of the client.

Comment: Several commenters asked if the facility is responsible for implementing the post-discharge plan. Other commenters asked if the client or guardian refuses to consent to the release of the client's discharge summary, would this prevent a client from being discharged. These commenters also asked whether a doctor's order was needed to discharge a client.

Response: A facility is required to develop a discharge plan of care for every client for whom it will no longer have responsibility as a result of the person moving to a new living environment. However, for purposes of certification, the facility would not be responsible for implementing this plan of care, since the client would be living in a new environment over which the facility has no authority or administrative control.

Discharge summaries are required to facilitate a client's transition to a new living environment. Therefore, if appropriate consent is given, a discharge summary should be made available to the new agency. However, failure to obtain consent for release of the discharge summary should not preclude a client from being discharged. Also, although an agency may decide to secure a physician's order before discharging a client, this is not required by the regulations.

T. Individual Program Plan (Proposed § 442.444; Final § 483.440(c))

Comment: Ten commenters requested further clarification concerning who should be appointed to the interdisciplinary team required by the proposed rule at § 442.444(a). They believe HCFA should specify the minimum number and type of individuals who must participate on an interdisciplinary team.

Response: In accordance with the proposed and final rules, a facility must establish for each client an interdisciplinary team that consists of those individuals who have the expertise required to design an effective plan that meets the needs of the client. Thus, the expertise that must be represented on a team is a case-by-case determination based on each client's needs as identified by the current comprehensive functional assessment. Therefore, we do not agree that the regulations should include more specific requirements regarding who should serve on an interdisciplinary team.

Comment: One commenter objected to the proposal at § 442.444 (c) and (d) that would require that the initial assessment of the client and the development of the IPP must be completed within 30 days after admission. This commenter suggested that 45 days after admission would be a more reasonable time frame for completing the initial assessment and the IPP.

Response: We disagree. The required time frame for completing the initial assessment and the IPP has been within 30 days after admission since the inception of the ICF/MR program. The 30 day requirement also is currently used in the ACDD standards. We believe it is commonly held by those who work in the field of mental retardation that 30 days is a reasonable length of time to complete the initial assessment and IPP for a newly admitted client.

Comment: Section 442.444(c)(5) of the proposed rule would require a facility to provide clients, "as applicable", with certain developmental assessments (including for example, assessments of affective development, vocational skills, and independent skills). Two commenters objected to the phrase, "as applicable", since they believe that all clients need to receive these assessments. Another commenter objected to this proposed provision because it would require an assessment of the independent living skills of all clients, even if it appears that the client will never be able to live in the community. An additional commenter wanted clarification as to what extent the team should identify a client's needs, if the services necessary to meet those needs are not available in the community.

Response: With respect to the use of the phrase "as applicable", we agree that it did not clearly convey what we intended. Therefore, we have moved it so that it only modifies the "vocational skills" assessment category.

Regarding the requirement to assess a client's needs, our intent is to ensure that each client receives a comprehensive functional evaluation that identifies all of his or her developmental needs, regardless of the availability of services to meet those needs. Thus, each client must receive a full and comprehensive assessment, irrespective of the availability of services to meet the client's needs, or the costs that would be involved in providing the services. Also, we believe that it is necessary to assess a client's independent living skills, even if it may

seem that the client will never be able to live in the community. This part of the assessment is important in order for the team to have a complete and comprehensive evaluation that identifies all of the client's needs and strengths. It has been our experience that facilities, which assess clients' independent living skills, often unexpectedly discover that clients may already possess some of these skills, having learned them prior to initial residential placement.

Comment: Sixteen commenters expressed concern that the list of assessment categories in the proposed rule at § 442.444(c)(5) did not include all of the categories needed to ensure that the assessments would be comprehensive. Thirteen of the commenters recommended that the following assessment categories be added to the list: feeding and menu planning by a registered dietitian; leisure and interpersonal communication skills; psychosocial skills; and social work needs. Also, one commenter recommended that the rule should require that the team must use only assessment procedures that have been demonstrated to be empirically reliable and valid.

Response: We do not agree that it is necessary to include in the rule all the additional assessment categories suggested by the commenters. However, to ensure that the assessments are comprehensive, we have amended the proposed language to include the following two additional assessment categories: nutritional status and social development. With the addition of these two categories, we believe the items listed will ensure that the clients receive comprehensive assessments. Also, it is our intent by this standard to require that the assessment data used by the team must be relevant and valid, and that the skills, abilities, and training needs identified by the assessment correspond to the client's actual status. Even though it is implicitly required that facilities must use assessment procedures that accurately describe the client's current status, we have amended the regulation at § 483.440(c)(3) explicitly to require accurate assessments.

Comment: Seven commenters asked whether the proposed requirement that the IPP state specific objectives for individual needs at § 442.444(d) meant that a separate IPP objective must be developed for each of the client's needs identified by the assessment or only for those needs that have been given priority. Two commenters stated that, because of the contingencies involved, projected completion dates could not be assigned accurately to IPP objectives. Therefore, they believed that the proposed standard at § 442.444(d)(2) should be changed to require review dates instead.

Response: The intent of the standard is to require that for each of the client's identified needs, there should be a corresponding IPP objective designed to meet that need. After all the objectives have been established, they should be ranked in order of importance as determined by the client's developmental needs. Objectives considered to be most important, or that need to be implemented before others can be accomplished, should be assigned priority. For each objective given priority, the team should assign a projected date by which it believes it can accomplish the desired outcome. Also, at least annually the team should review all of the client's performance data and the projected dates of completion for each objective, so that it can make any necessary revisions to ensure the accuracy of the plan. We believe developing projected dates of completion is an integral part of the planning process because it requires the team to determine what a client must do to accomplish a particular IPP objective, and to assess the client's potential for achieving a desired outcome.

Comment: One person objected to the proposal at § 442.444(d)(1) to require that IPP objectives be stated separately, in terms of a single behavioral outcome, since this would be too limiting. Two other commenters expressed concern that the proposal to require that the organization of IPP objectives reflect developmental progressions would force facilities to adhere strictly to child development standards.

Response: We have retained the requirement that IPP objectives be stated in terms of single outcomes because if multiple outcomes are used, client performance cannot always be clearly monitored or recorded. The requirement that IPP objectives be organized to reflect a developmental progression does not mean that clients must "learn" skills in the same sequence as children do as they grow up. The proposal specified and these final regulations will specify that the objectives be organized to reflect a developmental progression "appropriate to the individual".

Comment: Section 442.444(d) of the proposed rule would require that the IPP must include specific objectives that meet the client's individual needs. A few commenters suggested that we revise this section to require a facility to identify also the purpose or outcome it plans to achieve by accomplishing a series of IPP objectives. Another commenter suggested that the term "accomplishment" should be used in place of the word "performance" in the proposal to require that IPP objectives be expressed in behavioral terms that provide measurable indices of performance. This commenter suggested that by replacing the word "performance" with the word "accomplishment", we would require facilities to provide more exact indices for measuring the client's rates of progression or regression.

Response: We do not agree that a facility should be required to identify the outcome or purpose it plans to achieve by accomplishing a series of IPP objectives. We believe such a requirement would be too prescriptive. However, we propose to require, and the final rule retains the provision, that the IPP must state what planned sequence of specific objectives has been established to meet the client's needs. For the facility to establish a planned sequence of objectives for each client, it will have to consider the outcomes and goals it plans to achieve. Also, we do not agree with the suggestion that the term "accomplishment" be substituted for the term "performance". We believe that the term "performance" adequately conveys the concept that a facility must be able to measure accurately a client's progress or regression.

Comment: One commenter objected to the proposal at § 442.444(d)(6) to require that the IPP include the programs and strategies to be used in achieving plan objectives. This commenter suggested that, since the IPPs are not always found in locations accessible to direct care staff, we should require instead that the programs and strategies be available to direct care staff, rather than require that they be included or located in the IPP.

Response: We agree that the strategies and programs that are to be used to achieve IPP objectives should be kept in a location that is readily accessible to staff. This was our intent in requiring that the strategies and programs be included within the IPP. However, as a result of the comments, we have deleted the requirement that the progarms and strategies must be included within the IPP. The final regulations at § 483.440(c)(6)(ii) will require that program strategy information be available to relevant staff and that the IPP identify where this information can be found. It will be left to the discretion of the facility to arrive at an effective means of accomplishing this.

Comment: One commenter expressed concern about the proposed rule at § 442.444(e) that would require a facility to emphasize personal care skills in IPPs. The commenter mentioned that some clients, because of extreme and permanent physical limitations, might never be able to achieve the physical dexterity necessary to perform personal care skills. In these cases, the commenter suggested that for a client to describe or communicate his or her basic needs to a caretaker, may be the highest level of independence and self-help that the client can achieve.

Response: We agree. The proposed list of examples of personal care skills (bathing, self feeding, etc.) that must be included in the IPP, for those clients who lack them, did not include "communication of basic needs". Therefore, we have added this skill to the list.

Comment: Eighteen commenters questioned the proposed regulation at § 442.444(e) that would require individual program plans to emphasize personal care skills. These commenters stated that personal care skills are not the only types of skills or training that should be emphasized in the IPP. Moreover, they believed the rule should require that the IPP must include any skill necessary to help the client achieve greater independence. They also questioned what was meant by the term "developmentally incapable" as used in the proposed requirement that the IPP emphasize personal care skills until it has been demonstrated that the client is developmentally incapable of acquiring them.

Response: To ensure that all the items included in an IPP are given sufficient importance, we have modified the proposed language. Although in the final rule, we will not require that emphasis be placed on personal care skills, we will require that the IPP include training in personal care skills for those clients who lack them. Also, we have retained the proposed language that identifies those personal care skills that are most fundamental to a person's dignity, privacy, and independence, and that must be taught to those clients who are capable of acquiring them.

We have revised the proposed rule at § 442.444(e) (§ 483.440(c)(6)(iii) of this final rule), which would have required that a client must be trained in personal care skills until he or she has acquired these skills or it has been demonstrated that he or she is developmentally incapable of acquiring them. The phrase, "until the client has acquired these skills," has been deleted, because the single concept that we wanted to convey was that clients, should receive training in personal care skills until it has been demonstrated that they are "developmentally incapable" of acquiring them. The demonstration that a client is "developmentally incapable" of acquiring personal care skills, we believe must be made by the interdisciplinary team based on its assessment of the client's developmental strengths and needs.

Comment: Seven commenters expressed concern about the proposed requirement at § 442.444(b) that parents or guardians must participate in the interdisciplinary team meetings unless their participation is unobtainable or inappropriate. Some commenters felt that participation by parents or guardians should be encouraged rather than required. Other commenters suggested that the team should be required to discuss with parents what is to be included in the IPP, but that parents should not be required to attend team meetings.

Response: The purpose of active treatment is to assist the client is achieving maximum possible independence. For this to be done successfully, we believe that direct participation in team meetings by the client, the client's parents (if the client is a minor) or appointed legal guardian should be required, unless inappropriate. If the client is a minor or an adult who has been adjudicated incompetent, then direct participation by the parent or an appointed legal guardian is essential to ensuring that the client's interests are given sufficient consideration. In the interest of the client, the participation of the parents of minors, and the legal guardians of those adjudicated incompetent, should be solicited to the maximum extent possible. Our experience has shown that clients are generally willing to have their parents participate in the planning process. However, if the client is an adult who is competent to make decisions and who is not adjudicated, parents may not participate in the interdisciplinary process if their participation is opposed by the client.

Comment: Four commenters expressed concern that the proposed rule at § 442.444(d), which would require the IPP to state specific objectives, only referred to training objectives. Therefore, it would not require that other special activities and interventions needed by the client be specified in the IPP.

Response: We have revised the proposed language so that the final rule, at § 483.440(c)(6), requires the IPP to describe all the relevant interventions that are needed to support the client towards independence.

Comment: Three commenters made recommendations about the proposed rule at § 442.444(g), which would require that a copy of the IPP must be made available to all relevant staff and to the client's family or guardian. One commenter suggested that a written explanation or interpretation of the contents of the IPP, using clear and non-technical language, should be sent by the social worker to the client's family. Another commenter stated that a copy of the IPP should be made accessible only to those families requesting it. One commenter recommended that the rule require that facilities must comply with State and Federal privacy laws when making information available to staff or families.

Response: We have retained the proposed language that would require that a copy of each client's IPP must be made available to the client's parents or guardian. We also have added a requirement to the final rule that the IPP also must be made available to the client. While the suggestion to send an explanation or interpretation of the IPP to the family has merit, we believe that as a requirement in the regulations, it would be too prescriptive. Nevertheless, although it is not required, an agency may mail a copy of the IPP to them. We do not believe it is necessary to make an additional reference to State and Federal privacy laws, since these regulations at § 483.410(b) require compliance with all applicable Federal, State and local laws.

Comment: Two commenters expressed concern about the proposed rule at § 442.444(f), which would require multihandicapped clients to spend a major portion of each day out of their beds and outside the bedroom area, moving about by various methods and devices whenever possible. The commenters stated that this requirement should be waived if contraindicated by the qualified mental retardation professional or by the physician.

Response: We disagree. We believe that except for those clients who are acutely ill (such as those who are hospitalized or incapacitated by a short term illness), all clients should be out of bed and outside their bedroom area for as long as possible each day. Mentally retarded or developmentally disabled people are not sick because they are mentally retarded or developmentally disabled. Therefore, they should not be treated as sick people unless they become ill. Consistent with the developmental model, to the extent possible, the routines and schedules of a client's day should resemble those of any non-handicapped person.

U. Program Implementation (Proposed § 442.446; Final § 483.440(d))

Comment: The proposed regulation at § 442.446(a) would require a facility to implement a "continuous" active treatment program for each client. Forty-seven commenters requested a clarification concerning what is meant by a "continuous active treatment program." These commenters expressed concern that this phrase seemed to mean that facilities would be required to provide every client with 24 hours of structured programming each day, and that the clients would have no time during the day for recreation and unstructured activities. They stated that such a requirement was unreasonable and would make it impossible for clients to live by a normal schedule. Therefore, they recommended that we delete the word "continuous," and instead specify the minimum number of hours per day that active treatment must be provided.

Response: We disagree. The word "continuous," as used in the proposed rule, was meant to convey the principle that active treatment is not the mere provision of structured training and treatment services within certain scheduled time intervals. The word "continuous" was used to convey the concept that active treatment is not a static program, but an ongoing process that provides clients with needed training and treatment through appropriate and competent interactions and interventions that are applied to the client's structured and unstructured activities, in both formal and informal settings, and in sufficient number and frequency to assist the client effectively in accomplishing IPP objectives. Because active treatment is an ongoing and continuous process, it is not possible to specify the minimum number of hours per day that active treatment is required, or the maximum length of time allowed between active treatment interventions.

Comment: Two commenters asked what time frame was intended by the proposal at § 444.446(a) to require the facility to begin implementing active treatment as soon as the interdisciplinary team has formulated a client's IPP. They were uncertain whether implementation had to begin immediately following the IPP meeting, or whether the facility could wait until the IPP document had been written.

Response: The facility must begin implementing an active treatment program for a client as soon as the client's team has determined the type of program or plan of action that the client needs. Our intent is to ensure that a client begins receiving active treatment as soon as possible after the team identifies the client's needs through a comprehensive assessment. Thus, a facility should not delay implementation of active treatment because the written document identifying the contents of the IPP has not been completed.

Comment: One commenter requested us to amend the proposed rule to require, between the time of admission and the initial IPP meeting, a daily structured program for each newly admitted client.

Response: We disagree. The time immediately following admission should be primarily for the purpose of assisting the client to become adjusted and acclimated to his or her new living environment, and for the facility to conduct the comprehensive functional assessment of the client's status as required by § 483.440(c). Therefore, we do not believe it would be appropriate to require a daily structured program during this period of time.

Comment: Several commenters asked how the active treatment schedule, required by the proposed regulations at § 442.446(c), is different from the IPP. Ten commenters objected to the proposed rule at § 442.446(c) that would require that the active treatment schedule be attached to and distributed with the IPP. They stated that an active treatment schedule is meaningless unless it is updated continually, and the amount of paperwork that would be required to distribute copies of the active treatment schedule and continually to update these copies would be excessive and counterproductive.

Response: The IPP is the vehicle that a facility must use to develop, structure and implement an active treatment program for a particular client. It states the specific objectives and behavior outcomes that the team plans for the client to achieve. As an adjunct to and in support of the IPP, the team also must establish an active treatment schedule that shapes the basic structure of the clients experience throughout the day. The schedule gives form to the program and guides the work of the staff and clients and is, therefore, a vital organizational tool in the process of implementing an active treatment program.

Also, as recommended by the commenters, we are no longer requiring that the active treatment schedules be distributed with the IPPs. Instead, in keeping with our intent to use outcome oriented standards, we have modified the proposed language, so that the final rule at § 483.440(d)(2) will require that active treatment schedules must be readily available for review by all relevant staff.

Comment: Eleven commenters objected to the proposal at § 442.446(d) to require that an IPP be implemented by all staff who work with the client. These commenters stated that every staff member who works with a client is not qualified to implement every portion of the client's IPP. Therefore, the rule should require only that there be an "awareness" of the IPP by all staff.

Response: We cannot accept this comment. The intent of the regulation is to require that all staff who have regular contact with clients, be knowledgeable of the IPPs for these clients and participate in implementing them. For example, if a client spends time regularly with any staff member, then the facility is responsible for ensuring that during this time, the staff member is able to provide needed interventions or reinforce acquired skills in accordance with the IPP. This is how the facility can implement a *continuous* active treatment program.

Comment: To ensure that direct care staff are knowledgeable about how to implement the IPPs, one commenter suggested that we require them to meet with the qualified mental retardation professionals to discuss and review the IPPs.

Response: While we agree that direct care staff should be as knowledgeable as possible about the IPPs, we believe the commenter's suggestion of requiring meetings between the qualified mental retardation professionals and direct care staff is too prescriptive.

V. Program Documentation (Proposed § 442.448; Final § 483.440(e))

Comment: Several commenters requested clarification concerning the proposed requirement at § 442.448(a) that client performance in relationship to the IPP was to be documented in measurable terms. These commenters could not determine whether the regulation required documentation consisting of raw data, progress notes, or data summaries. Furthermore, eight commenters asked how often this documentation was to be completed.

Response: The intent of the proposal was to require that raw data be kept on each client's performance that would indicate whether or not IPP objectives were accomplished. However, the comments indicate that this intent was not clearly conveyed. Therefore, the proposed language has been revised to include the word data. The final regulation at § 483.440(e)(1) will require that "Data relative to accomplishment of the criteria specified in client IPP

objectives must be documented in measurable terms." Nevertheless, in addition to the raw data, a facility may decide to use supplementary methods, such as progress summaries, to document client performance. Also, we believe that the facility should determine how often to document the data, as long as the data are documented frequently enough to measure effectively a client's performance.

Comment: One commenter asked what specific types of client performance data had to be collected to meet the proposed program documentation requirements at § 442.448(a).

Response: The facility has the flexibility to determine the type of data it wishes to collect, as long as the data are relevant and can be used to measure effectively the accomplishment of the objectives specified in each client's IPP.

Comment: One commenter inquired whether or not the data required by the proposal are to be collected on all IPP objectives or only on those for which training is currently being conducted.

Response: Since the purpose of the data is to measure client performance, data must be collected only on those objectives for which training is being currently provided.

Comment: Twenty-six commenters objected to the proposed language at § 442.448(b) that states "the facility must document that significant developmental, behavioral and social objectives . . . have taken place." Some of the commenters thought this language was confusing and submitted examples of substitute language which they felt would clarify the meaning of the proposed requirement.

Response: The proposed language has been revised to clarify our meaning. The final regulation at § 483.440(e)(2) will require that the facility must document significant events that are related to the client's IPP and assessments, and that contribute to an overall understanding of the client's ongoing level and quality of functioning.

W. Program Monitoring and Change (Proposed § 442.450; Final §§ 483.430(a) and 483.440(f))

Comment: Fifty-two commenters expressed opinions about the qualifications we proposed at § 442.450(a), for the position of qualified mental retardation professional. The proposed regulations state that each qualified mental retardation professional must have at least one year of experience working directly with individuals with mental retardation or other developmental disabilities, and be either a physician, a registered nurse, or have at least a bachelor's degree in one of the professional service categories listed in the proposed regulations at § 442.460(e). One commenter felt that a master's degree should be the minimum requirement for any qualified mental retardation professional, since they are responsible for monitoring the quality of professional services provided to clients. Another commenter suggested that any educational degree, accompanied by acceptable work experience, would be sufficient to qualify an individual to perform qualified mental retardation professional duties. Typical of another group of commenters was the strong opinion that requiring "artificial" credentials did not guarantee acceptable performance, and demonstration of competencies should be stressed instead.

Response: We believe that a certain level of professional qualification is required for qualified mental retardation professionals because of their important role in supervising the delivery of care and assisting clients in meeting their developmental, behavioral and social needs. Thus, we have retained the proposed requirements for a qualified mental retardation professional. However, in the final rule, we have specified, in order to clarify our intent, that doctors of osteopathy are qualified to be qualified mental retardation professionals as well as doctors of medicine.

Comment: Fourteen commenters objected to the proposed requirement at § 442.450(c)(1) that the interdisciplinary team must approve all changes made to the objectives of a client's IPP. These commenters expressed concern that this requirement would increase administrative processing time and costs without resulting in any significant gains for the clients.

Response: The intent of the proposed rule was to ensure that the IPP would be reviewed regularly and that the team would approve any changes that were made to the individual objectives of a client's IPP. We agree that this proposed requirement could be too prescriptive, especially since we have retained the proposed requirement (at § 483.440(f)(1) of this final rule) that the IPP be reviewed and revised whenever a client accomplishes an objective, or is regressing or losing skills, or failing to progress. Therefore, we have revised the proposed language. The final rule will designate the qualified mental retardation professional as the agent responsible for reviewing and revising the IPP as necessary. This is consistent with the qualified mental retardation professional's responsibility to integrate, coordinate and monitor the IPP. However, the interdisciplinary team, in accordance with the final rule at § 483.440(f)(2), is responsible for revising each client's IPP, as appropriate, and for reviewing each client's comprehensive functional assessment for relevancy, at least annually, and for updating it as needed.

Comment: Twelve commenters objected to the proposed regulation at §442.450(c) because it does specify how often the IPP should be reviewed between the required annual reviews. These commenters asserted that facility staff could not be depended on to initiate reviews or revisions of the IPP when necessary (such as when objectives have been completed or when strategies are proven ineffective), unless the regulation requires them to do so. They suggested several examples of specific time intervals that they thought should be included in the rule to indicate how often IPPs must be reviewed.

Response: We do not believe it would be appropriate to specify in the rule how often the IPP must be reviewed between the required annual reviews, since the number of times an IPP should be reviewed depends on many factors. As stated earlier in this preamble, § 483.440(f)(1) of this final rule will require the qualified mental retardation professional to review and revise the IPP as necessary, including, but not limited to, when the client has successfully completed an objective, or is regaressing or losing skills, or is failing to progress, or is being considered for training towards new objectives. Thus, because there are many factors that determine when a review is needed, we do not agree with the commenters' suggestion.

Comment: Nine commenters objected to the proposal at §442.450(a)(1) to require qualified mental retardation professionals to be employees of the facility. These commenters expressed the view that it may be cost prohibitive for facilities, which serve very few clients, to hire someone full-time for this function, especially when the service of a qualified mental retardation professional could be obtained more cost effectively through suitable arrangements with an outside agency.

Response: We agree. Although the qualified mental retardation professional occupies a key position in terms of monitoring and overseeing a client's IPP, and we believe this role is central to the statutory active treatment requirements, we do not believe it is administratively feasible or cost

efficient to require that the qualified mental retardation professional be directly employed by the facility.

Comment: Seventeen commenters expressed numerous opinions about the requirement proposed at § 442.450(e)(1), that a specially designed outside committee must approve individual behavior management programs that involve a potential risk to the client. Comments ranged from suggestions for deleting this requirement totally, to giving the committee more authority and autonomy to do its job and requiring the committee to perform its oversight function at least quarterly. However, the concern expressed most frequently by commenters was that the membership of the committee should include individuals who have the expertise necessary to make appropriate decisions regarding the facility's practices and programs.

Response: The intent of the proposed regulation was to require a facility to establish a committee or committees that would serve as an advocate for the protection of the rights of individual clients, especially as they may be affected by behavior management programs. Under the proposed rule, membership was to include representatives from the facility's staff, clients, parents, and persons with no ownership or control interest in the facility. However, we agree that the committee also should include a person or persons who are knowledgeable about current practices for controlling inappropriate client behavior. Therefore, we have revised the proposed language, so that the final rule at § 483.440(f)(3), will require that the facility must include on the committee the participation of a qualified person or persons who have either experience or training in contemporary practices to change inappropriate client behavior.

Comment: A few commenters inquired whether the required outside committee have to review *all* IPP programs, or only those IPP programs that posed a potential risk to the client.

Response: The final rule will require the specially constituted committee to review at least those programs and facility practices that pose a potential risk to clients. However, as stated in the final rule, the committee is free to review any area it believes needs to be addressed.

Comment: One commenter wanted to know if a behavior management program that involved potential risks for a client, could be implemented *before* it was approved by the outside committee.

Response: The intent of the regulation is to require the approval of the outside committee before such programs are implemented. This is to ensure that if there are risks to the client that are unwarranted, the programs will not be implemented.

Comment: One commenter inquired whether or not access to confidential client information by the outside committee's non-staff members would place the facility out of compliance with the proposed rule at § 442.432(b) that would require the facility to keep all client information confidential.

Response: The committee needs to know relevant client information to function properly. Therefore, the facility could ask members to sign an agreement to maintain confidentiality if there is a concern in this regard.

Comment: Fourteen commenters requested clarification about the proposed language at § 442.450(e)(2) that would authorize the outside committee to review, monitor and make suggestions concerning any areas that it believes need to be addressed. Some of these commenters expressed concern that the committee might try to run the facility or that it might duplicate the role of other existing facility committees. Other commenters suggested that the role of the outside committee should be limited to "client risk" issues exclusively.

Response: The proposed rule would require a facility to establish a "specially constituted committee or committees," to protect client rights. The intent was to allow a facility the flexibility to decide whether to use one advisory committee or to use as many committees as it chooses, as long as at least one committee was established to protect client rights. As intended by the proposed regulation, the role of the outside committee or committees, was not to dictate facility policy or control management. Rather, the role of the committee was to review facility practices and programs in order to make recommendations concerning the protection of client rights. To clarify our intent in this area, the final rule at § 483.440(f)(3)(i) states that the role of the committee is to review, monitor and make suggestions to the facility about its practices and programs. It also requires that individual programs that involve risks to client protections and rights must be approved by the committee.

Comment: Three commenters supported the proposed rule at § 442.450(f) that would allow the requirement for an outside committee to be waived if State law or regulations provide equivalent client protection and consultation. However, the commenters suggested that the rule also should allow this requirement to be waived if an applicable court decree requires oversight mechanisms which result in equivalent client protections. These commenters pointed out that, in some instances, the oversight mechanisms established by judicial decrees are far more stringent than those required by the proposed rule.

Response: We agree. We have amended the proposed rule so that the final regulation at § 483.440(f)(4) states that the provisions of the rule that pertain to the specially constituted committee may be modifed, if, in the judgment of the survey agency, a court decree provides for equivalent client protection and consultation.

Comment: Six commenters objected to the proposed rule at § 442.450(d) that would require the facility, at least annually, to reassess the client and make revisions to the IPP. These commenters stated that it would be wasteful to require an annual assessment if the client's status had not changed since the last assessment. They suggested that we allow the team to determine how often it is necessary to reassess the client.

Response: We agree. The language of the proposed rule did not convey clearly out intent to allow the team to determine whether a client needs a new assessment. To clarify out intent, the final rule at § 483.440(f)(2) will state that, at least annually, the assessment of each client must be *reviewed* by the interdisciplinary team for relevancy and updated as needed.

Comment: One commenter inquired whether the annual review of the IPP required by the proposed rule at § 442.450(d) has to be conducted on the 365th day after the last review, by the 365th day after the last review, or within some other time interval.

Response: The interpretive guidelines will explain that to meet this requirement, the annual review of the assessment and the IPP generally must be completed by the 365th day after the last review. This is consistent with current regulations on utilization control at § 456.360(b)(2)(i).

Comment: Four commenters requested that HCFA specify in the rule the maximum number of clients that a facility would be allowed to assign to the caseload of a qualified mental retardation professional. These commenters felt that caseloads have been overextended in the past. They suggested that unless we specified what we consider to be an acceptable ratio of qualified mental retardation professionals to clients, we would continue to perpetuate paperwork as the primary function of the qualified mental retardation professional.

Response: We disagree. Each client's active treatment program must be effectively integrated, coordinated, monitored, reviewed, and revised, as necessary, by a qualified mental retardation professional. The number of qualified mental retardation professionals that a facility requires to provide these services effectively will vary depending on several factors including, but not limited to, how many clients it has, the needs of these clients, the number and qualifications of additional staff members, and other duties that may be assigned to the qualified mental retardation professionals. Thus, since these types of factors must be considered on an individual basis before a determination can be made, we do not believe it is feasible to attempt to specify in the rule the maximum number of clients that may be assigned to a qualified mental retardation professional. However, in the final rule, we have stated at § 483.430(b)(2) concerning professional program services that qualified professional staff must be sufficient in number to implement the IPP.

Comment: One commenter wished to know if a client's individual program plan could be coordinated and monitored by more than one qualified mental retardation professional.

Response: The interpretive guidelines will explain that a client's IPP may be coordinated and monitored by more than one qualified mental retardation professional. However, there must be one qualified mental retardation professional who is assigned primary responsibility for coordinating the client's IPP. This qualified mental retardation professional is responsible for serving as the primary advocate for the client and for ensuring that monitoring functions delegated to other qualified mental retardation professionals are completed appropriately.

Comment: One commenter asked if the regulations required that a person designated as a qualified mental retardation professional had to do the duties of a qualified mental retardation professional exclusively, or could the person be allowed to perform other professional staff duties in addition to the qualified mental retardation professional duties.

Response: We believe that it is up to the facility to allocate staff resources in whatever manner it believes is necessary as long as it ensures that the qualified mental retardation professional function is performed effectively for each client.

X. Behavior Management (Proposed §§ 442.452, 442.454, 442.456, 442.458; final § 483.450)

The four sections of the proposed rule dealing with management of client behavior, §§ 442.452 through 442.458, received the largest volume of comments overall. Pertaining to these four sections, we received comments from 83 different commenters. Most of the individual commenters raised issues that apply to several of the proposed sections. Due to the cross-cutting nature of these issues, we have grouped these four proposed sections together for the purpose of responding to public comments.

Comment: A significant number of commenters expressed concern that the way the proposed §§ 442.452 through 442.458 were organized was confusing and lacking sufficient safeguards to protect clients and ensure good practice. Several of these commenters submitted suggested language that would substantially revise the entire four sections. Many of the commenters also referred to the statement in the preamble of the NPRM, that our intent, in issuing new regulations, was to be consistent with accreditation standards published in 1983 by the Accreditation Council on Services for People with Developmental Disabilities (ACDD). They suggested that to the extent possible, we use the language of the ACDD standards in the regulations.

Response: We agree that the requirements of these four sections needed to be revised for purposes of clarification. To express our intent more clearly, we have reorganized the four standards pertaining to the management of client behavior into five. These are grouped under the condition of participation at § 483.450 of the final rule. In revising the proposed rule, we used in some instances the language of the ACDD directly, and in other instances, we borrowed heavily from the commenters.

Comment: Six commenters criticized §§ 442.452 through 442.458 of the proposed rule because in their opinion, the techniques mentioned in these sections (for example, time-out devices, aversive conditioning, drugs for behavior management, and physical restraints) did not reflect the "state of the art" technology used in the field of mental retardation and developmental disabilities.

Response: We made no attempt to determine what constitutes state-of-the-art techniques in the field of mental retardation. Instead, we attempted to ensure that whatever techniques are utilized by facilities to protect clients from abusive or neglective practices are appropriate.

Comment: Nine commenters objected to §§ 442.452 through 442.458 of the proposed rule because they believe these sections are too negative. They stated that the use of positive approaches, including positive reinforcement, known to be effective in managing inappropirate client behavior, was not required nor emphasized sufficiently. They also requested that the rule include a description of those positive principles that a facility should follow in the development of its policies, procedures and specific programs regarding the management of inappropriate client behavior.

Response: The purpose of the entire active treatment section of the final rule is to require facilities to provide positive environments and training methodologies that will result in clients acquiring more adaptive behavior. Also, the final rule incorporates several suggestions that were made by commenters on how to strengthen and emphasize the use of positive approaches to behavior management. For example, § 483.450(a)(ii) of the final rule regarding conduct toward clients, requires the facility to emphasize and accommodate client choice, self-determination, and self-management in the daily decision-making process. Also, in the final rule § 483.450(b), regarding management of inappropriate client behavior, requires not only that the facility guarantee that it will use the least restrictrive/least intrusive techniques that are effective to manage client behavior, but also that the client's safety, welfare, and human rights will be adequalty protected at the same time.

Comment: One commenter objected to the proposed rule because it allows use of aversive techniques to manage client behavior. The commenter stated that research evidence does not support the efficacy of aversive, behavioral interventions. Also, the use of aversives to manage client behavior raises disturbing legal and ethical issues, and diminishes the dignity of the client. Furthermore, the commenter suggested that HCFA specifically prohibit the use of any technique to manage inappropriate client behavior that would deprive clients of nutritional food or hydration, or that would inflict pain, whether physical or psychological, or that would use chemical restraint in place of programming.

Response: Varying opinions exists on the efficacy of these techniques. Rather than prohibiting techniques, our role is to ensure that if aversives are used, adequate safeguards are included.

Sometimes these techniques are more successful in halting severe, self-injurious behavior and other grotesque behaviors, than more positive methods would be. However, we do believe that client protections are necessary to safeguard clients against the misuse of these techniques. As originally proposed, to ensure that these techniques are properly used, the final rule at § 483.420(d)(1)(ii) prohibits staff from disciplining a client by withholding adequate food or hydration. The final rule at § 483.450(b)(3) will require that any technique used to manage inappropriate client behavior (including drugs) cannot be used as a substitute for an active treatment program. The final rule at § 483.450(e)(2) will require that drugs used for control of inappropriate behavior must be used only as an integral part of an IPP. It also will prohibit at § 483.420 (a)(5) and (d)(1)(i) physical, verbal, sexual or psychological abuse or punishment.

Comment: Seventeen commenters criticized our interchangeable use of the terms "behavior management" and "behavior modification," since the terms are not synonymous. These commenters stated that behavior modification is only one specific model within the field of behavior management, yet as used throughout the proposed § 442.454, behavior modification appears to encompass every type of program designed to alter or shape behavior. For example, in the proposal, § 442.454(b) refers to the use of drugs for "behavior modification purposes", and § 442.458(b) refers to "drugs used for behavior management".

Response: We agree that the two terms are not synonymous, and as used throughout the proposed rule, could cause confusion. Our intent in the proposed § 442.452 was to regulate "conduct toward clients by facility staff," and our intent in the proposed § 442.454 was to regulate the "management of inappropriate client behavior." Thus, we have renamed these standards accordingly. Also, in the final rule, the terms "behavior management" and "behavior modification" are not used in these specific standards, and other editorial changes have been made to describe our intent more clearly.

Comment: Seven commenters urged HCFA to include provisions in the final rule that would prohibit facilities from using restrictive techniques as part of an ongoing "program" or from making routine "programmatic usage" of these techniques, unless there is evidence to justify such usage. These commenters believe that such ongoing "programs" or "programmatic usages" of restrictive techniques are viewed by staff as a "standing order," to allow these techniques to be used. Therefore, they believe such "programs" are used to justify putting clients back into restrictive devices, even though their behavior does not warrant this. They believe also that the use of such "programs" makes it almost impossible to track the effectiveness of less restrictive techniques; and encourages teams to use aversive techniques in anticipation of behavior that may never happen or may happen only infrequently.

Response: We agree with the commenters' concerns. Restraining devices and time-out rooms should not be used to suit the convenience of the staff, to accommodate staffing shortages, or to substitute for effective active treatment. Therefore, we have revised the proposal to state at § 483.450(b)(3), that techniques to manage inappropriate client behavior must never be used for staff convenience or as a substitute for an effective active treatment program. Also, the final rule, at § 483.450(b)(5), will prohibit the use of standing or as needed programs to control inappropriate behavior; at § 483.450(d)(4) it will require that clients must be released from restraining devices as quickly as possible; and at § 483.450(d)(1)(ii), it will stipulate that restraints may not be used as an emergency measure unless the client's behavior threatens self or others.

Comment: Some commenters requested that, for purposes of emphasis, we move to the beginning of § 442.454, the requirement proposed at § 442.454(f), that less restrictive methods of managing behavior must be attempted and documented to have failed before more restrictive techniques, are employed. They believed that changing the location of this requirement would highlight for facilities that the use of positive behavior shaping techniques should always be the first method of choice.

Response: We agree that emphasis should be focused on the importance of using positive means for changing behavior. Thus, the proposal has been revised so that the standard at § 483.450(b) concerning the management of inappropriate client behavior will include the requirement that a facility must rank all the interventions it wishes to use to manage inappropriate client behavior along a hierarchy ranging in order from the most positive or least intrusive procedures, to the least positive or most intrusive procedures, and then implement them in that order. Moreover, a program using more restrictive techniques may not be used before programs using less intrusive techniques have been demonstrated to be ineffective.

Comment: Three commenters felt that the proposed rule at § 442.454(f), which requires facilities to demonstrate that more positive, less intrusive techniques are ineffective, before using more intrusive procedures, was too strict and did not allow a facility to use state-of-the-art technology to manage client behavior. Commenters suggested that this requirement should be waived if the team determines that less restrictive techniques of managing behavior would be unlikely to succeed.

Response: We agree that the team should determine what techniques are to be used with clients. However, the intent of the final rule, at § 483.450(b), is to protect clients' rights, and to ensure that the least restrictive technique, which can effectively change the client's behavior, is employed. Thus, the team is responsible to establish sufficient documentation and clear evidence to justify the use of a more restrictive technique. This standard does not take away the team's discretion, it only requires that there be evidence to support the team's decision not to use a less restrictive technique.

Comment: Sixteen commenters requested that we include a section in the final rule to define the techniques relevant to managing client behavior and specify the conditions under which these techniques can or cannot be used. Examples of techniques that commenters suggested be included in this section are: time-out; aversive conditioning; aversive techniques; physical restraints; drugs for behavior management; corporal punishment; psychological punishment; behavior modification; and behavior management.

Response: We do not agree that the regulations should specify what techniques a facility may use to manage client behavior. However, in the interpretive guidelines, we plan to provide more information concerning the meaning and use of behavioral management techniques. It should be noted that some of the terms that the commenters have requested us to define, have been deleted from the final rule.

Comment: Thirty commenters objected to our use of the term "physical restraint" throughout the proposed § 442.456 dealing with physical restraints. Commenters expressed concern that unless the term "physical restraint" was defined, the requirements pertaining to the use of physical

restraints could be applied inappropriately to devices that assist in the positioning of clients or facilitate the implementation of time-limited medical procedures. The commenters suggested that we define the term "physical restraint" and that separate provisions be included for positioning and medical restraining devices.

Response: Interpretive guidelines will define a physical restraint as any physical or mechanical device that the client is unable to remove easily, and that either restricts the free movement of the client, or the movement or normal function of a portion of the client's body, or deprives the client access to a portion or portions of the client's body. It was not our intent that the proposed physical restraint requirements should be applied to devices used for client positioning or for medical procedures. Therefore, we have accepted the commenters' criticism that this needs to be clarified, and we have made two revisions. In the final rule, § 483.440(c)(6)(iv) concerning IPPs specifically provides for the use of mechanical supporting devices. The other revision is located at § 483.450(d)(1)(iii) of the final rule, which allows facilities to use restraints as time-limited, physician prescribed, health-related, protective devices.

Comment: Two commenters requested clarification concerning who can authorize the use of physical restraints for a client. The commenters suggested that only a physician, or a physician together with a qualified mental retardation professional, should be allowed to authorize the use of physical restraints.

Response: We have modified the proposed requirement that the facility identify who can authorize restraints. The final rule at § 483.450(d) allows the interdisciplinary team to authorize the use of physical restraints as part of an IPP. The rule also recognizes that on occasion, emergency usage of restraints might need to occur. We believe that it would be too prescriptive to dictate to a facility who the authorizing person must be for emergency usage.

Comment: Nine commenters objected to the proposed rule at § 442.456(c) because they believe that written authorizations for restraints not used as part of a behavior modification program, should not be allowed to be in effect for up to 12 hours. These commenters also objected to the proposed rule at § 442.456(h), because they believe facilities should be required to release clients for more than a ten minute period for each two hours that a restraint is applied. They maintain that any client placed in a restriant for two straight hours, would forget why the restraint had been applied. They were especially concerned about how this would affect a client who was placed in a restraint for two or more consecutive two hour periods. They thought that such consecutive restraint applications would constitute punishment. They opposed allowing written authorization for restraints not used as part of an integrated program, to be in effect for up to 12 hours, because they believe such authorizations should be used only in the case of an emergency, and emergencies generally do not last for that length of time.

Response: We believe that allowing an authorization for the emergency use of a physical restraint to be in effect for up to 12 hours is appropriate. A 12-hour authorization does not mandate that a client must be placed in a physical restraint for 12 hours. It means that a client's situation is so unstable that the facility has determined that the continued or intermittent use of a physical restraint might be needed, and that official authorization for usage can occur for a 12-hour period. We also do not agree with the commenter's who preferred more frequent releases of restraints (for example, release for 10 minutes every hour rather than every two hours as was proposed). We note that the ACDD in their past and recently released new standards require release for ten minutes every two hours. We do not believe that it is appropriate to require a more stringent standard than that developed by experts. Also, to ensure the appropriate use of restraints, the final rule at § 483.450(d)(4) requires that a client must be released from a restraint as quickly as possible, and must be checked every 30 minutes while the restraint is applied.

Comment: Five commenters objected to the proposed rule at § 442.456(e) because they believe that clients placed in restraints shold be checked more often than every 30 minutes. They expressed concern that a 30-minute interval between checks was too long and that it may be traumatizing for some clients to be left alone for that length of time. Commenters' suggestions ranged from requiring checks every 15 minutes, to requiring "continuous" observation by staff.

Response: We do not agree that the interval should be shortened. The proposed rule stated and this final rule states that a client must be checked at least every 30 minutes by staff. We believe that to ensure a client's physical safety, it is sufficient to check a client at least once every 30 minutes. However, we recognize that in some cases a client's psychological and physical well being might be enhanced by more frequent checks, and for some of these clients continuous visual supervision might be appropriate. It is also true that for some manipulative clients, constant visual supervision or very frequent checks would serve to reinforce inappropriate behavior and thereby reduce the clinical effectiveness of using the restraint. Therefore, constant or very frequent monitoring may be helpful for some clients and contraindicated for others. Our purpose is not to address every particular case, but to stipulate that, as a minimum requirement, all clients in restraints must be checked at least every 30 minutes. In the final rule, this requirement is found at § 483.450(d)(4).

Comment: Four commenters requested us to modify the proposed rule at § 442.456(h) that would require that the opportunity for motion and exercise must be provided for a period of not less than 10 minutes during every two hours that a restraint is applied. Commenters suggested that if a restraint was worn by a client all night long, it would be unreasonable to wake the client to take the restraint off for 10 minutes every two hours. They suggested that we add to the regulations that the opportunity for 10 minutes of motion every two hours must be provided only when a client is wearing the restraint and awake.

Response: We do not agree. First, the burden of proof would fall on the facility to be able to justify why the continued usage of restraint is necessary during sleeping hours, as on the surface, it would seem that most clients, while asleep, would not do damage to self or others. However, some clients may awaken during the night and engage in assaultive or aggressive behavior. If restraints are used to replace staff shortages or in place of an active treatment program aimed at eliminating this behavior, then the rule forbids the practice. For those very small numbers of clients, whose behavior might warrant the use of a restraint during the night, the provisions pertaining to motion and exercise apply. Opportunity for motion and exercise for those clients, who wear physical restraints that limit their free movement, is necessary to maintain blood circulation and to ensure that clients do not become stiff or lose any range of motion. Thus, we have kept the proposed requirement, since a restraint can cause loss of range of motion to occur whether the person is awake or asleep. However, if a restraint is worn to deprive a client of access to a portion or portions of his or her body, and does not restrict range of motion, then exercise of the "restrained" area would not be needed.

Comment: A few commenters objected to the proposed rule at § 442.456(i) because it would allow a client to be placed in a totally enclosed device. Commenters suggested that if we allowed this practice, it would appear that we condone "putting a person in a cage", which would be demeaning and dehumanizing for the client, and potentially pose a fire hazard.

Response: We agree that the practice of putting an individual in a barred or totally enclosed device is very restrictive, and presents special fire safety problems. Therefore, we have deleted the provision proposed at § 442.456(i) regarding totally enclosed cribs. Also, it should be noted, that we have retained in the final regulations at § 483.450(d)(7) the provisions proposed at § 442.456(j) which prohibit the use of barred enclosures that have tops.

Comment: Twenty-seven commenters objected to the proposed regulations at § 442.452(d) because they would allow staff to place a client unobserved in a room or other area from which egress is prevented as part of systematic time-out program that meets all applicable standards. Commenters expressed concern that the proposed rule would allow facilities to use "seclusion" inappropriately, since it does not identify the "applicable standards" that must be met for the practice to constitute a proper use of time out. The commenters recommended that the regulations clarify that for "seclusion" to constitute a proper use of time out, it must be a procedure in which the client, due to inappropriate behavior, is removed from a situation that positively reinforces that behavior, in order to decrease the frequency of the behavior. Commenters also suggested that we use the language of the corresponding ACDD standard pertaining to the use of time-out rooms, to distinguish the use of "time out", from the practice of "seclusion".

Response: Our intent was to adopt the criteria used by the ACDD in addressing the issues pertaining to the use of time-out and seclusion since its criteria are widely accepted as reasonable standards. However, the comments indicate that we need to use clearer language in our attempt to adopt the criteria used by the ACDD to distinguish "seclusion" from "time-out". Therefore, in this final rule at § 483.450(c), we have consolidated in one standard all the requirements that must be met for a time-out activity to qualify as an acceptable procedure, and have used revised language to clarify our meaning.

Comment: Commenters were evenly divided in their opinions regarding whether or not the requirements pertaining to the use of time out, which were proposed at §§ 442.452(d), 442.454(b), and 442.454(e) (1) and (2), should apply to all time-out procedures, or only to those which use "devices" as part of the time out.

Response: The intent of the proposed rule was to prohibit seclusion, and to regulate the use of devices that are employed as part of a time-out procedure. As discussed, due to the volume of comments, we have reorganized the proposed rule and have included in this final rule a separate standard at § 483.450(c) that specifies the requirements that must be met in using time-out rooms. In addition to rooms, physical restraints are also devices that can be used for the purpose of providing time out. Physical restraints, including those that are used for purposes of time out, must meet the pertinent requirements in the standard concerning physical restraints located at § 483.450(d) of this final rule.

Comment: Opinions were expressed that were evenly divided concerning whether or not locks should be allowed on time-out rooms. Fifteen favored the use of locks, and fourteen were opposed. In addition, twenty-seven commenters stated that they could not support the proposal on the use of time-out rooms unless it included basic safeguards regarding the supervision and observation of clients, time limitations, training of staff, and room safety.

Response: We agree with the last group of commenters. Therefore, this final rule specifies the following: (1) A client may be placed in a time-out room only if placement is part of an approved program aimed at eliminating the behavior for which time out is employed; (2) emergency placement in a time-out room must not occur; (3) the client in a time-out room must be under the direct, constant, visual supervision of staff; (4) the door to the room must require constant physical pressure by staff to remain closed; (5) placement must not exceed one hour; and (6) clients must be protected from hazardous conditions while placed in time-out rooms. The final rule also includes other requirements (such as, the need for informed consent, outside committee approval, trained staff, and documentation on the effectiveness of previously tried techniques) that apply to the use of time-out rooms, as well as to the use of any restrictive technique.

Comment: Several commenters objected to the proposed rule at § 442.454(d) that would allow a professional staff member, under extraordinary circumstances, to approve placing a client in a time-out room for longer than one hour. Commenters expressed concern because they believe the term "extraordinary circumstances" is too vague to be used as a standard to regulate technique that is so intrusive to personal liberties. Also, they believe that being placed in a time-out room for longer than an hour would do no more for the client than serve as a punishment.

Response: One hour can be a very long period of time for a client to be kept in a time-out room and to be removed from positive reinforcement. We have found that most clients leave time-out rooms within a very short period of time after being placed there (usually within five to fifteen minutes) although some remain for much longer periods of time, usually on average around 45 to 60 minutes. Allowing time intervals beyond an hour, we agree invites potential for abuse. Therefore, in this final rule, we have deleted the provision that would have allowed a professional staff member to approve, in extraordinary instances, the use of time out for longer than an hour.

Comment: Some commenters objected to the requirement proposed at § 422.458(b) that drugs used for behavior management must be used only as an integral part of the client's IPP which is directed toward the reduction of, and eventual elimination of, the behaviors for which the drugs are employed. Commenters stated that this requirement is too idealistic because there are some individuals whose inappropriate behavior will never be totally eliminated and who will always need the support of drugs at a maintenance level. They suggested that the rule include separate requirements for those clients who are prescribed drugs for psychiatric disorders.

Response: We disagree. Our concern is that there must be an aggressive program to reduce and eliminate the behaviors for which the drugs are employed, regardless of the source or the nature of the diagnosis that is the basis for prescribing psychoactive medications. Thus, the facility must examine all the factors that might relate to the client's need for drugs. This includes the client's behavior, the staff's conduct toward the client, the family, the environment, and other factors that might influence the client's need for drugs, as well as the diagnosis and the medication regimen. Based on an evaluation of these factors, an active treatment program aimed at the acquisition of appropriate behavior by the client, and the eventual elimination of the need for drugs must be pursued within the context of a team process that draws on the expertise of all of its

members, including that of the physician.

Comment: Several commenters objected to our proposed standard at § 442.458 on drug usage, because in their opinion it did not adequately address issues pertaining to the need to obtain informed consent from the client regarding the use of drugs. Also, they believed that the standard did not adequately deal with issues pertaining to the prescription, monitoring, and review of psychotropic medications. Commenters stated that the misuse, and the inadequate monitoring and evaluation of psychotropic medications in mental retardation facilities has been well known and documented for years. They referred to a report from the American Psychiatric Association (APA) that medication to control inappropriate behavior may be prescribed for as many as 55 percent of those with developmental disabilities, despite research evidence that seriously questions the effectiveness of these drugs in treating behavioral disorders. They stated that the APA report indicates that physicians usually do not adequately evaluate the effectiveness of the medications, prescribe them for too long a period of time, and do not monitor their side effects or interactions with other medications.

Response: The purpose for this proposed standard was to prohibit the uninformed, misguided use of chemical agents to suppress and manipulate client behavior. Although guidance and information are available from psychopharmacologists, psychologists, and other professionals, on how to use medications in a facilitative rather than in an oppressive way, facilities have been slow to consult with these individuals in determining how best to utilize drugs for their clients. Therefore, to strengthen this standard in the final rule, we have included several additional provisions to safeguard clients and control the use of drugs in ICFs/MR.

The standard for drug usage in the final rule, at § 483.450(e) requires the following: (1) That drugs used in the control of inappropriate behavior must be approved by the interdisciplinary team; (2) that drugs prescribed to control inappropriate behavior must be monitored closely for desired responses and adverse consequences by facility staff; (3) that these drugs be gradually withdrawn at least annually, unless documented clinical evidence indicates that this is contraindicated because of the client's condition. Additionally, the final rule requires that, before approving the use of a drug, the interdisciplinary team must document that the harmful effects of the behavior clearly outweigh the potentially harmful effects of the drug. Also, in accordance with the final rule at § 483.440(f)(3)(ii), informed consent regarding the use of drugs is required from the client, parents (if the client is a minor), or legal guardian.

Comment: The proposed drug standard would require that a facility must not use drugs as punishment, for staff convenience, as a substitute for active treatment, or in doses that interfere with a client's IPP. Twelve commenters asked if these regulations would apply to all drugs, or only drugs prescribed to modify client behavior. These commenters suggested that they should apply only to drugs prescribed for a client's inappropriate behavior.

Response: We do not agree that these provisions should apply only to drugs prescribed to modify behavior. Historically, many types of medications used in the care of mentally retarded individuals, including laxatives and anti-convulsants, have been used inappropriately. Therefore, these requirements apply to all medications.

Comment: The proposed rule at § 442.456(k) would require that a physical restraint used as a time-out device must be used only during behavior modification exercises. Two commenters requested that we define what we mean by "behavior modification exercises".

Response: The intent of the proposed regulation was to ensure that a restraint used as a time-out device (like any other time-out device) would be used as part of a formal training or behavior shaping program and to prohibit the emergency use of time-out devices.

To clarify what we meant by "behavior modification exercises", the final rule at § 483.450(d)(1) states that a facility may employ physical restraints only as an integral part of an IPP.

Comment: Seven commenters requested clarification of the proposed requirement at § 442.454(e)(2) that restrictive programs to manage inappropriate client behavior cannot be implemented until written consent of the client or his or her parents or legal guardian, if available, has been obtained. Commenters expressed concern about obtaining informed written consent from minor clients, who do not have parents, or adults who are clearly incompetent, but do not have a legal guardian assigned because they have not yet completed formal adjudication procedures. These commenters suggested that for these clients, the outside committee required by the proposed rule at § 442.450(e), or the State's protection and advocacy agency should be responsible for providing consent to the use of restrictive procedures.

Response: It was our intent to require consent, if available, for the use of aversive techniques from either the client, or his or her "parents" (if the client is a minor), or a "legal guardian". Ordinarily, it is one of these three persons who can act in a client's behalf unless someone else had been designated to do so by the State. Thus, by listing these three persons, we did not intend to limit the State's authority to designate someone else to represent the client. Also, we are aware that in some instances a client's legal status may not yet have been adjudicated, even though the client is not able to give informed consent. That is why the proposed rule stipulated that consent was required, "if available". Nevertheless, we believe that the use of the phrase, "if available", has only confused the meaning of this requirement. Therefore, it has been deleted. For those clients who are minors, or who are clearly incompetent but have no appointed legal guardian, interpretive guidelines will explain that written consent for these clients should be obtained from someone designated by the State to represent the client. However, in many cases, a facility would serve as an advocate for these clients by trying to facilitate the timely adjudication of their legal status.

Comment: Several commenters submitted additional opinions on the proposed requirement, at § 442.454(e)(2), that would prohibit restrictive programs from being implemented until consent was given. Some objected to requiring that consent be obtained only if it is available. They felt that this requirement was so vague that it would allow a facility to implement an intrusive program without making a sufficient effort to obtain consent. For example, if a guardian was not "available" to give consent by phone, a facility might not make any additional efforts to obtain consent. Also, a few commenters felt that a legally competent adult would never consent to receiving aversive conditioning. Others believed that it was unreasonable for us to require for incompetent clients, who do not have a legal guardian because their status had not been adjudicated, that legal guardianship must be established in order to obtain required consent. One commenter requested us to state explicitly in the final rule, that failure by a client to give consent to a restrictive program, would not be grounds for discharge from the facility.

Response: As discussed in the previous response, we have deleted from the rule the phrase, "as available", because of the confusion it had caused. Also, the final rule does not require that legal guardianship be established for an adult client, or a minor child without parents, who is unable to give informed consent, but whose legal status has not yet been adjudicated. In those cases, we believe it is sufficient for someone designated by the State as the client's representative, to approve the use of intrusive treatment until the client's status has been adjudicated and a guardian appointed. Also, we know that clients are not only able to, but do in fact, give informed consent for intrusive programs to be conducted. However, we believe that the more salient issue is whether or not refusal to give consent for a restrictive procedure would be automatic grounds for discharge from the facility. When a client refuses to give consent to an aversive procedure, the facility must first review its documentation to ensure that all techniques that are more positive or less intrusive have been tried and demonstrated to be ineffective. If all less intrusive techniques have been proven to be ineffective, then the facility must decide how, if at all, it can continue to meet the active treatment needs of the client. If a facility believes that it cannot meet the active treatment needs of the client, unless it provides the intrusive technique for which consent has been refused, this could constitute grounds for discharge. However, should the client want to contest the discharge, he or she has the right to pursue legal redress.

Comment: One commenter suggested that the proposed rule at § 442.454(e)(2), which would allow restrictive programs to be conducted only with written consent, be amended to require "informed" written consent.

Response: It was our intent to require informed consent. However, to ensure that this is clearly understood, the final rule at § 483.440(f)(3)(ii) specifically states that informed written consent is required.

Comment: Four commenters suggested that we mandate that physicians and behavior management specialists must participate on the interdisciplinary teams of those clients who need programs to change inappropriate behavior. Commenters stated that this is necessary, because the development of effective programs to manage inappropriate client behavior, which may necessitate addressing such problems as drug usage and determining whether organicity is the cause of the client's behavior, should only be done by qualified and experienced personnel.

Response: We appreciate the intent of the commenters. We believe the proposed requirement at § 442.444(a) would ensure adequately that those professionals who are needed to develop effective programs, would participate on each client's team. However, to further clarify our intent, the language of the final rule at § 483.440(c)(1) requires that a client's interdisciplinary team must represent those professions and disciplines relevant to each client's needs as identified in the client's comprehensive assessment, and to the design of programs to meet the client's needs. Moreover, we do not agree that it is necessary for those professionals named by the commenters to participate on the team of every client who needs a program to manage inappropriate behavior. Whether or not these professionals are needed will depend on the particular behavior management needs of the client. Also, participation on the team may vary at times contingent upon whether the task the team is completing pertains to the design, implementation or review of the client's IPP.

Comment: Five commenters were concerned that we did not require staff who implement restrictive programs to be trained. A few of these commenters specifically stressed the importance of requiring training for staff who implement restraint programs.

Response: It was our belief that this issue was addressed by the proposed provisions at § 442.430(c), which would mandate that staff must be able to demonstrate the skills and techniques necessary to implement the IPPs for each client under their care, and the proposed provisions at § 442.456(e) which would require that staff applying restraints must be trained in their use. However, we have concluded that it was necessary to add a provision in the final rule at § 483.430(e)(3) to require staff training on all techniques to manage inappropriate behavior, as well.

Comment: Two commenters recommended that the regulation require that baseline data be kept on all programs which are for the purpose of managing inappropriate client behavior, so that the pattern and frequency of such behavior can be assessed.

Response: We agree that such data should be kept. The facility is required by the final regulations at § 483.450(b)(1)(iii) to demonstrate the ineffectiveness of all previously tried behavior shaping techniques prior to the use of more restrictive techniques. Therefore, it is already implicitly required that baseline data must be maintained. The facility would not be able to evaluate, without baseline data, the effectiveness of previously tried programs and techniques to manage inappropriate behavior. Furthermore, § 483.440(e) of the final rule requires that data pertaining to the accomplishment of criteria specified in IPP objectives must be documented in measurable terms.

Comment: One commenter requested that we specify how often programs designed to manage inappropriate client behavior must be reviewed for effectiveness. This commenter believes that since we have deleted the existing requirement that client IPPs be reviewed monthly, we no longer have a mechanism to ensure that restrictive and intrusive programs will be reviewed and revised as often as needed.

Response: We appreciate the commenters' concern, but believe it would be to prescriptive to specify how often these programs must be reviewed. In accordance with the final rule, a client's IPP (including any IPP objective targeted to eliminate maladaptive behavior) must be revised as needed. We believe that the facility should develop its own process for ensuring that this is accomplished effectively.

Comment: Two commenters suggested that we should not require facilities to describe in a client's IPP all the methods that are used to manage inappropriate client behavior, such as the application of "house rules" or "standard contingencies" that apply to all clients in a residence.

Response: We do not agree. In applying "house rules" or "standard contingencies," which pertain to *all* clients in a residence, the facility must still take into account the individual needs of each client, and ensure that if any contingencies result in the abrogation of client rights or protections, that this does not amount to neglect or abuse. All the objectives for which the client is being trained must be included in the IPP. If it is in a client's best interest to participate in a program, in which contingencies are applied based on the client's behavior, then there should be a corresponding behavioral objective in the client's IPP, so that the effects of the program on the client, and the use of the contingencies, can be evaluated by the team.

Comment: One commenter recommended that the proposed requirement at § 442.444(d)(6), that an IPP must include the written strategies which are to be used to reach the objectives, should be waived for those

objectives that are designed to eliminate maladaptive behaviors. The commenter stated that these written strategies are usually very long (two to six pages). Therefore, if they are included as part of the IPP, they would make the document too bulky.

Response: As discussed earlier in this preamble, the proposed rule has been revised and the final regulations at § 483.440(c)(6)(ii) no longer require that the IPP include the strategies to be used, but only that it identify the location where program strategy information can be found.

Comment: A few commenters recommended that we require each facility to have a "behavior management" review committee in addition to the specially constituted committee required by the proposed rule at § 442.450(e). These commenters felt that the rule should require each facility to establish a separate committee consisting of members with expertise in behavior management in order to ensure that proposed restrictive and aversive programs were technically appropriate, and that a client's rights were not abridged.

Response: We appreciate the concern of the commenters, but we believe that it would be too prescriptive to require the establishment of another committee in addition to the one required by the final rule at § 483.440(f)(3). However, as mentioned before, we have included in the final rule at § 483.440(f)(3) that a qualified person or persons who have either experience or training in contemporary practices to change inappropriate client behavior must be on the outside committee.

Comment: One commenter expressed confusion about the meaning of the term "punishment", as used in the proposed rule at § 442.458(a) that would prohibit the use of drugs as a punishment. The commenter could not determine if our intent was to use it in a generic sense, to mean "discipline", or to use it as it is clinically defined.

Response: The word "punishment", as used for example, in the proposed rule concerning physical restraints and drug use at §§ 442.456(g) and 442.458(a), respectively, means the application of very intrusive measures (such as physical restraints) in order to "discipline" a client. To clarify our intent, we have referred to "disciplinary purposes" in the final rule at § 483.450(b)(3), instead of punishment.

Comment: A few commenters felt that the proposed requirement at § 442.452(c), which would prohibit staff from using corporal punishment, or verbal, physical, or sexual abuse, would have been given greater importance if it was relocated to the standard concerning staff treatment of clients at §442.424.

Response: We agree. We have made revisions so that the standard for staff treatment of clients in the final rule at §483.420(d) now includes the provisions on the mistreatment of clients that were originally proposed at § 442.452(c).

Comment: One commenter recommended that we require facilities to have special procedures to review their behavior management programs that result in contingencies that may abridge clients' rights or protections.

Response: We do not agree that this is necessary. The outside committee, which is required by the final rule at 483.440(f)(3), already has the responsibility of ensuring that client rights are protected.

Y. Professional Program Services (Proposed § 442.460; Final § 483.430(b))

Comment: Several commenters criticized the proposed requirements at § 442.460 (e)(1) through (e)(9), regarding professional qualifications. These commenters stated that our emphasis on "credentials", such as requirements pertaining to academic degrees, work experience, or membership in professional associations, did not guarantee provision of quality services, and was extremely prescriptive and inconsistent with our stated intent to develop outcome-oriented standards. They suggested instead that work performance should be stressed. They also stated that if employment credentials were required for certain positions, that they should be the same as those specified in State licensure and certification standards. Others recommended that State licensure requirements should be waived for those unlicensed professional and paraprofessional staff who work under the direct supervision of licensed professional personnel.

Response: One of the most important requirements in the ICF/MR regulation is that each client's active treatment program must be developed and implemented by qualified staff. However, we agree that requiring staff, who meet State licensure requirements, to meet additional qualifications, is too "process" oriented. Therefore, we have amended the proposed rule so that only staff who do not fall under the jurisdiction of State licensure or certification requirements must meet the professional qualifications listed in the final regulation at § 483.430(b). Moreover, if there is no conflict with State licensure and certification requirements, we will now allow facilities to utilize professionals who do not meet the qualifications specified in the final rule at § 483.430(b)(5)(i) through (5)(x), if it can be demonstrated that clients' IPPs are being successfully implemented. Regardless, there must be a foundation of knowledge that can be drawn upon in the facility, and we believe that setting qualifications for professionals helps to ensure (but does not guarantee) that needed knowledge is available. Also, we have consolidated into a single requirement, at § 483.430(b) of the final rule, the various references in the proposed rule to the standard that professional staff must be licensed, certified, or registered if required by State law. It is important to note that the final regulations do not specify qualifications for positions, but rather set qualifications for those who are referred to as "professional" staff.

Comment: A few commenters stated that the educational qualifications required by the proposed rule at § 442.460(e)(6) would decrease the number of social workers eligible to provide professional services in ICFs/MR. Commenters suggested that we either retain the requirements of the current rule, or include a "grandfather" clause to allow those who meet the existing requirements to continue in their present positions.

Response: We disagree. Under the final rule, for a person to be designated as a "social worker", the person must meet the qualification requirements at § 483.430(b)(5)(vi), or be licensed or certified as a social worker by the State. However, while a person who is not qualified as a social worker may not be referred to as a social worker per se; nevertheless, such a person may be able to provide social services in an ICF/MR if there is no conflict with State law and as long as the clients' needs are being met. The final rule at § 483.430(b)(5)(xi) allows facilities to utilize staff to provide professional services who do not meet the qualifications specified at § 483.430(b) (5)(i) through (5)(x), if it can be demonstrated that clients' IPPs are being successfully implemented. Furthermore, the proposed rule does not raise the standards that must be met by those who function as qualified mental retardation professionals. In accordance with the existing regulations, those individuals who have a bachelor's degree in a human services field, and who have three years of experience working under the supervision of a social worker, can function as qualified mental retardation professionals. Under the new rule, these persons can still function as qualified mental retardation professionals, because the final rule at § 483.430(a) does not require qualified

mental retardation professionals to meet one of the standards at § 483.430(b) (5)(i) through (x), which apply to specific categories of professional program staff, since staff who meet the requirements at paragraph (5)(x) of the section may also qualify as qualified mental retardation professionals.

Comment: A few commenters criticized the proposed required qualifications for professional program staff, at § 442.460(e), as being too lax. Commenters stated that, generally, graduates from most professional educational programs have no training or experience in working with persons with mental retardation or developmental disabilities. Therefore, they suggested that all professional program staff should be required to have the equivalent of one year of either completing coursework pertaining to mental retardation or other developmental disabilities, or working directly with the ICF/MR population.

Response: We disagree. We believe the commenters' suggestion pertaining to required coursework and work experience is too prescriptive, and would interfere with a facility's ability to recruit qualified professional staff. We agree that many professional training programs do not include distinct coursework on the nature of mental retardation or developmental disabilities, and many graduates from these programs have no experience working with this population. However, we believe that most professional educational programs in the field of human services, provide training that can be adapted by graduates to enable them to work effectively, as professionals, in ICFs/MR. Therefore, since the commenters' suggested change would not allow facilities to hire these individuals for professional positions, we have not included it in the final rule. Nevertheless, we believe that a facility should recruit and hire the most experienced and knowledgeable professional staff that it can. Also, in connection with this comment, under the final regulation at § 483.430, a facility must provide each employee with initial and continuing training that enables the employee to perform his or her duties effectively, efficiently, and competently.

Comment: A few commenters criticized the proposed qualifications at § 442.460(e) because, in some instances, a professional was required only to "be eligible for" certification, rather than be certified or registered by the applicable professional association. These commenters stated that this standard was too lenient, and that the regulation should require that these professionals be certified within a specified period of time.

Response: For the regulations to require that staff must be certified with a particular professional association, rather than to require them to be eligible for certification, would mean that HCFA was mandating that certain ICF/MR staff must be members of or affiliated with specific professional associations. We do not believe that it would be appropriate for HCFA to include such a requirement in the regulation.

Comment: Some commenters found the proposed requirements at § 442.450 that specify the experience qualifications of a qualified mental retardation professional and at § 442.460 that state the academic requirements for a qualified mental retardation professional, to be duplicative and unclear. A few commenters suggested that we identify the titles of those professional positions which may qualify a person to be a qualified mental retardation professional, and specify the required credentials for these positions. Other commenters suggested that all provisions relating to the qualifications of qualified mental retardation professionals, located in the proposed § 442.450, should be relocated to § 442.460.

Response: We do not agree that the changes suggested would improve the readability or clarity of the regulations. We believe that the rule, without the suggested changes, clearly identifies the professional requirements that must be met for a person to qualify as a qualified mental retardation professional. These requirements are contained in the final regulations at § 483.430(a).

Comment: A few commenters questioned the need of establishing required job qualifications for some paraprofessional positions (that is, occupational therapy assistants and physical therapy assistants), while not including required qualifications for others, such as teacher assistants and recreation assistants. These commenters suggested that to be consistent, we should either establish required qualifications for all paraprofessional positions, or for none of them.

Response: Qualifications were included in the proposed regulations for occupational and physical therapy assistants because national standards exist for these two positions that have been established by their national associations. We have not included teacher assistant standards because we do not believe that there are national employment standards established for the position of teacher assistant, or for any other paraprofessional position that is frequently employed in ICFs/MR. It should be noted, however, that if these "assistants" have less than a bachelor's degree, they cannot serve as qualified mental retardation professionals.

Comment: A few commenters, including the applicable national professional association, criticized the proposed professional standards for occupational therapists at § 442.460(e)(1), and occupational therapy assistants at § 442.460(e)(2) that would require that individuals in these positions be eligible for certification by their national association, or a graduate of a program accredited by that association. The commenters asserted that these two requirements are redundant, since a graduate of a program accredited by the American Occupational Therapy Association, would also be eligible for certification by that association. Therefore, the commenters suggested that we delete the proposed provisions requiring graduation from an accredited program.

Response: We agree. The proposed provisions requiring graduation from an accredited program have not been included in this final rule.

Comment: The proposed professional qualifications at § 442.460(e)(5), that would require that a person must have at least a master's degree in psychology in order to be designated as a psychologist, elicited widely varying comments. Suggestions for changes included various combinations of requirements regarding the type of degree, the credentials of the person who supervises the psychologist, and the number of years of experience necessary to be "qualified." For example, one commenter stated that a person with a bachelor's degree in psychology should be allowed to practice as a psychologist if his work is supervised by a psychologist with a master's or doctoral degree. Another commenter suggested that to be consistent with other Federal programs (such as the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), Social Security Disability Insurance (SSDI), and the Federal Employee Health Benefits Program) only Ph.D. level psychologists should be considered qualified to provide psychological services to clients of ICFs/MR.

Response: Licensure or certification requirements in most States require psychologists to have at least a master's degree in order to provide professional services. Requiring psychologists to have at least a master's degree to qualify to provide psychological services is a widely accepted standard. Thus, in

those States where there are no applicable State licensure requirements, we believe it is appropriate to require a master's degree as a minimum qualification for a person to be designated as a psychologist.

Comment: One commenter pointed out that the proposed regulation at § 442.460(e)(5), which would require a psychologist to have a master's degree from an accredited program, is not an appropriate requirement because the American Psychological Association accredits only doctoral level programs. The commenter suggested that we delete the word "program" and substitute the word "school".

Response: We agree. In the final rule, at § 483.430(b)(5)(v) we now use the word "school" rather than the word "program".

Comment: One commenter criticized the proposed rule at § 442.460(e)(6)(iii) because it would allow a person with a bachelor's degree in social work to practice as a professional social worker. The commenter believes a master's degree should be required.

Response: We disagree. Technically, a person with a bachelor's degree might not be as qualified to provide social services, as a person with a master's degree. However, the Council on Social Work Education accredits professional training programs at the bachelor's degree level. Therefore, we do not believe it is necessary to stipulate standards in excess of that.

Comment: Several commenters recommended that we amend the proposed rule at § 442.460(e)(7)(i) requiring that speech and language pathologists or audiologists must be eligible for certification by the American Speech, Language, and Hearing Association (ASHA), in accordance with the requirements that the Association has in effect at the time of this rule's publication. Commenters stated that by using the proposed language, the regulation would be out-of-date as soon as ASHA's requirements changed. They suggested that this would be avoided if the rule referred to ASHA's "current requirements", instead.

Response: We agree with the commenters' recommendation and have deleted the reference to the time of publication of the regulation (see § 483.430(b)(5)(vii) of the final rule). We have not, however, made a specific reference to "current requirements". HCFA keeps abreast of changes that are made to the professional standards of organizations and will amend this regulation as appropriate.

Comment: Several commenters objected to the proposed language at § 442.460(e)(8) that would allow an individual to qualify as a professional recreation staff member by having a degree either in recreation or in a specialty area such as art, dance, music, physical education, or recreation therapy. Commenters stated that an individual with a degree in recreation receives much less training and experience in working with the disabled population than individuals who have a degree in one of the creative art specialty areas named in the proposed rule. Therefore, because of the distinct differences in the training and experience they receive, the commenters recommended that the qualification standards for professional recreation staff members should be completely separate from those that apply to individuals training in one of the creative art specialty areas. Some commenters also objected to the proposed language at § 442.460(e)(8) because it would allow a person with a fine arts degree in music, art, or dance to qualify as a professional staff member in an ICF/MR, even though the individual may not have had training in how to work with special populations. Therefore, they suggested that the regulation specifically require that individuals trained in music, art, or dance must have degrees in music therapy, art therapy, or dance therapy, to qualify as professional staff members.

Response: We have retained the proposed language in these final regulations. We believe that the thrust of the comments is that, within the universe of individuals appropriate to serve as recreation staff, distinctions can be drawn based on education and training. None of the commenters suggested that the universe of individuals covered under the language of the proposal would not be suitable as recreation staff. Since our objective in these regulations is to provide flexibility to the extent feasible, we see no useful purpose in drawing additional distinctions within the universe. We expect that ICFs/MR will employ those individuals necessary to achieve the desired outcomes.

Comment: Some commenters criticized the proposed rule at § 442.460(e)(8) because it would require professional recreation staff members to have a bachelor's degree. These commenters stated that this was too strict a requirement and would decrease the number of people who could qualify for this position. They suggested that we either retain the qualification requirements for recreation staff members contained in existing regulations, or that we include a "grandfather" provision to allow those who occupy this position currently, to continue to do so under final regulations.

Response: Under current regulations at section § 442.493(b), a person with sufficient experience and proficiency may qualify to conduct the recreation program for an ICF/MR, even though the person does not have a bachelor's degree in recreation. Under this final rule, these persons may still qualify to perform this function, because the rule at § 483.430(b)(5)(xi) does not require that a person has to be designated as a professional recreation staff member to provide these services to clients. Nevertheless, if they are not licensed or certified in their State, these persons would not be able to call themselves "professional recreastion staff" members unless they have a bachelor's degree in recreation. However, we do not believe that "grandfathering" is necessary, because the new rule, and the existing rule, allow individuals who have sufficient experience and proficiency to conduct recreation programs for ICFs/MR.

Comment: Several commenters expressed concern that since the professional qualifications for dietitians were included in the proposed standard for facility staffing, at § 442.426(f) instead of in the proposed standard for professional program services, at § 442.460, dietitians would not qualify as qualified mental retardation professionals. This would happen because the proposed rule at § 442.450(a)(3)(iii) would include individuals who hold a bachelor's degree in a professional category listed at § 442.460 among those who qualify to be qualified mental retardation professionals. Therefore, they suggested that we relocate the qualifications for dietitians to the standard on professional program services, at § 442.460.

Response: We agree and have transferred the provisions of the regulation regarding the required qualifications for professional dietitians to the standard for professional program services contained in final regulations at § 483.430(b)(5)(ix).

Comment: Twenty commenters criticized the proposed rule at § 442.460(e)(9) because it would not allow persons with a bachelor's degree in psychology to function as human services professionals. The proposed rule at § 442.460(e)(9) states that a human services professional must be a person with at least a bachelor's degree in a human services field, other than those mentioned in § 442.460(e)(1) through (e)(8) of this section. The proposed § 442.460(e)(5) specifically

mentioned psychology and would require that a psychologist have a master's degree. The commenters objected because they believe that a person with a bachelor's degree in psychology would be as qualified to be a human services professional as a person with a bachelor's degree in any of the disciplines mentioned at proposed § 442.460(e)(9), such as sociology, special education, rehabilitation counseling. Therefore, the commenters suggested that the rule be amended to allow individuals with a bachelor's degree in psychology to qualify as human services professionals, since psychology provides detailed training in principles directly related to active treatment and human behavior.

Response: We agree and have modified the proposed rule. The amendment is contained in the final rule at § 483.430(b)(5)(x). As discussed earlier in the preamble, the purpose for including in the regulation a human services professional category was to expand the number and types of persons who could qualify as qualified mental retardation professionals, while still maintaining acceptable professional standards. However, our intention also was to clarify that a person who qualifies as a "human services professional" does not necessarily meet the qualifications necessary to practice as a psychologist, social worker, etc. To further clarify our intent, we have revised the proposed rule to include the language suggested by one commenter. This revision is reflected in § 483.430(b)(5) of the final rule. Normally, for each specific professional discipline listed in § 483.430(b)(5)(i) through (5)(x), we have added the phrase, "To be designated as . . .". This phrase means that to function as a psychologist, social worker, etc., one must meet certain qualifications that are more specific than those that must be met to function as a "human services professional".

Comment: Some commenters criticized the propose rule for not specifying what qualifications must be met by professionals in the fields of special education and rehabilitation counseling. The commenters objected because they believe that a degree in these two fields of study requires more specialized training in mental retardation and developmental disabilities, than is required for a degree in the other disciplines for which the rule does list required professional qualifications. These commenters submitted suggested language to include in the final rule, as distinct and separate requirements, the qualification standards for these two disciplines.

Response: We disagree. The particular professions for which required qualifications were proposed at § 442.460, are the professions most commonly employed by ICFs/MR. Special education teachers and rehabilitation counselors are employed mostly by other types of programs such as special school districts which are not part of the ICF/MR, rather than by ICFs/MR. Also, it would not be practical to specify in the regulations, the required qualifications for every type of professional position found in an ICF/MR. However, to acknowledge the very specialized training in developmental disabilities that is required for a degeee in special education or rehabilitation counseling, we have specifically identified in the final rule at § 483.430(b)(5)(x) these disciplines as examples of academic degrees that could qualify a person as a human services professional.

Comment: Several commenters objected to the proposed rule at § 442.460(e)(9) because it mentions only sociology, special education, and rehabilitation counseling, as types of degrees that would qualify a person to be a human services professional. These commenters interpreted the proposed rule to mean that a person would have to have a degree in one of these three fields to qualify as a human services professional.

Response: Our intent, at proposed § 442.460(e)(9), was to give examples of acceptable human services degrees. To clarify that the three disciplines listed are intended only as examples and not as a complete list, we use in the final rule at § 483.430(b)(5)(x) the phrase "including, but not limited to".

Comment: A few commenters inquired whether or not, under the proposed rule, a professional staff member, who met the proposed requirements at § 442.460(e)(9), but did not meet State licensure requirements, could qualify as a human services professional.

Response: We do not believe that there are any applicable State licensure or certification requirements that must be met to be designated as a human services professional. Thus, in accordance with the final rule at § 483.430(b)(5)(x), anyone with a bachelors degree in a human services field can qualify as a human services professional. If that person has at least one year's experience working directly with mentally retarded or developmentally disabled individuals, then he or she could also qualify as a qualified mental retardation professional.

Comment: A few commenters criticized the human services professional category proposed at § 442.460(e)(9) because in their opinion the language was too vague and thus, subject to misinterpretation by providers and surveyors. They suggested that we define the term "human services field"; identify all the human service degrees that are acceptable; or, include in the meaning of human services, any discipline related to the type of services provided in ICFs/MR.

Response: We do not believe it would be practical to attempt to catalogue in regulations all the human service degrees that are acceptable. Also, in some instances, in taking into consideration a facility's needs and the type of training and coursework that a person has completed, it will be necessary for the facility and the surveyors to exercise judgment to determine what constitutes an acceptable human services degree.

The final rule also contains the provision at § 483.430(b)(5)(xi), which allows a facility, if it is able to implement clients' IPPs successfully, to use professional program staff, including human service professionals, who do not meet the qualifications stipulated in the regulation, as long as there is compliance with State licensure requirements.

We also have modified § 483.430(b)(5)(xi), which excuses providers from personnel qualification requirements under certain circumstances, to make it clear that it does not apply to the provision at § 483.430(b)(2) requiring enough staff to carry out the interventions necessary to achieve the objectives and goals of the IPP.

Comment: Additional commenters expressed various opinions about the proposed required qualifications at § 442.460(e)(9) for the human services professional category. Opinions ranged from statements that we were "too strict", to those that we were "too lax". For example, one commenter stated that the educational requirements should be deleted and replaced by some measurement of ability based on an examination. Another commenter stated that requiring a bachelor's degree in any field, plus three years of work experience in the field of developmental disabilities, would be more acceptable than the proposed standard. One commenter suggested that we delete the entire proposed category, because its inclusion in the rule decreased the level

of professionalism required of program staff in ICFs/MR.

Response: The proposed qualifications for the human services professional category generated a wide variety of comments. However, the majority of the commenters supported retaining this category in the regulation. Thus, we have decided to retain a separate human services professional category in the final rule at § 483.430(b)(5)(x), including the revisions to this category that were previously discussed in the preamble.

Comment: A few commenters stated that because of the proposed qualifications for professional personnel at § 442.460 (e)(1) through (e)(9), some professional staff members in ICFs/MR who are currently able to qualify as qualified mental retardation professionals will no longer be able to do so. Commenters suggested that we either retain the existing regulation as it applies to qualified mental retardation professionals, or that we establish a "grandfather" provision, which would allow any staff member currently functioning as a qualified mental retardation professional to continue in that position.

Response: We do not believe there are any substantive differences between the requirements contained in existing regulations and those in the proposed rule regarding the qualifications that must be met by a qualified mental retardation professional. Therefore, we are making no changes and believe that, generally, anyone who is qualified to function as a qualified mental retardation professional under the existing regulations also would be qualified under the regulations contained in this final rule.

Comment: Eleven commenters requested clarification about the proposed rule at § 442.460(c) which would require professional program staff to participate as team members in relevant aspects of the active treatment process. Commenters inquired whether "participation" could be obtained through written reports and recommendations, or whether the professionals would be required to be physically present at team meetings.

Response: The purpose of the interdisciplinary team process is to provide team members with the opportunity to review and discuss face-to-face, information and recommendations relating to the client's needs, and to reach decisions as a team rather than individually on how to best address those needs. Should a designated member of a particular client's team be unable or unwilling to participate in any meeting, the team should obtain the absent members' input through alternative means.

Comment: One commenter expressed concern that facilities would not be able to recognize when there is a need for special professional input regarding a particular client, and they would not be sufficiently knowledgeable about the services available from the various professional disciplines.

Response: We believe that for a facility to be able to perform adequately the comprehensive client assessments that are required by the regulations, its staff would have to be sufficiently knowledgeable about the services offered by the various professional disciplines. Generally, we believe that facilities that are able to assess client needs effectively also are able to assemble the expertise needed to develop and implement an effective program for their clients. We also believe that our outcome-oriented survey protocol identifies those facilities that are unable to perform effective assessments.

Comment: Five commenters were opposed to the proposed rule at § 442.460(a) that would require professionals to work directly with clients. They interpreted this section of the rule to mean that professional program staff must work directly with all clients on a daily basis. These commenters stated that this would be too costly and that the primary duty of professional personnel should be to direct the activity of paraprofessional and nonprofessional staff. Also, the commenters stated that many clients in ICFs/MR do not need direct professional contact, that often they only need programs that are developed and monitored by professionals, but which can be implemented by nonprofessional staff. They suggested that we revise the proposed rule so that it requires professional staff to work directly with clients only "as needed".

Response: We agree that there are clients residing in ICFs/MR who can often have their needs effectively met without having direct contact with professional program staff on a daily basis. The needs of these clients can often be met by competent nonprofessional staff who are supervised or directed by professionals. The intent of the rule is not to require that professionals work directly with clients on a daily basis, but only as often as a client's needs indicate that direct professional contact is necessary. The amount and degree of direct care that professionals must provide will depend on the needs of the clients and the ability of other staff to train and direct clients on a day-to-day basis. However, to have an effective program, professionals must evaluate clients, make recommendations, set planned outcomes, develop strategies, implement interventions, train staff, monitor the implementation of strategies, and review the effectiveness of programs.

Comment: One commenter stated that staff should not be allowed to provide services or implement interventions unless they are competent to do so, and suggested that this be included as a requirement.

Response: We agree. The proposed rule at § 442.430(c) would require that anyone providing services to a client should be able to demonstrate competency. This requirement has been kept in the final rule and is now contained in § 483.430(e).

Comment: One commenter requested that we specify the minimum professional staff-to-client ratios that must be met by a facility to ensure that its professional services are being adequately provided.

Response: We believe requiring specific professional staff to client ratios would be overly prescriptive. What constitutes an acceptable professional staff-to-client ratio in a particular facility is determined by the needs of its individual clients.

A facility must evaluate each of its clients, and then determine how many professional staff are necessary to provide the direct and indirect services required in order to meet their needs adequately.

Z. Physician Services (Proposed § 442.462, Final § 483.460)

Comment: Nine commenters objected to the proposed regulation at § 442.462(a) that would require facilities to provide or arrange for the provision of physician services 24 hours a day. They were concerned that the provision of physician services 24 hours a day could be interpreted to mean that the physician must be on the premises.

Response: We have accepted these comments and included revised language in the final regulations at § 483.460. Section 483.460 specifies that "the facility must ensure the availability of physician services 24 hours a day." This should make it clear that the physician does not need to be on the premises. The revised wording, however, does not negate the fact that facilities not having a physician directly employed must have a formal arrangement for physician services. With respect to these arrangements, the final rule at § 483.410(d)(2), concerning services provided through outside arrangements, requires that services not

provided directly must be provided under a written agreement.

In revising this regulation, it came to our attention that the proposed regulations contained some redundancy with regard to physician services. Both the proposed § 442.462 concerning physician services, and the proposed § 442.466 concerning comprehensive health services had statements requiring physician services 24 hours a day. To eliminate this repetition, as well as make other changes that will be explained in subsequent sections of the preamble, we have reorganized the material that was contained in the three proposed sections: § 442.462, "Physician services"; § 442.464, "Physician participation"; and, § 442.466, "Comprehensive health services". In the final rule, we have incorporated them into two sections: § 483.460(a), "Standard: Physician services", and § 483.460(b), "Standard: Physician participation in the individual program plan". The revised statement regarding 24 hours a day availability of physician services is contained in the final rule under standard § 483.460(a), Physician services.

AA. Physician Participation (Proposed § 442.464, Final § 483.460(b))

Comment: Nineteen commenters objected to the requirement that physicians develop a medical care plan on clients when they determine such a plan is necessary. The commenters felt that the regulations should include a more precise definition of when a medical care plan is required.

Response: We agree with these comments and have modified the language contained in proposed regulations to now state that a medical care plan is necessary when 24 hour licensed nursing care is needed. This revised language is located in the final rule at § 483.460(a), "Standard: Physician services".

BB. Comprehensive Health Services (Proposed § 442.466; Final § 483.460(a))

Comment: Eight commenters expressed an opinion on the components of the physical examination required under proposed § 442.466(b). These annual physicals require examinations of vision and hearing; routine immunizations and tuberculosis control; screening laboratory examinations as determined necessary by the physician, and special studies if needed. Some commenters preferred the words "evaluate" vision and hearing rather than "examination" of vision and hearing. Additionally, some commenters preferred the language as it appears in current regulations at § 442.477, over the language in the proposed rule. The current § 442.477 requires the physician to use the guidelines of the Public Health Service Advisory Committee on Immunization Practices and the American Academy of Pediatrics regarding immunizations and the American College of Chest Physicians or the American Academy of Pediatrics regarding tuberculosis control. It also requires the reporting of communicable diseases and infections in accordance with law.

Response: We have accepted these comments and have made revisions in the final regulations. We will use the term "evaluate" vision and hearing rather than "examination" of vision and hearing. We also have reinstated the language of current regulations § 442.477 that urges physicians to follow the guidelines of the Public Health Service and the American Academy of Pediatrics with regard to immunizations and the American College of Chest Physicians or the American Academy of Pediatrics regarding tuberculosis control. However, we have not incorporated into the final rule that part of the current regulations at § 442.477 that requires the reporting of communicable diseases. We believe this requirement is well established in State law, compliance with which is required by § 483.410(b) of these final regulations.

Also, in making the changes recommended by the commenters, we have incorporated into the condition concerning health care services under § 483.460 of the final rule, the material that was contained in the three proposed sections: § 442.462, "Physician services", § 442.464, "Physician participation" and § 442.466, "Comprehensive health services". Section 483.460(a) of the final rule contains the standard for physician services, and paragraph (b) contains the standard for physician participation in the IPP.

In the final rule, the standard for physician services at § 483.460(a) will retain the requirement for the availability of physician services 24 hours a day as well as the requirement that to the extent permitted by State law the facility may utilize physician assistants and nurse practitioners. The material regarding the development of a medical care plan previously under proposed § 442.464, has been moved to this section. Additionally, the requirement for general medical and preventive health services as well as annual physical examinations previously under the standard for comprehensive health services at the proposed § 442.466 has been moved to this section. Also, as mentioned in the response to the comments on section § 442.466, the components of the physical examination have been revised to include the same general requirement of current regulations § 442.477.

The new standard at § 483.460(b) concerning physician participation in the individual program plan will contain two of the requirements previously found under the proposed standard for physician participation at § 442.464. These are the requirements for physician participation in the establishment of each newly admitted clients' IPP as well as physician participation in the review and update of the IPP as appropriate.

CC. Nursing Services (Proposed § 442.468, Final § 483.460(c))

Comment: Thirty-one commenters objected to the proposed regulations at § 442.468(a) that would require nursing services to include the development, review, and update of an IPP as part of the interdisciplinary team process. They recommend that the regulations specify that nurses participate in the IPP process only when clients have nursing needs.

Response: We have accepted these comments. We have revised the regulations to read nursing services must include participation as appropriate in the development, review, and update of an IPP as part of the interdisciplinary team process.

Comment: Six commenters expressed views on the proposed regulations at § 442.468(c) that would require an onsite, direct physical review at least quarterly by licensed nurses for clients who do not have a medical care plan. Specific comments were: The direct physical review does not necessarily need to take place in the facility and therefore the word onsite should be removed; the term direct physical review should be defined; and finally a quarterly review may not be frequent enough for some clients.

Response: We have revised the regulations to omit the word onsite. The

purpose of the direct physical review is to identify any health problems that might need medical intervention or any potential health problems that could be prevented. We have, however, retained the word "direct" which means that the nurse must review the client directly and not through another staff member such as a member of the direct care staff or through a medical record review.

We have also revised the regulations to read "direct physical examination" rather than "direct physical review". We will explain in interpretive guidelines that this means a visual review of the body as well as any tactile examination that might be necessary. A paper review of the patient's medical record and health statistics is not a direct physical examination.

We agree with the commenters that a quarterly physical review of each client by licensed nurses may not be frequent enough for some clients. Although the proposed regulation reads "at least quarterly", we have emphasized the fact that this is a minimal requirement by rephrasing the regulations to read "on a quarterly or more frequent basis". This will mean that the facility will have to conduct quarterly reviews on all clients, but potentially more frequent reviews on clients who may require more frequent nurse surveillance.

In making the above revisions, we realized that the proposed §§ 442.468(c) and 442.470(d) contained duplicative requirements for health surveillance of clients on a quarterly basis. The only difference between the requirements is that the proposal at § 442.470(d) would require that licensed nursing personnel conduct the health surveillance. In this final rule, we have eliminated the duplication. The requirement for the quarterly health surveillance of clients by a licensed nurse appears in final regulations at § 483.460(c).

Comment: There were two comments on the proposed regulation that would require nurses to participate in training clients and staff as needed in appropriate health and hygiene methods. The commenters questioned whether or not the topics of health and hygiene included sex education.

Response: It is the intent of the proposed regulation that training in health and hygiene methods include the topic of sex education. This will be made clear in the interpretive guidelines.

DD. Nursing Staff (Proposed § 442.270, Final § 483.460(d))

Comment: Twenty commenters objected to the provision in § 442.470(c) requiring a facility to employ a licensed nurse on one full shift 7 days a week. Seventeen of the twenty felt that the requirement was too costly; one felt that job-sharing should be recognized as an appropriate means to accomplish the full-time equivalency; one suggested that contractual arrangements be recognized as an appropriate means of providing nursing services; one commenter felt the requirement should be changed to require a licensed nurse at least 16 hours a day, 7 days a week with a licensed nurse "on call" during the remaining 8 hours.

Response: We have accepted these comments except for the one requesting that facilities be required to provide 16 hours of licensed nursing time per day, 7 days a week. Since they had the same basic intent, we have combined the proposed requirements at § 442.470 (b) and (c) and incorporated them into the final rule at § 483.460(c) to state that the facility must employ or arrange for licensed nursing services sufficient to care for clients health needs including those clients with medical care plans. This gives each facility more freedom to determine what nursing services are required for its particular client population. Also, there is nothing in these final regulations which prohibit the use of job-sharing to meet the nursing personnel requirement.

Comment: The proposed § 442.460(d) would require facilities that use only licensed practical or vocational nurses to have a formal arrangement with a registered nurse for consultation. One commenter suggested that the consultation be a monthly activity with a flexible amount of time. Another commenter requested that the frequency of consultation and amount of time for consultative activities be specified. Finally, one commenter suggested that four hours of R.N. consultation per week be required in facilities with 16 or fewer beds.

Response: We disagree with the general thrust of these comments because we believe that the consultation needs of each facility cannot be specified in regulations. The nursing care needs of clients vary considerably from facility to facility. The amount of R.N. consultation time should be based on the needs of the clients. Thus, we have allowed facilities flexibility by not prescribing in regulations the number of R.N. consultation hours they must provide.

The proposed § 442.460(d) that would require a quarterly nurse surveillance of each client without a medical care plan was duplicative of the material in the proposed § 442.468(c). Therefore, it has been removed. (See the discussion under the response to comments regarding the proposed § 442.468(c), Nursing services.)

EE. Dental Services (Proposed § 442.472, Final § 483.460(e))

Comment: Twenty commenters objected to the proposed regulation that would require dental professionals to participate as appropriate in the development, review, and update of the IPP as part of the interdisciplinary process. The majority of the commenters requested clarification on how the dentist is expected to participate. Most of the commenters felt that the dentist should be able to submit a written report to the interdisciplinary team.

Response: We have accepted these comments. We agree that participation of the dentist can be through a written report. We therefore have modified the regulation to read: If appropriate, dental professionals must participate in the development, review, and update of an IPP as part of the interdisciplinary process either in person or through a written report to the interdisciplinary team.

Comment: One commenter requested that we retain current regulations found at § 442.459, "Education and training". These regulations require the facility to provide education and training in the maintenance of oral health.

Response: We have accepted the commenter's suggestion and have added a provision to final regulations § 483.460(e)(3) to require the facility to provide education and training in the maintenance of oral health.

FF. Comprehensive Dental Treatment (Proposed § 442.476, Final § 483.460(f))

Comment: Several commenters expressed views on the proposed requirement for comprehensive dental treatment services including dental care needed for relief of pain and infections, restoration of teeth and maintenance of dental health. In their view, reimbursement for comprehensive services is not available in every State and the regulations should not require services for which there is no reimbursement.

Response: Dental services are included in the ICF/MR benefit, even though a particular State may elect not to cover them separately for *non*-ICF/MR recipients. The law and regulations require that States make adequate payments (see § 447.253(b)(i)). The Medicaid statute (at section 1902(a)(13)(A)) states, in part, that payment rates for ICF/MR services must be "* * * reasonable and adequate to meet the costs which must be incurred by efficiently and economically operated facilities in order to provide care and services in conformity with

applicable State and Federal laws, regulations, and quality and safety standards * * *". Thus, we would expect a State's ICF/MR payment rates reasonably to reflect the various items and services which constitute the ICF/MR benefit.

Comment: Four commenters expressed opinions on the proposed regulation that would require the provision of emergency dental treatment on a 24-hour-a-day basis by a licensed dentist. In their view, it is the availability of the services that is at issue, not the provision.

Response: We have accepted these comments and have amended the regulation to require that comprehensive dental treatment services include the availability of emergency dental treatment on a 24-hour-a-day basis by a licensed dentist.

GG. Documentation (Proposed § 442.478; Final § 483.460(h))

Comment: Three commenters expressed an opinion on the proposed standard that would require the facility to provide a copy of the dental record (if available) or the most recent dental summary to the client, his parents, or guardian upon discharge from the facility. In their view, the requirement is not necessary and increases program costs.

Response: We agree with the commenter and have deleted this requirement entirely. A general requirement found in these final regulations at § 483.410(c)(3) addresses the general issue of confidentiality of client records and requires the facility to develop policies and procedures for the release of client information.

HH. Pharmacy Services (Proposed § 442.480; Final § 483.460(i))

Comment: Thirteen commenters expressed approval of this standard because it would place the responsibility for the provision of drugs and biologicals on the facility whether the facility does so directly or through arrangement. One commenter objected to the requirement that would allow facilities to use "off site" pharmacies because they would not be able to meet the *immediate needs* of ICF/MR clients.

Response: Current regulations allow a facility to obtain pharmaceutical services from an outside resource, and we believe that these final regulations should continue that practice especially with the growth of small facilities with 16 or fewer beds that could not realistically operate their own pharmacies.

II. Drug Regimen Review (Proposed § 442.482; Final § 483.460(j))

Comment: A number of commenters objected to the proposed requirement that would involve the pharmacist, as appropriate, in the development of the IPP. Many did not feel that the participation of the pharmacist was necessary. Others thought the pharmacist's participation could take place by means of written comment. Still others thought that the pharmacist should have input from the indisciplinary group instead of the pharmacist participating, as appropriate, in the development of the client's IPP.

Response: We have accepted the suggestion of the commenters who thought the pharmacist could participate in the IPP by means of a written report and have revised the regulations accordingly at § 483.460(j)(5). We also agreed with the commenter who suggested that the pharmacist reviewer must conduct reviews with input from the interdisciplinary team and have added this provision to the final rule at § 483.460(j)(1).

Comment: We received only one public comment on the issue of requiring a pharmacist rather than a registered nurse to conduct quarterly drug regimen reviews. However, we received many comments on this issue in response to a proposed rule published on May 16, 1986 (51 FR 17997) concerning drug regimen reviews in skilled nursing and intermediate care facilities. In that proposal, we again had stated that we would allow either a pharmacist or a nurse to conduct these reviews. Approximately 100 commenters objected stating that they believed that only a pharmacist should conduct the reviews. The commenters stated that registered nurses did not have the time or the knowledge base to conduct the reviews adequately. As a result of the public comments concerning drug regimen reviews in skilled nursing and intermediate care facilities, we issued, on June 15, 1987 (52 FR 22638), a final regulation that permits only a pharmacist to conduct these reviews in skilled nursing and intermediate care facilities.

Response: In response to the public comments received on the May 16, 1986 rule, and in order to achieve consistency in the regulations, and because we believe that the proper conduct of these reviews can best be assured by requiring that a pharmacist perform them, we have modified the final rule to permit that only a pharmacist may conduct these reviews.

JJ. Drug Administration (Proposed § 442.484; Final § 483.460(k))

Comment: There were 49 commenters who expressed opinions on this proposed standard. A significant number of these commenters objected to the requirement at the proposed § 442.484(b) for administering drugs without error. Many felt this standard was unrealistic and asked that it be deleted. Others believed that medication errors should be addressed but some tolerance should be allowed. Others wished to defer to State law on this issue, and some complained that the facility should not be held responsible for clients who make errors while "on pass" from the facility. Finally, one commenter complained that the facility would modify records to cover-up medication errors.

Response: We have carefully reviewed these comments and our current survey procedures for identifying medication errors and have decided not to modify the proposed regulation. The current surveyor procedure for medication errors relies on an observation technique and not on records. It allows an overall tolerance of five percent for non-significant medication errors but faults the facility for any one error considered a threat to the health and safety of an individual client. This medication error detection methodology has been in use for several years and has demonstrated its ability to change the behavior of the facility so that errors are identified and a genuine effort is made to reduce their incidence. The surveyor procedure used to detect medication errors does not include the observation of drugs administered while clients are "on pass" from the facility. Since medication errors have been shown to be a significant problem in a wide variety of health care facilities, we are retaining this requirement unchanged.

Comment: A significant portion of the commenters also expressed concern about the provision at the proposed § 484.484(g) that would require a pharmacist to package and label all drugs used by the client while the client is not under the direct control of the facility. This proposal was an effort to assure proper labeling and packaging of the drugs that clients must possess while enroute to and at various off-site workshops, classes, and home visits. Many commenters expressed concern about the availability of the pharmacist to perform this task on short notice as is the case with many home visits. Another commenter emphasized that some States now have standards that allow facility

personnel under specific circumstances to repackage and label drugs for clients "on pass".

Response: We were convinced by these arguments and have modified the final regulation (§ 483.460(k)(7)) to state that such drugs are "packaged and labeled in accordance with State law" instead of "packaged and labeled by the pharmacists".

Comment: Several commenters complained that medication errors and adverse drug reactions when they do occur should be reported only to a physician and not to the registered nurse as would be allowed under the proposed § 442.484(i).

Response: We have accepted this comment. We are not including registered nurses among those to whom these events can be reported.

Comment: There was general support for the use of unlicensed personnel to administer drugs if State law permits. However, some commenters expressed concern about the proposed regulation at § 442.484(c) that would require a registered nurse to teach unlicensed personnel about the facility-specific aspects of drug administration.

Response: The original objective of this training was to assure that the unlicensed personnel have training in the unique aspects of a particular facility's drug distribution system. Because this requirement may present interpretive problems and because the objective is basically covered under the standard for staff training at § 483.430(e) of this final rule, it has been deleted as a specific requirement under the standard for drug administration.

KK. Drug Storage and Record Keeping (Proposed § 442.486; Final § 483.460(l))

Comment: One commenter wanted to add a requirement to the proposal to require the pharmacist to inspect drug storage areas in the facility.

Response: We have no objections to a pharmacist periodically inspecting drug storage areas and reporting problems to the facility. However, we do not believe that it is necessary to mandate this through regulation.

Comment: One commenter suggested that the receipt and disposition of controlled drugs be reconciled on a routine basis (for example, every shift or everyday) rather than on a sample basis as required by the proposed rule at § 442.486(d).

Response: We do not wish to mandate a routine reconciliation of controlled drugs unless a sample reconciliation indicates a more frequent reconciliation is necessary (for example, in the case of missing controlled drugs). We believe it is unnecessary to require a facility to perform routine checks for missing controlled drugs unless there is a good reason to do so.

LL. Labeling (Proposed § 442.488; Final § 483.460(m))

Comment: One commenter objected to the requirement at proposed § 442.488(b) that would prohibit the facility from retaining outdated drugs or drugs with missing or torn labels. The commenter suggested that such drugs be removed from use.

The same commenter suggested that drugs discontinued by the physician be "immediately removed from the client's current medication supply" rather than the wording at proposed § 442.488(c) that states that such drugs must "not be available for administration".

Response: We have accepted both of these comments and have incorporated the new language into these final regulations.

MM. Laboratory Services (Proposed § 442.489; Final § 483.460(n))

Comment: There were seven commenters on the proposed requirement at § 442.489(d)(1) that the laboratory director must be either a pathologist or a doctor of medicine or osteopathy with training and experience in clinical laboratory services; or a laboratory specialist with a doctoral degree in physical, chemical or biological sciences, and training and experience in clinical laboratory services. Most of the commenters felt that the requirements were unnecessarily high. Commenters had a variety of suggestions for changing the provision, such as requiring: a baccalaureate degree with a major in a physical, chemical, or biological science plus appropriate experience; a laboratory technologist certified by the American Society of Clinical Pathologists; a trained laboratory technologist with regular consultations from a Clinical Pathologist. One commenter said the requirement should be guided by State law.

Response: We have not adopted the comments requesting lower qualifications for the position of laboratory director. However, currently the Department has underway a thorough review of all clinical laboratory regulations. During the next year, the Department will be proposing regulation changes and other reforms intended to remove inconsistencies and eliminate unnecessary credentialing requirements while continuing to ensure patient health and safety. We have adopted the request that the requirement be guided by State law when State laws address the qualification requirements for directors of laboratory services.

Comment: Two commenters felt that requirements for laboratory services in ICFs/MR should be the same as the conditions for coverage of services of independent laboratories found at 42 CFR Part 405, Subpart M.

Response: The proposed requirements for laboratory services in ICFs/MR are fundamentally the same as the conditions for coverage of services of independent laboratories currently found in Subpart M. For example the requirements contained in Subpart M at §§ 405.1314(a), 405.1316 and 405.1317 were incorporated into the proposed regulations by the cross reference found in § 442.489 (c), (e) and (f). This cross-reference was retained in the final rule. The personnel requirements in both the proposed and final laboratory standards are considerably less detailed than those found in Subpart M. As stated in our response to the previous comment, the Department has currently underway a thorough review of all clinical laboratory regulations including personnel requirements. Following this review, changes to the regulations may be proposed that would impact on laboratory services, including laboratory services in ICFs/MR.

Comment: Two commenters felt that it may be necessary to limit laboratory testing in small institutions of under 50 beds. Additionally one of the commenters recommended prohibiting on-premises testing in those facilities with 16 or fewer beds.

Response: We cannot accept the comment regarding limiting laboratory testing in small institutions because there is no consensus as to what tests should and should not be performed in smaller facilities. We also did not accept the comment recommending prohibiting on-premises testing in those facilities with 16 or fewer beds. This prohibition is unnecessary because we believe that such small facilities would not attempt to meet the laboratory services requirements in order to do the few tests their clients might require. The new regulations will, however, require small facilities that collect their own specimens to refer those specimens for testing to laboratories that are approved for participation in the Medicare program.

Comment: Several commenters felt that the proposed regulations were unclear with regard to when or if facilities are to provide laboratory services.

Response: We agree with the commenters that the proposed regulations were unclear on these

points. The proposed § 442.489(b) stated, "If an ICF/MR that meets the requirements of this subpart operates its own laboratory, the laboratory must * * *". The intent of the proposal was to permit facilities to choose whether or not they wish to provide laboratory services. If a facility does wish to provide these services, it must meet the proposed requirements of § 442.489. To make this point clear, we have incorporated in the final regulations at § 483.360(n) language that reads, "If a facility chooses to provide laboratory services", the laboratory must meet the specified requirements.

Comment: Commenters stated that it was unclear whether or not the laboratory is simply to be used as a drawing station for the collection of specimens which are then sent out to an independent laboratory for study.

Response: The proposed requirements for laboratory services were not intended for a laboratory that operates only as a drawing station. We indicated in the proposal at § 442.489(a) that for purposes of this section, "laboratory" would mean a facility for the performance of specified laboratory tests. Nothing in the proposed or final regulations, however, prohibits an ICF/MR from operating a drawing station; that is, the referral of specimens to other laboratories. We have attempted to make this clear in the regulation by requiring that if the facility chooses to refer specimens for testing to a laboratory, the referral laboratory must be approved by the Medicare program either as a hospital laboratory or an independent laboratory.

Comment: Section 442.416 of the proposed regulations would require that facilities must be in compliance with all applicable provisions of Federal, State and local laws. The proposed regulations at § 442.489(b)(1) would require that a laboratory be licensed or approved according to State law if it is located in a State that provides for the licensing or approved of laboratories. Commenters stated that this is duplicative and therefore should be removed.

Response: We have accepted this comment and have removed this provision from the standard on laboratory services.

NN. Client Living Environment (Proposed § 442.500; Final § 483.470(a))

Comment: Several commenters noted that there is an apparent contradiction in the proposed § 442.500 between paragraph (a), which would prohibit a facility from housing together clients of grossly different ages, developmental levels, and social needs unless the housing promotes their mutual growth and development, and paragraph (b), which would prohibit segregating clients on the basis of physical handicaps and requires integration of physically handicapped clients with others of comparable social and intellectual development.

Response: We note that a client living pattern which takes into account such factors as age, developmental levels, and social needs (paragraph (a)) is not equivalent to a client living pattern based on physical handicap (paragraph b)). Paragraph (a), in referring to "grossly different ages," is intended to ensure, for example, that very young children are not inappropriately housed together with much older, adult clients. While it can be argued that a certain degree of client mix promotes normalization, extreme differences may in some instances actually impede appropriate training and pose a threat to the safety of younger, more vulnerable clients. If clients of grossly different ages, developmental levels, or social needs are housed in close proximity, the facility must demonstrate that it has planned this housing to promote the clients' mutual growth and development. Paragraph (b), on the other hand, prohibits segregation on the basis of physical handicap: that is, housing clients together only because they have physical disabilities. This paragraph indicates that the facility should house its clients based on common skill levels; that is, comparable social and intellectual levels of development, rather than by physical disability. Therefore, we do not believe that there is any contradiction between paragraphs (a) and (b).

Comment: A number of commenters asserted that the proposed prohibition of segregation by handicap under § 442.500(b) of the proposed rule potentially conflicts with other important objectives, such as the ability to address individual clients' specialized training needs; fire safety (for example, placement of wheelchair-bound clients near fire exits); and the ability to establish specialized ICFs/MR for clients with specific developmental disabilities.

Response: We do not believe that clients with a common physical disability necessarily must be housed together in order to meet their specialized training needs. Such housing would be appropriate only if all of the clients with a particular disability also happened to be at the same skill level and, thus, had identical training needs. Again, in this situation, the facility should look to the client's skill level, rather than physical disability, in determining appropriate housing patterns.

Regarding the comment about the possible effect of housing patterns based on concerns for fire safety, we note that housing of non-ambulatory individuals currently is permitted in facilities such as community group homes, as long as the facility meets applicable fire safety requirements. Also, we do not believe that the provisions of this section of the regulations prevent the establishment of specialized ICFs/MR for clients with specific developmental disabilities, since it does not deal with the types of individuals that a facility admits, but only with the housing of clients once they are admitted.

Comment: Some commenters suggested that, in the proposed § 442.500(b), the term "handicaps" should be replaced with "disabilities," and the term "epileptic" should be replaced with "persons with seizure disorders".

Response: We accept these comments, and have revised the final regulations accordingly.

Comment: One commenter suggested that, in implementing these regulations, a distinction should be made between large facilities and small homes.

Response: The basic purpose of this provision is to establish the general principle that the facility should house together clients who are at comparable developmental levels, and to permit housing of disparate clients together only if it promotes their mutual growth and development. We believe that a special distinction regarding small facilities is unnecessary, since the population in such settings normally tends to be more homogeneous. Also, we note that even in small facilities, these regulations do not preclude housing clients at different developmental levels in close proximity, as long as the housing promotes their mutual growth and development.

OO. Client Bedrooms (Proposed § 442.502; Final § 483.470(b))

Comment: We received comments suggesting that various provisions of current regulations §§ 442.436 (Personal possessions); 442.442 (Resident clothing); and 442.404(g)(6) (permitting married couples to share a room) relating to individual rights should be retained.

Response: Section 442.401(k) of the proposed regulations (final § 483.420(a)(11)) already addressed two of the commenters' concerns in that it would require that clients be permitted to retain and use personal possessions and appropriate clothing. We are

restoring the provision regarding married couples sharing a room to the section on protection of clients' rights (final regulations at § 483.420(a)(12)).

Comment: Two commenters suggested adding a requirement for an appropriately sized window to the proposal at § 442.502(a)(1) that would require each room to have at least one outside wall.

Response: This requirement was already addressed in the proposed § 442.508(a)(1) that would require each bedroom to have at least one window to the outside, and in the proposed § 442.502(b) that would require that the window in a below-grade bedroom be usable as a second means of escape. In the final rule, these provisions are lcoated at § 483.470(b)(1) and (2)(i).

Comment: Several commenters requested us to define "newly certified," as used in the proposed § 442.502(a)(5) that would require floor-to-ceiling walls in all "newly certified" facilities.

Response: We are revising the final regulations at § 483.470(b)(1)(v) to clarify our intent. In the final rule, we have used the word "initially" instead of "newly", and have modified the regulation so that all facilities "initially certified" on or after the effective date of these regulations must have walls that extend from floor to ceiling. This regulation affects only those facilities "initially certified" after the effective date of the regulations. A facility that is certified for participation in Medicaid after a period of non-participation (because its certification had been terminated or voluntarily withdrawn) is considered an "initial certification" and will be required to install floor to ceiling walls.

We note that the proposed rule did not address the issue of floor to ceiling walls when an ICF/MR carried out new construction, renovation or conversion. To address this issue, we have modified the regulation so it requires a facility to install floor to ceiling walls in newly constructed portions and during major renovations or conversions. We will explain in interpretive guidelines that, in our view, "new construction and major renovations or conversions take place if: (1) Clients must vacate the facility; (2) no Medicaid billing takes place; (3) a resurvey is required before clients return.

Comment: Several commenters requested clarification of proposed § 442.502 paragraph (b) that would permit below-grade bedrooms and provide specifications for windows in them. Points requiring clarification included: ground level versus floor level windows; requiring that windows be usable as a means of escape by the client occupying the room; and, that window measurements are taken from the sill.

Response: We are revising the final regulations at § 483.470(b)(2) to clarify that, in a below-grade level bedroom, the window must be no more than 44 inches above floor level (for facilities surveyed under the Health Care Occupancy Chapter of the Life Safety Code, the window must be no more than 36 inches above the floor); that the window must be usable as a second means of escape by the client occupying the room; and, that floor-to-window measurements are taken to the sill.

Comment: Since the proposed § 442.502(c) mentions only a medical basis for granting a variance to permit more than four clients per bedroom, a physician, rather than psychologist, should make this determination.

Response: We agree with this comment, and will delete the words "or psychologist" from the language describing the type of individual that can grant a variance to the limit of four clients per bedroom (final regulation § 483.470(b)(3)).

Comment: One commenter suggested granting a variance to the four-client-per-bedroom limit for behavioral as well as medical problems; still others suggested eliminating the variance provision altogether, or granting a variance only with the interdisciplinary team's approval. Other commenters recommended a maximum of two, rather than four, clients per bedroom.

Response: We are retaining the variance provision. While we do not regard broadening the variance procedure (for example, to include behavioral problems) as appropriate, we also believe that eliminating the variance altogether would pose serious problems for some facilities.

Comment: A number of commenters requested clarification of the proposal at § 442.502(d)(2) that would require a "fire safe" mattress. Several indicated that a mattress which is literally fire safe is impossible to obtain or, at best, is uncomfortable, expensive, and inappropriate for use in a health care facility. Others suggested requiring instead a "fire resistant" mattress cover or simply a reference to applicable Life Safety Code or National Fire Protection Association standards.

Response: The Consumer Product Safety Commission (CPSC) administers regulations that prohibit the sale of mattresses that have not passed their requirements for Flammability of Mattresses (and Mattress Pads) (16 CFR Part 1632). These regulations prohibit the sale of mattresses manufactured or imported in the United States unless they have passed a standard test for cigarette ignition, which is generally regarded as being one of the leading causes of mattress fires. These requirements became effective June 22, 1973. Thus, all mattresses purchased by ICFs/MR after that date were subject to CPSC requirements. As facilities replace mattresses, we expect this potential risk to diminish (a CPSC study of hotels and similar occupancies showed that about ⅔ of the mattresses have been replaced since June 22, 1973). Because CPSC enforces these regulations, there is no need for HCFA to establish separate standards defining fire safe mattresses. Therefore, in these final regulations we have deleted the reference to fire safe mattresses.

Comment: One commenter requested that the proposed requirement at § 442.502(d)(3) for appropriate bedding be clarified specifically to permit the use of a single bedspread year-round if it is appropriate for all seasons. Several others suggested that the proposal at § 442.502(d)(4), which would require an individual closet for each client, be changed to allow the alternative of individual space in a shared closet.

Response: With regard to bedspreads, we believe that interpretative guidelines would be a more appropriate vehicle for making this clarification, and we will include it in the guidelines when they are published.

With regard to closets, we are clarifying the final regulations at § 483.470(b)(4)(iv) by requiring the facility to provide each client with individual closet space in the client's bedroom. This permits the facility either to provide the client with an individual bedroom closet or with a designated area in a shared bedroom closet, but precludes the use of clothing bins in a facility clothing room.

Comment: Some commenters indicated that the proposed § 442.502(d)(4), in describing bedroom furniture, should simply require furniture "as appropriate to the needs of the client" rather than requiring a desk for a client who cannot use it. Another commenter suggested that a night table be required rather than a table or desk, as being closer to normal bedroom furniture.

Response: Regarding the types of "appropriate" furniture described in this provision, we note that these items are mentioned as illustrative examples only; we did not intend this language to require a particular type of furniture, such as a desk, for a client who is unable to use it, or for whom it is otherwise contraindicated. Rather, each client should have furniture, appropriate to his or her needs, that is used by the

client alone. However, in order to avoid possible confusion, we are deleting the examples and revising the final regulations at § 483.470(b)(4)(iv) to require that the facility furnish each client with functional furniture appropriate to that client's needs. We use the descriptive term "functional" furniture to distinguish these items from the use of decorative "furnishings," such as plants, pictures, etc., which, though encouraged as being an appropriate and desirable aspect of a normalized living environment, cannot serve as a substitute for appropriate furniture.

PP. Storage Space in Living Units (Proposed § 442.504; Final § 483.470(c))

Comment: One commenter requested that we define "living unit" as used in the proposed §§ 442.504, 442.508 and 442.510.

Response: We are deleting this term where it appears in the proposed regulations, and substituting the terms "bedroom" and "area used by clients", as appropriate.

Comment: One commenter suggested that proposed § 442.504(b) should provide not only for storage of the client's personal possessions, but for the safety of these possessions as well.

Response: We believe that the safety of the possessions is implied in the requirement that there be "suitable" storage space, therefore, no change is being made.

Comment: Another commenter on proposed § 442.504 paragraph (b) advocated limitations on accessibility of personal possessions under a behavior modification program or when the interdisciplinary team determines that access would endanger the client or others.

Response: We agree that limitations on accessibility of personal possessions can be appropriate in certain situations. However, we do not believe that prescriptive regulations are necessary in order to permit this. Proposed paragraph (b) merely requires that the client have access to the space in which his or her personal possessions are ordinarily stored. While this implies access to the possessions themselves, it does not require unrestricted access in situations where this is precluded by an active treatment program designed to eliminate inappropriate behavior or in which the interdisciplinary team determines that unrestricted access would endanger the client or others.

Comment: The proposed § 442.504(c) would require adequate clean linen and dirty linen storage areas. Several commenters said that small facilities should not be required to have separate storage rooms for clean and dirty laundry; rather, it would be sufficient to require specific procedures to prevent contamination and unsanitary practices. Others suggested that we permit a bedroom hamper, if sanitary and odor-free, to be used for dirty laundry storage.

Response: The laundry storage requirement in this provision requires clean linen and dirty linen storage "areas" rather than "rooms." This means that clean linen and dirty linen must be stored separately, but need not be stored in different rooms. A bedroom hamper would be an acceptable dirty linen storage "area" if kept clean and odor-free, consistent with the infection control requirements of final regulations at § 483.470(l).

QQ. Client Bathrooms (Proposed § 442.506; Final § 483.470(d))

Comment: One commenter suggested that under the provisions of the proposed § 442.506 each bathroom should be equipped with a mirror and sink/toothbrush training area.

Response: We believe that this is already implied in proposed § 442.506(a)'s requirement for "bathing facilities appropriate * * * in design to meet the needs of the clients".

Comment: Several commenters expressed concern about the proposed requirement for bathroom privacy unless contraindicated by the client's condition. One commenter stated that any contraindications to bathroom privacy should be determined by the interdisciplinary team and should be indicated in the client's individual program plan.

Response: We agree with those commenters who stated that individual privacy in toilets, bathtubs, and showers does not preclude assistance given from the facility's staff when necessitated by the individual client's condition. Accordingly, we have deleted the provision "unless contraindicated by the client's condition" from the final rule at § 483.470(d)(2). However, we do not think that the regulations should attempt to identify every situation that can conceivably be placed in the individual program plan. Placement of this information in the IPP should be at the discretion of the facility.

Comment: Other commenters stated that exceptions to privacy should be programmatic rather than incorporated in the physical plant and asserted that locked bathroom doors should be encouraged when appropriate.

Response: As noted above, the provisions of the regulations already assure bathroom privacy. We do not believe it is necessary to include prescriptive provisions in the regulations regarding structural design or use of locked bathroom doors.

Comment: Another commenter stated that privacy should extend through the entire living unit, not just the bathroom.

Response: We agree with the general objective of providing for privacy, whenever possible, in the client's living unit; however, this objective must be balanced against the need for a reasonable degree of interpersonal contact and interaction, in order to approximate more closely a normalized environment. In this context, we believe that the client's general right to privacy is already sufficiently ensured by final regulations at § 483.420(a)(7) that require that each client is provided with the opportunity for personal privacy.

Comment: A number of comments were received on proposed § 442.506(c), which restricts water temperature from hot water taps to 110 degrees F. or less in areas of the facility serving clients who have not been trained to regulate water temperature. Several of these commenters expressed support for the exception to the temperature restriction for suitably-trained clients, noting that this offers a more normalized setting; others noted that the regulations need to be flexible enough to address facilities where clients are participating in (but have not yet completed) a training program to regulate water temperature.

Response: We believe that the issue of clients who are in the process of being trained to regulate water temperature can be addressed in interpretive guidelines, which would be based on the assumption that such clients are under direct supervision while being trained to operate hot water temperature controls.

Comment: One commenter suggested a waiver of the water temperature restriction when the program director can demonstrate that client safety is addressed by means other than a control valve.

Response: The regulations require only that water from the hot water tap be maintained at or below a prescribed temperature if clients have not been trained to regulate temperature, but do not prescribe the specific method (such as a control valve) for doing so.

Comment: One commenter asserted that having hot water temperatures below 120 degrees F. results in the water temperature being too cold for showers.

Response: We believe that the longstanding limit of 110 degrees F. represents an acceptable balance between comfort and safety factors, and should be retained. A hot water tap that is limited to this temperature, when appropriately operated in conjunction with the cold water tap, should produce

sufficiently warm water temperatures to ensure comfort without posing a threat to the safety of clients who have not been trained to regulate water temperature.

RR. Heating and Ventilation in Living Units (Proposed § 442.508; Final § 483.470(e))

Comment: One commenter suggested that the proposed § 442.508(a)(1) that would require each client bedroom to have at least one outside window, be changed to at least one outside window or door (that is, allow a door to be used for room ventilation in lieu of an outside window).

Response: Since a door serves primarily to provide egress rather than to perform the ventilation and aesthetic functions of an outside window, we do not believe the language in the proposed rule should be changed. In addition, the outside window serves in an emergency as an alternate means of escape from a below-grade bedroom (see final regulations § 483.470(b)(2)(i)).

Comment: Three commenters requested that we include a definition of the term "normal comfort range" in the proposed § 442.508(b)(1).

Response: We plan to address this issue in interpretive guidelines, which would define a normal comfort range in most instances as not going below a temperature of 68 degrees F. or exceeding a temperature of 81 degrees F. However, the term could also be interpreted to include temperatures that exceed the upper range of 81 degrees F. for facilities in geographic areas of the country (primarily at the northernmost latitudes) where that temperature is exceeded only during rare, brief episodes of unseasonably hot weather. This interpretation would apply in cases where it does not adversely affect client health and safety, and would enable facilities in areas of the country with relatively cold climates to avoid the expense of installing air conditioning equipment that would only be needed very infrequently.

SS. Floors in Living Units (Proposed § 442.510; Final § 483.470(f))

Comment: Regarding the proposed requirement at § 442.510(a) for floors with a "slip-resistant" surface, one commenter noted that any surface is slippery when wet. Regarding the proposal at § 442.510(b) for "nonabrasive" carpeting is carpeted areas serving clients who crawl, this commenter noted that additional factors should be considered as well, such as mobility, sanitation, and safety. The commenter suggested that we require only that attention be given to floor coverings in living units based on the needs of the clients living therein.

Response: We note that the regulations do not require that floors be "slip-free," but merely "slip-resistant;" there is a presumption that the floor surface will ordinarily be dry and when wet, precautions taken. Regarding the comment concerning mobility, sanitation, and safety, we are adding a requirement to final regulations at § 483.470(f)(3) for exposed floor surfaces and floor coverings to promote mobility and maintenance of sanitary conditions.

Comment: One commenter suggested rewording of proposed § 442.510(b) that would require nonabrasive carpeting (if the floors are carpeted) for clients who crawl. The commenter thought the phrase "clients who crawl" should be replaced with "clients who lie on the floor or ambulate with parts of their bodies, other than feet, touching the floor."

Response: We agree with this comment, and have revised the final regulations at § 483.470(f)(2) to include this language.

TT. Space and Equipment in Dining, Health Services and Program Areas (Proposed § 442.512; Final § 483.470(g))

Comment: Regarding the proposed § 442.512(a), that describes space and equipment requirements for various activities, two commenters suggested that we specifically mention recreation and leisure activities.

Response: We agree with this comment, and have added in final regulations the word recreation to the list of areas (for example, dining, program areas) for which the facility must provide sufficient space and equipment.

Comment: One commenter suggested that the space and equipment requirement be relocated under the nursing services section of the active treatment provisions.

Response: We believe that this requirement is appropriately located as proposed, in the section dealing with physical environment. Issues directly involving health services are already adequately dealt with elsewhere in these regulations.

Comment: The proposed rule at § 442.512(b) would require the facility to furnish, maintain in good repair, and encourage the use of devices such as dentures, eyeglasses, hearing and other communications aids, and braces needed by clients. Almost all of the comments we received on this paragraph stressed that the facility should be responsible for furnishing these items only if Medicaid will pay for them; if Medicaid will not cover these items, the facility should only be required to facilitate their acquisition or assist clients in purchasing them.

Response: We note that, under these regulations, the above items are included in the ICF/MR benefit, even though a particular State may elect not to cover them separately for non-ICF/MR recipients. The Medicaid statute (at section 1902(a)(13)(A)) states, in part, that payment rates for ICF/MR services must be "* * * reasonable and adequate to meet the costs which must be incurred by efficiently and economically operated facilities in order to provide care and services in conformity with applicable State and Federal laws, regulations, and quality and safety standards * * *". Thus, we would expect a State's ICF/MR payment rates reasonably to reflect the various items and services which constitute the ICF/MR benefit.

Comment: With respect to dentures, eyeglasses, etc., one commenter asked us to define the terms "furnish" and "maintain in good repair".

Response: The term "furnish" in this context indicates that the facility is responsible (including financial responsibility) for obtaining these items, and is responsible for making any necessary arrangements to enable the client actually to receive them. (If an item is available free of charge, the facility would satisfy this requirement simply by making the necessary arrangements for the client to receive it.) The term "maintain in good repair" indicates that the facility is responsible for ensuring that these items are kept in good working order, and is responsible for any resulting expense that may be incurred. As noted above, we would expect a State's ICF/MR payment rate to reflect reasonably these items and services.

UU. Emergency Plan and Procedures (Proposed § 442.550; Final § 483.470(h))

Comment: One commenter stated that the proposed regulation at § 442.550, that would require a facility to make its plan for emergencies available to staff, should also require that staff be trained in implementation of the plan.

Response: As we had proposed, the facility is charged (see final regulations at § 483.470(h)(2)) with the responsibility of training the staff in use of the emergency plan and procedures.

Comment: One commenter requested clarification of the term "periodically review", as it was used in the proposed § 442.550(b), that would require that a facility periodically review its plan to meet emergencies and disasters.

Response: We will explain in interpretive guidelines that the periodicity of this review is a judgment made by the facility based on the circumstances of the facility. If the facility changes its physical plant or if changes external to the facility necessitate a review of the disaster plan, then the facility is responsible for carrying out that review.

VV. Evacuation Drills (Proposed § 442.552; Final § 483.470(i))

Comment: One commenter suggested that the proposed rule at § 442.552 that requires evacuation drills include provisions for the non-evacuation of those whose health precludes evacuation during drills.

Response: We do not agree with this comment. The drills required by this section are not only for fire but for other disasters such as hurricanes, tornadoes, floods, etc. In these circumstances, the entire occupancy may have to be evacuated. Thus, the entire occupancy must practice these drills.

Comment: The proposed rule reserved § 442.554. One commenter suggested that we use the reserved section to include explicit requirements on building accessibility for the physically handicapped.

Response: The issue of building accessibility is covered by civil rights laws which are invoked under final regulations at § 483.410(b), Compliance with Federal, State and local laws. The Office for Civil Rights implements Department-wide regulations (see 45 CFR 84.22 and 84.23) relative to building accessibility for the physically handicapped and HCFA does not wish to duplicate or conflict with those regulations.

Comment: One commenter proposed adoption of the "buddy system" of evacuation and was concerned that drills not be conducted in sub-zero weather without assistance.

Response: There is nothing in the proposed regulation that would preclude the use of the "buddy system". The regulations do require drills to be conducted under varied conditions but we would not expect drills to be conducted in sub-zero weather.

Comment: The proposed § 442.552(a) would require evacuation drills to be conducted under "varied conditions". One commenter suggested that the term "varied conditions" be defined.

Response: We will explain in interpretive guidelines that the term "varied conditions" principally refers to different times of the day and night and location of clients in respect to rooms in the building. It also refers to weather conditions since quarterly drills would necessitate varied weather conditions.

Comment: One commenter expressed concern that fire safety standards not be used to exclude persons with physical handicaps.

Response: The adoption of the 1985 Life Safety Code (see **Federal Register,** Friday, April 18, 1986, page 13224) incorporates chapter 21 of the Code that defines three levels of physical plant requirements depending on the ability of clients and staff to evacuate the building in the event of fire. This new chapter of the Life Safety Code may enable individuals with physical disabilities to reside in the facility depending on the disability, the staff in the facility and the physical plant characteristics. We expect that the adoption of Chapter 21 of the Code will allow many more clients with physical disabilities to reside in small facilities than was previously the case.

Comment: One commenter suggested that each facility be required to have at least one fire extinguisher per floor.

Response: The Life Safety Code specifies extinguishment requirements for various types of occupancies. As a consequence of the adoption of the 1985 Life Safety Code (see **Federal Register,** Friday, April 18, 1986, page 13224) HCFA has adopted the extinguishment requirements of that Code.

Comment: Several commenters expressed concern that requirements for evacuation drills do not allow a client to move to a "safe area" or from one smoke barrier to another as current regulations allow.

Response: We have modified the final regulation at § 483.470(i)(2)(v) to allow for evacuation to "safe areas" in facilities certified under the Health Care Occupancies Chapter of the Life Safety Code (note that current regulations found at 42 CFR 442.506(b)(1) allow evacuation to a safe area).

Comment: One commenter stated there should be greater emphasis on staff training for fire evacuation drills. Another commenter thought that clients should have evacuation drills as part of their IPP.

Response: We believe that the proposal is adequate in the number of training drills it requires staff to conduct. Additionally, it could be very appropriate to include evacuation drills as part of an IPP if the interdisciplinary team, as a result of the client's comprehensive functional assessment, determined that improved performance during evacuation drills was of high priority for the client to learn. In any case, the final rule at § 483.440(c) (3) and (4) requires that objectives, reflective of a client's needs, be included as part of the IPP.

Comment: One commenter thought that the time it takes clients to evacuate a building would determine what fire safety requirement the facility must meet. That is, the slower the clients exit the building the more fire safe it must be.

Response: Evacuation drills conducted by the facility will not be the criteria for deciding which physical plant requirements a facility must meet in order to comply with Life Safety Code requirements. The State surveyor will determine the level of fire safety requirements on the basis of an objective assessment of the clients, the staff and characteristics of the physical plant.

Comment: One commenter asked whether these regulations should contain a reference to the Life Safety Code.

Response: We have included in final regulations at § 483.470(j) requirements for meeting the Life Safety Code. These requirements are located in current regulations at § 442.508.

Comment: Several commenters indicated that the distinction made in the proposed § 442.552(b) between clients who can cooperate and cannot cooperate in an evacuation is confusing and open to different interpretations. Another commenter did not feel that the proposed requirement for three evacuation drills per year was satisfactory for clients who could not cooperate.

Response: We have deleted in final regulations the reference to clients who can and cannot cooperate. Instead, we are retaining the language of current regulations at § 442.506 that require all clients actually to evacuate during at least one drill each year on each shift.

Comment: One commenter indicated that fire drills should be unannounced.

Response: Good practice dictates that actual, full drills be unannounced, since real emergencies (fire, tornadoes, gas clouds), are immediate and unexpected. However, in order to train staff and clients in evacuation procedures, it is often necessary to practice evacuations without the element of surprise. Thus, it is not possible or advisable simply to require that all drills be unannounced. Rather, by requiring the drills, we meet Life Safety Code requirements and still leave to the facility needed flexibility in how the drills are accomplished.

WW. Paint (Proposed § 442.556; Final § 483.470(k))

Comment: One commenter suggested that a new requirement stating that

clients cannot be housed in buildings that contain asbestos ceilings or insulation be added to the proposed § 442.556 that contained requirements concerning lead paint.

Response: We fully appreciate the importance of ensuring protection from the hazards of exposure to asbestos fibers within buildings. We note that Congress also is concerned with this issue, as evidenced by its enactment last year of the Asbestos Hazards Emergency Response Act. This legislation established a program under which the Environmental Protection Agency (EPA) sets standards to inspect for, identify, and abate hazardous asbestos in schools. Congress is currently considering legislation that would direct the EPA to expand these activities to include nonschool buildings. In view of this pending legislation, and EPA's experience and technical expertise in this area, we do not believe it would be appropriate for HCFA unilaterally to impose its own standards on asbestos abatement.

Comment: One commenter suggested the proposed regulation be modified to state that paint or plaster containing lead must be removed rather than "removed or covered"

Response: We believe this suggestion would create an unnecessary hardship on facilities. We believe that client safety and health will be assured by requiring the facility either to remove or cover interior paint containing lead.

Comment: One commenter indicated that in the past there was a requirement that paints be non-flammable, and asked if this requirement was still applicable.

Response: We were unable to locate a Federal ICF/MR regulation that prohibited the use of flammable paints.

XX. Food and Nutrition Services (Proposed § 442.558; Final § 483.480(a))

Comment: Several commenters indicated that the proposed § 442.558(a) would unnecessarily restrict facilities because it would require that the facility actually provide each client with a nourishing, well balanced diet. They note that while clients are in "day care" programs the facility cannot be held responsible for the food served.

Response: We agree that emphasis should be placed on the client outcome of receiving an appropriate diet rather than on the facility's provision of it and have amended final regulations by indicating that each client must receive an adequate diet even though the facility does not provide it directly. However, responsibility for the food served to clients by outside programs continues to remain with the ICF/MR, as the legally responsible entity.

Comment: One commenter suggested that the regulation be modified to require a nourishing, well-balanced diet to "meet the individual needs of the clients".

Response: We do not agree that addition of this phrase is necessary. The final regulations at § 483.480(a)(1) include language that states that "each client must receive a nourishing, well-balanced diet". A diet cannot be nourishing nor well balanced for each client unless his or her individual needs have been addressed.

Comment: One commenter suggested that a new section be added to indicate that if behavior modification programs include the use of food, such programs must be reviewed by a registered dietitian to assure provision of a nutritional diet.

Response: We agree with this comment and have revised final regulations to include a provision at § 483.480(a)(4) that requires the interdisciplinary team, including the physician and the dietitian to participate in decisions that include the provision of food as part of a program to manage inappropriate client behavior.

Comment: One commenter suggested that all facilities be required to maintain a current diet manual, and that the manual be approved by the dietitian and medical director and be kept in a convenient location for use in preparing diets.

Response: We believe this suggestion is too prescriptive and believe that the requirement stating that diets be prepared in accordance with the Food and Nutrition Board of the National Research Council, National Academy of Sciences will help to assure the provision of nutritionally sound diets.

Comment: One commenter suggested that the proposed requirement in § 442.558 that would require diets to be prepared in accordance with the Food and Nutrition Board of the National Research Council be modified to provide flexibility for individual choice in food for those clients in independent cooking programs.

Response: These regulations do not preclude a facility from providing individual food choice for clients participating in an independent cooking program.

Comment: One commenter asked whether every facility would be required to obtain a copy of the dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences.

Response: If a facility can prepare meals in accordance with the standards specified without having a copy (for example, through its dietitian), then it need not possess a copy.

Comment: One commenter pointed out that the standards set by the Food and Nutrition Board of the National Research Council, National Academy of Sciences represent minimum guidelines and not a maximum, and that the nutritional needs of some clients may not be met by compliance with a minimum standard.

Response: We agree and have modified final regulations accordingly. As amended, the language of the final rule at § 483.480(a)(6) requires that diets must be prepared *at least* in accordance with the Food and Nutrition Board standards.

Comment: Two commenters expressed concern that the proposed regulation contains no provisions regarding safety and sanitation in food storage, food preparation or food service.

Response: We believe that these are issues that are well covered by existing State and local laws. Under the final regulations at § 483.410(b), a facility is required to adhere to State and local laws; therefore, we believe there is no need for the suggested change since it would be duplicative.

Comment: One commenter suggested that the duties of the dietitian should be expanded in this regulation to include being responsible for providing annual nutrition assessments and conducting periodic follow-up menu reviews, providing guidance to the food service operations, and being included in the interdisciplinary assessment of client feeding problems.

Response: There is nothing in this section that would preclude the dietitian from performing these functions; however, we believe it is best that each facility utilize personnel according to the facility's individual needs.

Comment: A number of commenters expressed views about the proposed requirement for physician and dietitian participation in decisions about modified and special diets. One commenter wanted other appropriate team members to be involved in decisions about these diets, another questioned the need for a physician and a dietitian to participate in these decisions, and another wanted the interdisciplinary team to make decisions about these diets. Another commenter wanted the physician and dietitian to participate in decisions about the caloric levels and nutritional adequacy of diets. Finally, one commenter wanted the word "participation" to be defined in regulation and another wanted a

definition of "modified and special diets".

Response: We do not believe these regulations should specify who should develop modified and special diets as long as the physician and dietitian participate in those decisions. The physician's and dietitian's participation should assure the necessary quality of modified and special diets, but we do not believe it is necessary to regulate their involvement in caloric levels. The facility as a whole is held responsible for nutritional adequacy as required by § 442.558(a) of the proposed regulations. The words "participates in decisions about" contained in proposed § 442.558(b) have been deleted from final regulations. Instead, the final regulations at § 483.480(a)(4) now require the physician and dietitian, as part of the interdisciplinary team, to prescribe all modified and special diets. Finally, we will define "modified and special diets" in the interpretive guidelines as diets that are needed to enable the clients to eat (for example, food that is chopped, pureed, etc.) or diets that are intended to correct or prevent a nutritional deficiency or health problem.

Comment: One commenter suggested that meals be developed by a Food and Nutrition Unit.

Response: We do not believe it necessary to require a Food and Nutrition Unit. However, there is nothing to preclude the establishment of a Food and Nutrition Unit if an individual facility so desires.

Comment: One commenter suggested that a dietitian-to-client ratio be established in these standards.

Response: We believe that to establish dietitian-to-client ratios would be unnecessarily prescriptive.

Comment: One commenter asked that the dietitian be a part of the "feeding team" and another commenter asked that the dietitian be a part of the "infection control team".

Response: The regulations do not require the establishment of either of these teams. However, if a facility chooses to establish such teams, there is nothing that would preclude a dietitian's participation on these teams.

Comment: One commenter suggested that the "nutrition unit" be required to conduct nutrition education programs for direct care personnel, clients and their families.

Response: Section 483.430(e) of final regulations mandates staff training. We believe that this requirement is sufficient to assure that staff is trained. There is nothing in this regulation that precludes the kind of training suggested by the commenter for clients and their families.

YY. Meal Services (Proposed § 442.560; Final § 483.480(b))

Comment: Several commenters objected to the proposed requirement at § 442.560(a) for actually serving three meals a day to clients, since many clients eat lunch at day care programs.

Response: We agree with these commenters and have modified final regulations to incorporate language at § 483.480(b)(1) that specifies that each client must receive at least three meals each day. This would maintain the facility's responsibility to see to it that clients receive three meals a day without requiring them actually to serve the meals themselves.

Comment: Several commenters stated that the prohibition under § 442.560(a)(1) of the proposed regulations that breakfast be served no longer than 14 hours after the evening meal unnecessarily restricted clients' eating habits on weekends and holidays. They noted that this requirement did not allow clients to sleep in on weekends and holidays.

Response: We agree with the comments and, while we have retained the 14 hour meal span requirement, we have included in final regulations at § 483.480(b)(1) an exception allowing an extension to 16 hours on weekends and holidays if a nourishing snack is served at bedtime.

Comment: Several commenters suggested a change to the proposed standard that requires discarding food that has been served and uneaten. They wanted wording that would allow reuse of food served "family style".

Response: We agree with this comment and have changed the final regulations to include language at § 483.480(b)(3) that requires that when food is served "to clients individually" it must be discarded.

Comment: One commenter objected to the deletion in the proposed rule of a provision in current regulations that requires food to be served under sanitary conditions.

Response: We of course agree that it is important that food be served under sanitary conditions; however, we believe this can best be accomplished by relying on local and State laws. Section 442.416 of the proposed rule, now incorporated into § 483.410(b) of final regulations requires compliance with these laws.

Comment: One commenter suggested that the proposed § 442.560(b) regarding the serving of food be revised to require that food be served in sufficient quality as well as quantity.

Response: The issue of quality was dealt with in proposed section § 442.558 (final § 483.480(a)) that requires a nourishing and well balanced diet for each client.

Comment: One commenter proposed adding a new subsection that would mandate: attention being paid to clients' reasonable food preferences; maintaining records of each client's likes, dislikes, and food allergies; and observing each client to determine acceptance of diet.

Response: While we believe that the ends sought in this comment are laudable, we believe that it is too prescriptive to specify these details in the regulations. We note, however, that the final rule at § 483.440(c)(3)(v) requires that the comprehensive functional assessment of each client must identify the client's nutritional status.

Comment: One commenter suggested adding a new subsection (d) to proposed § 442.560 pertaining to recipes, detailing the number of clients to be served from each recipe and the methods used in recipe preparation to assure nutritional value, texture, flavor and appearance, etc.

Response: We believe these suggestions are too prescriptive in nature to be beneficial.

ZZ. Menus (Proposed § 442.562; Final § 483.480(c))

Comment: One commenter stated that the provision in proposed § 442.562 to include average portion sizes for menu items was not necessary.

Response: We do not believe this requirement should be deleted since it can be used as a tool to help determine adequacy of diet.

Comment: Three commenters indicated that we should require that menus be prepared at least one week in advance of their usage.

Response: We believe this to be overly prescriptive in nature. This is an area where the facility should have flexibility.

Comment: Four commenters wanted a requirement for menu approval by a dietitian for nutritional adequacy and for therapeutic corrections of modified diets.

Response: We believe that the concerns addressed in this comment are addressed in proposed § 442.558, Food and Nutrition Services that requires diets to be nourishing and well-balanced and requires a dietitian and a physician to participate in decisions about modified and special diets.

Comment: One commenter indicated the desire to see a prohibition against

"fast food/junk food" appearing on the menu.

Response: The requirement contained at the proposed § 442.558(a) (final § 483.480(a)) that would mandate that each client receive nourishing, well-balanced meals to assure that clients' dietary needs are met. Whether the foods are considered "fast or junk foods" is not a concern so long as the client is receiving a nutritious and well-balanced diet. Therefore, we have not made this change.

Comment: The remainder of the commenters on this section suggested a variety of additions. One wanted retention of an existing regulation requiring the facility to maintain food purchase records. Another wanted menus to be posted in cooking and serving areas. One commenter wanted a regulation on between-meal feedings. Another commenter wanted a section stipulating that modified diets be accurately written and correctly served. Finally, one commenter suggested greater flexibility for clients trained in food purchases and preparations.

Response: We have not modified the proposed regulations to incorporate these comments. It is our view that these requirements are too restrictive, and that sufficient client protections relative to these issues are already contained in the final regulations at § 483.480 and other sections of the final rule.

AAA. Dining Areas and Service (Proposed § 442.564; Final § 483.480(d))

Comment: One commenter suggested that the proposed requirement for provision of table service to all clients who can and will eat at a table be changed to encompass several levels of client functioning.

Response: We do not believe the regulation should be modified to designate table service classifications by client functional status. Clients of grossly different ages, developmental levels and social needs generally are not allowed to be housed together (see final regulations at § 483.470(a)(1)). We do not believe it necessary to extend this requirement to table service as well.

Comment: One commenter suggested that a new subsection be added that would require the facility to provide enough staff trained in appropriate feeding techniques and client positioning.

Response: The final regulations at § 483.430 (c) through (e) already make provisions for sufficient staff and for the training of that staff. We believe these requirements adequately address these issues.

Comment: Section § 442.564 of the proposed rule would require the facility to serve meals to clients in dining areas unless otherwise specified by the interdisciplinary team or a physician. Two commenters suggested that a dietitian also be allowed to exempt clients from this general rule. Another commenter wanted physicians deleted from the list.

Response: We have not changed this standard. The fundamental reason a client would not eat in a dining area relates to the existence of a medical care plan or because of a behavioral or developmental problem that either the interdisciplinary team or the physician would have knowledge of. If the problem relates to a significant dietary problem, the dietitian would be on the interdisciplinary team as a consequence of that problem and would provide input by that means.

Comment: One commenter believes that the provision in current regulations § 442.472(c) requiring clients to eat in an upright position, unless medically contraindicated, should be retained.

Response: Our final regulations at § 483.480(d)(2) require the facility to provide table service to all clients that can and will eat at a table. They also require at § 483.480(d)(1) that the facility serve all clients in dining areas unless exceptions are made by the interdisciplinary team or a physician. It was our intent that these provisions should be sufficient to assure that clients are fed in an upright position unless medically contraindicated. however, to ensure that our intent is clearly understood, we have mentioned it explicitly in the final rule at § 483.480(d)(5).

Comment: One commenter suggested a new standard be established for food service sanitation that would indicate that sanitary standards must be in compliance with State and local laws.

Response: Such a standard would be redundant since § 483.410(b) of the final regulations requires that facilities must be in compliance with all applicable provisions of Federal, State and local laws pertaining to health, sanitation, safety and research.

Comment: One commenter prescribed a series of requirements that a facility's diet services must include. Among these were requirements relating to specifications for supplies and equipment, standards to assure proper storage of food, and other health and safety features.

Response: In general, we believe these requirements would be too prescriptive and would unnecessarily interfere with the effective management of the facility. Additionally, those suggestions relating to food storage and food health issues are best addressed, we believe, by State and local enforcement of applicable regulations and laws.

Comment: One commenter suggested that paragraph (a) of the proposed § 442.564 should be more flexible since not all meals are served in dining areas; for example, picnics and parties.

Response: We will specify in interpretive guidelines that on special occasions such as picnics and parties, clients would not have to be served in established "dining areas".

IV. Provisions of the Final Rule

We are adopting the provisions set forth in the NPRM with the exception of the changes noted in the "Discussion of Comments" (section III above), including the reorganization of the proposed standards into a condition format and the redesignation of these as a new Part 483. As a result of adopting the conditions format and the redesignation, we are making several conforming changes thoughout the regulations. We also are making many technical and clarifying changes.

The conforming changes that we are making will change references to the standards for ICFs/MR to read "conditions of participation". These changes are located at §§ 442.117, 442.118, 442.119 and 442.254. Other conforming changes at §§ 440.150, 442.30, 442.100, 442.101, 442.105, 442.117, and 442.254 will reflect the move from Part 442, Subpart G to Part 483, Subpart D.

We also are making changes to clarify our policies concerning provider agreements and facility certifications. In § 442.13(c), we are adding language to clarify that it is acceptable for a provider to submit a correction plan only if it meets any applicable conditions of participation. This is consistent with our policy that under conditions of participation, a provider agreement may not be entered into with a facility that has deficiencies at the condition-level. A facility may obtain a provider agreement under certain circumstances with deficiencies at the standard-level. We also are revising §§ 442.101, 442.105 and 442.110 to clarify that a facility may be certified by the survey agency with deficiencies at the standard-level only. (Note: Section 442.110 was previously § 442.111. HSQ-127-F, Correction and Reduction plans for Intermediate Care Facilities for the Mentally Retarded (53 FR 1984) redesignated the section.) We are further revising § 442.101 (d) and (e) to clarify which subparts contained the requirements that each type of facility (that is, SNFs, ICFs and ICFs/MR) must meet.

In many cases, the regulations use the phrase "Federal standards" in a general sense; that is, the phrase refers to both standards and conditions of participation. In order to avoid confusion and to maintain the distinction between standards and conditions of participation, we are changing several of these general references to "requirements". These changes are located at §§ 431.610, 442.13, 442.14, 442.16, and 442.30. We also are deleting the general reference to standards used, and intermediate care facilities for the mentally retarded in § 442.1. That section refers to requirements for facility certification which we believe encompasses facility standards and conditions of participation.

Additionally, throughout the proposed regulation, we included language that stated that "The facility must provide * * *" or "The facility must develop * * *". In this final rule, we have changed that language in many instances to "Each client must receive * * *". We believe that this change clarifies our intent to emphasize client needs.

V. Regulatory Impact Statement

A. Executive Order 12291

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

While we believe that the regulations will accomplish these results, for several reasons we are not able to state the economic impact in quantitative terms. First, current cost reporting requirements do not provide data broken down by cost centers that would allow us to determine the impact of either our present or future health and safety requirements on facility expenditures. Second, ascribing cost of care is difficult because of the variations among facilities in terms of facility size and type, and diversity in per diem rates within a State. Third, the variety of client characteristics makes it difficult to ascribe costs of care based on these characteristics.

Nonetheless, we have found no available data or analyses that indicate that these changes would have an annual economic impact of $100 million, or meet the other thresholds specified in the Executive Order. For these reasons, we have determined that a regulatory impact analysis is not required.

B. Regulatory Flexibility Analysis

1. Introduction

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 treat all ICFs/MR as small entities. Because many facilities may be significantly affected by these final regulations, we have prepared the following regulatory flexibility analysis.

2. Affected Entities

As of December 1986, there were about 3,660 certified ICFs/MR ranging in size from four to approximately 1500 beds, as follows:

Number of beds	Number of ICFs/MR	Percent of total
4 to 15	2,785	76
16 to 100	754	21
Over 100	121	3
Total	3,660	100

Nonprofit ICFs/MR comprise about 54 percent of certified ICFs/MR, for-profit facilities about 23 percent, and governmental facilities about 24 percent.

We expect restructuring of the requirements in this regulation will have a substantial effect on facility performance. These revised regulations de-emphasize paper work and focus on the active treatment of clients. Initially, facilities may experience more deficiency findings from surveys. However, we do not expect more terminations to result because we expect facility performance to change in ways that would improve compliance and quality of care.

Although we anticipate significant changes on the part of facilities as they focus more on the provision of active treatment to clients, we do not expect a substantial increase in their costs. By publishing these rules, we are giving facilities both the notice and the incentive to refocus their attention. Under these provisions, as under the existing rules and survey protocols, deficiencies will commonly result in plans of correction that afford an adequate opportunity for facilities to come into compliance. The new rules will create the opportunity and the incentive for facilities to reallocate their resources more efficiently and effectively, thus increasing emphasis on the provision of active treatment.

We believe that affected facilities will benefit by the new conditions of participation because of the reduced paperwork burdens and costs, and increased administrative flexibility. While some paperwork is legally and programmatically necessary and important, much of it is performed only to meet specific and discrete requirements specified in current regulations. The final regulations' emphasis on staff and client performance, rather than paper compliance, could reduce the production of paper significantly in some of the large public facilities. However, State licensing requirements and internal facility policies and practices, by retaining some of the same requirements, may also affect the extent to which potential savings are realized under these conditions.

There is an established trend to smaller ICFs (that is, facilities with fewer than 16 beds). These regulations afford these facilities the flexibility they need to operate more effectively. While these facilities will benefit from reduced paperwork and increased focus on client outcomes, because of their size they typically experience fewer of the administrative and programmatic problems in delivering and accounting for services to clients which result from the prescriptive, generally inflexible standards contained in the current regulations.

Specific provisions of this regulation which may significantly affect individual facilities include:

(a) Physician services—To the extent allowed by State law, physician assistants (PAs) and nurse practitioners (NPs) may perform physician functions. This provision could result in significant savings for those facilities that can use PAs and NPs for routine health care.

(b) Nursing personnel—Those facilities that serve 16 or fewer persons and that do not now require professional nursing services will be required to arrange for nursing personnel to conduct an in-person health review of each client at least quarterly. This may represent an increased cost over present requirements for affected facilities because we cannot calculate the expected offset in savings that will occur under these conditions. However, this requirement will be balanced by a decrease in costs because facilities that serve 16 or more clients, none of whom have a medical care plan ordered by a physician, will not need a licensed nurse on duty.

(c) Dental services—The new provisions make explicit that which was always intended; that is, comprehensive

dental treatment including emergency care and annual check-ups are required. Some facilities may experience a cost increase, depending on the extent to which they have met the existing standards.

(d) Client bedrooms (floor to ceiling walls)—For facilities initially certified, or in buildings constructed or with major renovations or conversions on or after October 3, 1988, walls must extend from the floor to the ceiling between living quarters. Clients benefit by increased privacy and a slight degree of increased safety by the containment of possible spreading fires. Since this provision reflects state-of-the-art design and construction practices, we expect the economic impact of this requirement on new facilities planning to come into the program to be negligible. Very few new facilities planning to come into the program would not already meet this requirement. Although the requirement for floor to ceiling walls would have an economic impact on facilities undergoing major renovation or conversion, we do not anticipate that many facilities will be affected due to the trend toward smaller facilities.

(e) Client bedrooms (variance to the four-to-a-bedroom rule)—This regulation limits the conditions under which a facility can claim variance to the rule that no more than four persons may be allowed per bedroom. Only physicians may order this arrangement for clients with severe health problems that require continuous monitoring during sleeping hours. For those facilities that have relied on this variance in existing standards, this provision may represent significant increased capital expenditures. Alternatively, facilities (or buildings) affected could face the loss of certification in the ICF/MR program.

(f) Laboratory services—These final regulations will require that ICFs/MR that choose to provide directly inhouse laboratory services must now meet the requirements of § 483.460(n). We had stated in the NPRM that we had identified 110 public ICFs/MR that used inhouse labs and that would be affected by this provision. A more recent survey showed 80 ICFs/MR that operate their own labs. We believe the difference may be because separate labs in other than ICFs/MR were not included in the more recent survey. We are unable to determine the economic impact upon these ICFs/MR because these labs have not been surveyed previously and we do not know to what extent they would meet the requirements of these final rules. However, we believe that any impact upon the ICFs/MR resulting from an attempt to meet these requirements would be offset by increased accuracy of testing and quality of care received by the facility's clients.

(g) Use of interdisciplinary team—We expect that provisions specifying an interdisciplinary team to coordinate and establish one plan of treatment per client will result in increased quality of care and reduced administrative burden.

3. Effect on Clients

We expect that clients will benefit by better quality of care, by more attention to clients' rights, and by more opportunity for self determination. The net result of these revised regulations will be to focus much more attention on the active treatment of individual clients. Instead of multiple treatment plans developed and implemented by different disciplines, there will be a single treatment plan coordinated and integrated by one interdisciplinary team. The individual treatment plan will establish client objectives and set priorities for those objectives into a meaningful progression of treatment activities and programs with a single professional, the qualified mental retardation professional directly furnishing services for the facility, in charge. Client rights have been made more explicit by clearly stating in positive language the rights that each client has and by establishing explicit standards for staff treatment of clients that reaffirm each of these clients' rights.

C. Conclusion

The actual impact on an individual ICF/MR would represent the extent of the incremental difference between a facility's current level of compliance with our regulations and the effort and cost, if any, required to meet these revisions. Overall, we believe that most facilities will be able to improve performance at lower cost and will have greater flexibility to administer their programs. As explained above, smaller facilities already have substantial flexibility, so that the net gain is not expected to be substantial for most of these facilities. Nonetheless, we expect that the quality of care in smaller facilities will be enhanced.

VI. Paperwork Burden

Sections 483.410 (c) and (d); 483.420(d); 483.440 (b) through (f); 483.450 (a) and (b); 483.460 (a), (b), (c), (e), (f), (h), (j), (k) and (l) and, 483.470 (b), (h), (i) and (l) of this final rule contain information collection requirements. The public is not required to comply with the information collection requirements until the Executive Office of Management and Budget approves these requirements under Section 3507 of the Paperwork Reduction Act (44 U.S.C. 3507). A notice will be published in the Federal Register when approval is obtained.

List of Subjects

42 CFR Part 431

Grant programs—health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 435

Aid to Families with Dependent Children, Grant programs—health, Medicaid, Reporting and recordkeeping requirements, Supplemental Security Income (SSI), Wages.

42 CFR Part 440

Grant programs—health, Medicaid.

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 483

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

42 CFR Chapter IV is amended as set forth below:

A. The table of contents for Chapter IV, Subchapter E is amended by adding a new Part 483 to read as follows:

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

* * * * *

SUBCHAPTER E—STANDARDS AND CERTIFICATION

Part

* * * * *

483 Conditions of participation for long term care facilities

* * * * *

PART 431—STATES ORGANIZATION AND GENERAL ADMINISTRATION

B. Part 431 is amended as follows:

1. The authority citation for Part 431 continues to read as follows:

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

§ 431.610 [Amended]

2. In § 431.610(f)(1), remove the word "standards" and add in its place the word "requirements".

PART 435—ELIGIBILITY IN THE STATES, DISTRICT OF COLUMBIA AND THE NORTHERN MARIANA ISLANDS

C. Part 435 is amended as follows:

1. The authority citation for Part 435 continues to read as follows:

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

2. In § 435.1009, the introductory language is republished and the definition of "Active treatment in institutions for the mentally retarded" is revised as follows:

§ 435.1009 Definitions relating to institutional status.

For purposes of FFP, the following definitions apply:

"Active treatment in intermediate care facilities for the mentally retarded" means treatment that meets the requirements specified in the standard concerning active treatment for intermediate care facilities for persons with mental retardation under § 483.440(a) of this subchapter.

* * * * *

PART 440—SERVICES: GENERAL PROVISIONS

D. Part 440 is amended as follows:

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

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

§ 440.150 [Amended]

2. Section 440.150(c)(3) is amended by removing the phrase "defined in § 435.1009" and adding in its place the phrase "specified in § 483.440".

PART 442—STANDARDS FOR PAYMENT FOR SKILLED NURSING AND INTERMEDIATE CARE FACILITY SERVICES

E. Part 442 is amended as set forth below:

1. In the table of contents, § 442.252 and the entire Subpart G (consisting of §§ 442.400—442.516) are removed; and, the titles of §§ 442.105 and 442.110, and the authority citation for Part 442 are revised to read as follows:

PART 442—STANDARDS FOR PAYMENT FOR SKILLED NURSING AND INTERMEDIATE CARE FACILITY SERVICES

Sec.

* * * * *

442.105 Certification with standard-level deficiencies: General provisions.

* * * * *

442.110 Certification period: Facilities with standard-level deficiencies.

* * * * *

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

2. In § 442.1(a), the first sentence is revised to read as follows:

§ 442.1 Basis and purpose.

(a) This part states requirements for provider agreements and facility certification relating to the provision of services furnished by skilled nursing facilities and intermediate care facilities to Medicaid recipients. * * *

* * * * *

3. In § 442.13(b)(1), remove the word "standards" and add in its place the word "requirements", and revise paragraph (c) to read as follows:

§ 442.13 Effective date of agreement.

* * * * *

(c) *All Federal requirements are not met on the date of the survey.* If the provider fails to meet any of the requirements specified in paragraph (b) of this section, the agreement must be effective on the earlier of the following dates:

(1) The date on which the provider meets all requirements.

(2) The date on which the provider is found to meet all applicable conditions of participation and submits a correction plan for other deficiencies to the State survey agency or an approvable waiver request, or both.

§ 442.14 [Amended]

4. Section 442.14(b)(3) is amended by removing the word "standards" and adding in its place the word "requirements".

§ 442.16 [Amended]

5. Section 442.16(b) is amended by removing the word "standards" and adding in its place the word "requirements".

6. In § 442.30(a), the introductory language is republished and paragraphs (a)(1) and (4) 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 SNF and ICF 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 certification requirements under Subpart D, E, or F of this part or Subpart D of Part 483, which sets forth the conditions of participation for ICFs/MR;

* * * * *

(4) The survey agency failed to use the Federal requirements and the forms, methods and procedures prescribed by HCFA in current general instructions, as required under § 431.610(f)(1) of this chapter, for determining the qualifications of providers; or

* * * * *

7. Section 442.100 is revised to read as follows:

§ 442.100 State plan requirements.

A State plan must provide that the requirements of this subpart and Part 483 are met.

8. In § 442.101, paragraphs (d) and (e) are revised to read as follows:

§ 442.101 Obtaining certification.

* * * * *

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

(1) The facility meets the applicable requirements:

(i) A SNF meets the requirements in Subpart D of this part and each of the conditions of participation in Part 405, Subpart K of this chapter.

(ii) A ICF meets the requirements in Subparts E and F of this part.

(iii) A ICF/MR meets the requirements of Subpart E of this part and each of the conditions of participation in Part 483, Subpart D of this chapter.

(2) The facility is considered to meet applicable requirements based on waivers or variances granted by HCFA or survey agency if such waivers or variances are allowed under the applicable subpart.

(3) The facility has been certified with deficiencies in accordance with the following:

(i) An ICF has been certified if deficiencies are covered by an acceptable plan of correction.

(ii) An SNF or ICF/MR has been certified with standard-level deficiencies if—

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

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

(e) For SNFs and ICFs/MR, the failure to meet one or more of the applicable conditions of participation is cause for termination or non-renewal of the provider agreement.

9. Section 442.105 is amended by revising the title and the introductory paragraph to read as follows:

§ 442.105 Certification with standard-level deficiencies: General provisions.

If a survey agency finds a facility deficient in meeting the standards specified under Subpart D, E or F of this part or under Subpart D of Part 483, the agency may certify the facility for Medicaid purposes under the following conditions:

* * * * *

10. Section 442.110 is amended by revising the title to read as follows:

§ 442.110 Certification period: Facilities with standard-level deficiencies.

11. In § 442.117(a), the introductory paragraph is republished and paragraph (a)(1) is revised to read as follows:

§ 442.117 Termination of certification facilities whose deficiencies pose immediate jeopardy.

(a) A survey agency must terminate a facility's certification if it determines that—

(1) The facility no longer meets applicable conditions of participation (for SNFs and ICFs/MR) or standards (for ICFs) specified under Subpart D, E, and F of this part or Part 483, Subpart D of this chapter; and

* * * * *

§ 442.118 [Amended]

12. In § 442.118, paragraph (b)(1) is amended by adding the phrase "ICFs/MR" after "SNFs", and paragraph (b)(3)(i) is amended by removing the phrase "conditions of participation (for SNFs) or standards (for ICFs and ICFs/MR)" adding in its place the phrase "conditions of participation (for SNFs and ICFs/MR or standards (for ICFs)."

§ 442.119 [Amended]

13. In § 442.119, paragraphs (a)(1) and (b)(1) are amended by removing the phrase "conditions of participation (for SNFs) or standards (for ICFs and ICFs/MR)" and adding in its place the phrase "conditions of participation (for SNFs and ICFs/MR) or standards (for ICFs)".

§ 442.252 [Removed]

14. Subpart E is amended by removing § 442.252.

15. Section 442.254(b) is revised to read as follows:

§ 442.254 Standards for hospitals and SNF's providing ICF services.

* * * * *

(b) If a hospital or SNF participating in Medicare or Medicaid is also a provider of ICF/MR services, it must meet each of the conditions of participation specified in Part 483, Subpart D of this chapter.

§§ 442.400–442.516 [Removed]

16. Subpart G, (Consisting of §§ 442.400–442.516) is removed.

F. A new Part 483 is added to Subchapter E to read as follows:

PART 483—CONDITIONS OF PARTICIPATION FOR LONG TERM CARE FACILITIES

Subpart A–C—[Reserved]

Subpart D—Conditions of Participation for Intermediate Care Facilities for the Mentally Retarded

Sec.

Authority: Secs. 1102, 1905(c) and (d) of the Social Security Act (42 U.S.C 1302, 1396d(c) and (d)).

Subpart A–C—[Reserved]

Subpart D—Conditions of Participation for Intermediate Care Facilities for the Mentally Retarded

§ 483.400 Basis and purpose.

This subpart implements section 1905 (c) and (d) of the Act which gives the Secretary authority to prescribe regulations for intermediate care facility services in facilities for the mentally retarded or persons with related conditions.

§ 483.405 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 conditions of participation under this Part, their violation may result in the termination or suspension of, or the refusal to grant or continue, Federal financial assistance.

§ 483.410 Condition of participation: Governing body and management.

(a) *Standard: Governing body.*

The facility must identify an individual or individuals to constitute the governing body of the facility. The governing body must—

(1) Exercise general policy, budget, and operating direction over the facility;

(2) Set the qualifications (in addition to those already set by State law, if any) for the administrator of the facility; and

(3) Appoint the administrator of the facility.

(b) *Standard: Compliance with Federal, State, and local laws.*

The facility must be in compliance with all applicable provisions of Federal, State and local laws, regulations and codes pertaining to health, safety, and sanitation.

(2) *Standard: Client records.*

(1) The facility must develop and maintain a recordkeeping system that includes a separate record for each client and that documents the client's health care, active treatment, social information, and protection of the client's rights.

(2) The facility must keep confidential all information contained in the clients' records, regardless of the form or storage method of the records.

(3) The facility must develop and implement policies and procedures governing the release of any client information, including consents necessary from the client, or parents (if the client is a minor) or legal guardian.

(4) Any individual who makes an entry in a client's record must make it legibly, date it, and sign it.

(5) The facility must provide a legend to explain any symbol or abbreviation used in a client's record.

(6) The facility must provide each identified residential living unit with appropriate aspects of each client's record.

(d) *Standard: Services provided under agreements with outside sources.*

(1) If a service required under this subpart is not provided directly, the facility must have a written agreement with an outside program, resource, or service to furnish the necessary service, including emergency and other health care.

(2) The agreement must—

(i) Contain the responsibilities, functions, objectives, and other terms agreed to by both parties; and

(ii) Provide that the facility is responsible for assuring that the outside services meet the standards for quality of services contained in this subpart.

(3) The facility must assure that outside services meet the needs of each client.

(4) If living quarters are not provided in a facility owned by the ICF/MR, the ICF/MR remains directly responsible for the standards relating to physical environment that are specified in § 483.470 (a) through (g), (j) and (k).

§ 483.420 Condition of participation: Client protections.

(a) *Standard: Protection of clients' rights.* The facility must ensure the rights of all clients. Therefore, the facility must—

(1) Inform each client, parent (if the client is a minor), or legal guardian, of the client's rights and the rules of the facility;

(2) Inform each client, parent (if the client is a minor), or legal guardian, of the client's medical condition, developmental and behavioral status, attendant risks of treatment, and of the right to refuse treatment;

(3) Allow and encourage individual clients to exercise their rights as clients of the facility, and as citizens of the United States, including the right to file complaints, and the right to due process;

(4) Allow individual clients to manage their financial affairs and teach them to do so to the extent of their capabilities;

(5) Ensure that clients are not subjected to physical, verbal, sexual or psychological abuse or punishment;

(6) Ensure that clients are free from unnecessary drugs and physical restraints and are provided active treatment to reduce dependency on drugs and physical restraints;

(7) Provide each client with the opportunity for personal privacy and ensure privacy during treatment and care of personal needs;

(8) Ensure that clients are not compelled to perform services for the facility and ensure that clients who do work for the facility are compensated for their efforts at prevailing wages and commensurate with their abilities;

(9) Ensure clients the opportunity to communicate, associate and meet privately with individuals of their choice, and to send and receive unopened mail;

(10) Ensure that clients have access to telephones with privacy for incoming and outgoing local and long distance calls except as contraindicated by factors identified within their individual program plans;

(11) Ensure clients the opportunity to participate in social, religious, and community group activities;

(12) Ensure that clients have the right to retain and use appropriate personal possessions and clothing, and ensure that each client is dressed in his or her own clothing each day; and

(13) Permit a husband and wife who both reside in the facility to share a room.

(b) *Standard: Client finances.* (1) The facility must establish and maintain a system that—

(i) Assures a full and complete accounting of clients' personal funds entrusted to the facility on behalf of clients; and

(ii) Precludes any commingling of client funds with facility funds or with the funds of any person other than another client.

(2) The client's financial record must be available on request to the client, parents (if the client is a minor) or legal guardian.

(c) *Standard: Communication with clients, parents, and guardians.* The facility must—

(1) Promote participation of parents (if the client is a minor) and legal guardians in the process of providing active treatment to a client unless their participation is unobtainable or inappropriate;

(2) Answer communications from clients' families and friends promptly and appropriately;

(3) Promote visits by individuals with a relationship to the client (such as family, close friends, legal guardians and advocates) at any reasonable hour, without prior notice, consistent with the right of that client's and other clients' privacy, unless the interdisciplinary team determines that the visit would not be appropriate;

(4) Promote visits by parents or guardians to any area of the facility that provides direct client care services to the client, consistent with the right of that client's and other clients' privacy;

(5) Promote frequent and informal leaves from the facility for visits, trips, or vacations; and

(6) Notify promptly the client's parents or guardian of any significant incidents, or changes in the client's condition including, but not limited to, serious illness, accident, death, abuse, or unauthorized absence.

(d) *Standard: Staff treatment of clients.* (1) The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect or abuse of the client.

(i) Staff of the facility must not use physical, verbal, sexual or psychological abuse or punishment.

(ii) Staff must not punish a client by withholding food or hydration that contributes to a nutritionally adequate diet.

(iii) The facility must prohibit the employment of individuals with a conviction or prior employment history of child or client abuse, neglect or mistreatment.

(2) The facility must ensure that all allegations of mistreatment, neglect or abuse, as well as injuries of unknown source, are reported immediately to the administrator or to other officials in accordance with State law through established procedures.

(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 designated representative or to other officials in accordance with State law within five working days of the incident and, if the alleged violation is verified, appropriate corrective action must be taken.

§ 483.430 Condition of participation: Facility staffing.

(a) *Standard: Qualified mental retardation professional.* Each client's active treatment program must be integrated, coordinated and monitored by a qualified mental retardation professional who—

(1) Has at least one year of experience working directly with persons with mental retardation or other developmental disabilities; and

(2) Is one of the following:

(i) A doctor of medicine or osteopathy.

(ii) A registered nurse.

(iii) An individual who holds at least a bachelor's degree in a professional category specified in paragraph (b)(5) of this section.

(b) *Standard: Professional program services.*—(1) Each client must receive the professional program services needed to implement the active treatment program defined by each client's individual program plan. Professional program staff must work directly with clients and with paraprofessional, nonprofessional and other professional program staff who work with clients.

(2) The facility must have available enough qualified professional staff to carry out and monitor the various professional interventions in accordance

with the stated goals and objectives of every individual program plan.

(3) Professional program staff must participate as members of the interdisciplinary team in relevant aspects of the active treatment process.

(4) Professional program staff must participate in on-going staff development and training in both formal and informal settings with other professional, paraprofessional, and nonprofessional staff members.

(5) Professional program staff must be licensed, certified, or registered, as applicable, to provide professional services by the State in which he or she practices. Those professional program staff who do not fall under the jurisdiction of State licensure, certification, or registration requirements, specified in § 483.410(b), must meet the following qualifications:

(i) To be designated as an occupational therapist, an individual must be eligible for certification as an occupational therapist by the American Occupational Therapy Association or another comparable body.

(ii) To be designated as an occupational therapy assistant, an individual must be eligible for certification as a certified occupational therapy assistant by the American Occupational Therapy Association or another comparable body.

(iii) To be designated as a physical therapist, an individual must be eligible for certification as a physical therapist by the American Physical Therapy Association or another comparable body.

(iv) To be designated as a physical therapy assistant, an individual must be eligible for registration by the American Physical Therapy Association or be a graduate of a two year college-level program approved by the American Physical Therapy Association or another comparable body.

(v) To be designated as a psychologist, an individual must have at least a master's degree in psychology from an accredited school.

(vi) To be designated as a social worker, an individual must—

(A) Hold a graduate degree from a school of social work accredited or approved by the Council on Social Work Education or another comparable body; or

(B) Hold a Bachelor of Social Work degree from a college or university accredited or approved by the Council on Social Work Education or another comparable body.

(vii) To be designated as a speech-language pathologist or audiologist, an individual must—

(A) Be eligible for a Certificate of Clinical Competence in Speech-Language Pathology or Audiology granted by the American Speech-Language-Hearing Association or another comparable body; or

(B) Meet the educational requirements for certification and be in the process of accumulating the supervised experience required for certification.

(viii) To be designed as a professional recreation staff member an individual must have a bachelor's degree in recreation or in a specialty area such as art, dance, music or physical education.

(ix) To be designated as a professional dietitian, an individual must be eligible for registration by the American Dietetics Association.

(x) To be designated as a human services professional an individual must have at least a bachelor's degree in a human services field (including, but not limited to: sociology, special education, rehabilitation counseling, and psychology).

(xi) If the client's individual program plan is being successfully implemented by facility staff, professional program staff meeting the qualifications of paragraph (b)(5) (i) through (x) of this section are not required—

(A) Except for qualified mental retardation professionals;

(B) Except for the requirements of paragraph (b)(2) of this section concerning the facility's provision of enough qualified professional program staff; and

(C) Unless otherwise specified by State licensure and certification requirements.

(c) *Standard: Facility staffing.* (1) The facility must not depend upon clients or volunteers to perform direct care services for the facility.

(2) There must be responsible direct care staff on duty and awake on a 24-hour basis, when clients are present, to take prompt, appropriate action in case of injury, illness, fire or other emergency, in each defined residential living unit housing—

(i) Clients for whom a physician has ordered a medical care plan;

(ii) Clients who are aggressive, assaultive or security risks;

(iii) More than 16 clients; or

(iv) Fewer than 16 clients within a multi-unit building.

(3) There must be a responsible direct care staff person on duty on a 24 hour basis (when clients are present) to respond to injuries and symptoms of illness, and to handle emergencies, in each defined residential living unit housing—

(i) Clients form whom a physician has not ordered a medical care plan;

(ii) Clients who are not aggressive, assaultive or security risks; and

(iii) Sixteen or fewer clients.

(4) The facility must provide sufficient support staff so that direct care staff are not required to perform support services to the extent that these duties interfere with the exercise of their primary direct client care duties.

(d) *Standard: Direct care (residential living unit) staff.* (1) The facility must provide sufficient direct care staff to manage and supervise clients in accordance with their individual program plans.

(2) Direct care staff are defined as the present on-duty staff calculated over all shifts in a 24-hour period for each defined residential living unit.

(3) Direct care staff must be provided by the facility in the following minimum ratios of direct care staff to clients:

(i) For each defined residential living unit serving children under the age of 12, severely and profoundly retarded clients, clients with severe physical disabilities, or clients who are aggressive, assaultive, or security risks, or who manifest severely hyperactive or psychotic-like behavior, the staff to client ratio is 1 to 3.2.

(ii) For each defined residential living unit serving moderately retarded clients, the staff to client ratio is 1 to 4.

(iii) For each defined residential living unit serving clients who function within the range of mild retardation, the staff to client ratio is 1 to 6.4.

(4) When there are no clients present in the living unit, a responsible staff member must be available by telephone.

(e) *Standard: Staff training program.* (1) The facility must provide each employee with initial and continuing training that enables the employee to perform his or her duties effectively, efficiently, and competently.

(2) For employees who work with clients, training must focus on skills and competencies directed toward clients' developmental, behavioral, and health needs.

(3) Staff must be able to demonstrate the skills and techniques necessary to administer interventions to manage the inappropriate behavior of clients.

(4) Staff must be able to demonstrate the skills and techniques necessary to implement the individual program plans for each client for whom they are responsible.

§ 483.440 Condition of participation: Active treatment services.

(a) *Standard: Active treatment.* (1) Each client must receive a continuous active treatment program, which includes aggressive, consistent

implementation of a program of specialized and generic training, treatment, health services and related services described in this subpart, that is directed toward—

(i) The acquisition of the behaviors necessary for the client to function with as much self determination and independence as possible; and

(ii) The prevention or deceleration of regression or loss of current optimal functional status.

(2) Active treatment does not include services to maintain generally independent clients who are able to function with little supervision or in the absence of a continuous active treatment program.

(b) *Standard: Admissions, transfers, and discharge.* (1) Clients who are admitted by the facility must be in need of and receiving active treatment services.

(2) Admission decisions must be based on a preliminary evaluation of the client that is conducted or updated by the facility or by outside sources.

(3) A preliminary evaluation must contain background information as well as currently valid assessments of functional developmental, behavioral, social, health and nutritional status to determine if the facility can provide for the client's needs and if the client is likely to benefit from placement in the facility.

(4) If a client is to be either transferred or discharged, the facility must—

(i) Have documentation in the client's record that the client was transferred or discharged for good cause; and

(ii) Provide a reasonable time to prepare the client and his or her parents or guardian for the transfer or discharge (except in emergencies).

(5) At the time of the discharge, the facility must—

(i) Develop a final summary of the client's developmental, behavioral, social, health and nutritional status and, with the consent of the client, parents (if the client is a minor) or legal guardian, provide a copy to authorized persons and agencies; and

(ii) Provide a post-discharge plan of care that will assist the client to adjust to the new living environment.

(c) *Standard: Individual program plan.* (1) Each client must have an individual program plan developed by an interdisciplinary team that represents the professions, disciplines or service areas that are relevant to—

(i) Identifying the client's needs, as described by the comprehensive functional assessments required in paragraph (c)(3) of this section; and

(ii) Designing programs that meet the client's needs.

(2) Appropriate facility staff must participate in interdisciplinary team meetings. Participation by other agencies serving the client is encouraged. Participation by the client, his or her parent (if the client is a minor), or the client's legal guardian is required unless that participation is unobtainable or inappropriate.

(3) Within 30 days after admission, the interdisciplinary team must perform accurate assessments or reassessments as needed to supplement the preliminary evaluation conducted prior to admission. The comprehensive functional assessment must take into consideration the client's age (for example, child, young adult, elderly person) and the implications for active treatment at each stage, as applicable, and must—

(i) Identify the presenting problems and disabilities and where possible, their causes;

(ii) Identify the client's specific developmental strengths;

(iii) Identify the client's specific developmental and behavioral management needs;

(iv) Identify the client's need for services without regard to the actual availability of the services needed; and

(v) Include physical development and health, nutritional status, sensorimotor development, affective development, speech and language development and auditory functioning, cognitive development, social development, adaptive behaviors or independent living skills necessary for the client to be able to function in the community, and as applicable, vocational skills.

(4) Within 30 days after admission, the interdisciplinary team must prepare for each client an individual program plan that states the specific objectives necessary to meet the client's needs, as identified by the comprehensive assessment required by paragraph (c)(3) of this section, and the planned sequence for dealing with those objectives. These objectives must—

(i) Be stated separately, in terms of a single behavioral outcome;

(ii) Be assigned projected completion dates;

(iii) Be expressed in behavioral terms that provide measurable indices of performance;

(iv) Be organized to reflect a developmental progression appropriate to the individual; and

(v) Be assigned priorities.

(5) Each written training program designed to implement the objectives in the individual program plan must specify:

(i) The methods to be used;

(ii) The schedule for use of the method;

(iii) The person responsible for the program;

(iv) The type of data and frequency of data collection necessary to be able to assess progress toward the desired objectives;

(v) The inappropriate client behavior(s), if applicable; and

(vi) Provision for the appropriate expression of behavior and the replacement of inappropriate behavior, if applicable, with behavior that is adaptive or appropriate.

(6) The individual program plan must also:

(i) Describe relevant interventions to support the individual toward independence.

(ii) Identify the location where program strategy information (which must be accessible to any person responsible for implementation) can be found.

(iii) Include, for those clients who lack them, training in personal skills essential for privacy and independence (including, but not limited to, toilet training, personal hygiene, dental hygiene, self-feeding, bathing, dressing, grooming, and communication of basic needs), until it has been demonstrated that the client is developmentally incapable of acquiring them.

(iv) Identify mechanical supports, if needed, to achieve proper body position, balance, or alignment. The plan must specify the reason for each support, the situations in which each is to be applied, and a schedule for the use of each support.

(v) Provide that clients who have multiple disabling conditions spend a major portion of each waking day out of bed and outside the bedroom area, moving about by various methods and devices whenever possible.

(iv) Include opportunities for client choice and self-management.

(7) A copy of each client's individual program plan must be made available to all relevant staff, including staff of other agencies who work with the client, and to the client, parents (if the client is a minor) or legal guardian.

(d) *Standard: Program implementation.* (1) As soon as the interdisciplinary team has formulated a client's individual program plan, each client must receive a continuous active treatment program consisting of needed interventions and services in sufficient number and frequency to support the achievement of the objectives identified in the individual program plan.

(2) The facility must develop an active treatment schedule that outlines the

current active treatment program and that is readily available for review by relevant staff.

(3) Except for those facets of the individual program plan that must be implemented only by licensed personnel, each client's individual program plan must be implemented by all staff who work with the client, including professional, paraprofessional and nonprofessional staff.

(e) *Standard: Program documentation.* (1) Data relative to accomplishment of the criteria specified in client individual program plan objectives must be documented in measureable terms.

(2) The facility must document significant events that are related to the client's individual program plan and assessments and that contribute to an overall understanding of the client's ongoing level and quality of functioning.

(f) *Standard: Program monitoring and change.* (1) The individual program plan must be reviewed at least by the qualified mental retardation professional and revised as necessary, including, but not limited to situations in which the client—

(i) Has successfully completed an objective or objectives identified in the individual program plan;

(ii) Is regressing or losing skills already gained;

(iii) Is failing to progress toward identified objectives after reasonable efforts have been made; or

(iv) Is being considered for training towards new objectives.

(2) At least annually, the comprehensive functional assessment of each client must be reviewed by the interdisciplinary team for relevancy and updated as needed, and the individual program plan must be revised, as appropriate, repeating the process set forth in paragraph (c) of this section.

(3) The facility must designate and use a specially constituted committee or committees consisting of members of facility staff, parents, legal guardians, clients (as appropriate), qualified persons who have either experience or training in contemporary practices to change inappropriate client behavior, and persons with no ownership or controlling interest in the facility to—

(i) Review, approve, and monitor individual programs designed to manage inappropriate behavior and other programs that, in the opinion of the committee, involve risks to client protection and rights;

(ii) Insure that these programs are conducted only with the written informed consent of the client, parent (if the client is a minor), or legal guardian; and

(iii) Review, monitor and make suggestions to the facility about its practices and programs as they relate to drug usage, physical restraints, time-out rooms, application of painful or noxious stimuli, control of inappropriate behavior, protection of client rights and funds, and any other area that the committee believes need to be addressed.

(4) The provisions of paragraph (f)(3) of this section may be modified only if, in the judgment of the State survey agency, Court decrees, State law or regulations provide for equivalent client protection and consultation.

§ 483.450 Condition of participation: Client behavior and facility practices.

(a) *Standard: Facility practices—Conduct toward clients.* (1) The facility must develop and implement written policies and procedures for the management of conduct between staff and clients. These policies and procedures must—

(i) Promote the growth, development and independence of the client;

(ii) Address the extent to which client choice will be accommodated in daily decision-making, emphasizing self-determination and self-management, to the extent possible;

(iii) Specify client conduct to be allowed or not allowed; and

(iv) Be available to all staff, clients, parents of minor children, and legal guardians.

(2) To the extent possible, clients must participate in the formulation of these policies and procedures.

(3) Clients must not discipline other clients, except as part of an organized system of self-government, as set forth in facility policy.

(b) *Standard: Management of inappropriate client behavior.* (1) The facility must develop and implement written policies and procedures that govern the management of inappropriate client behavior. These policies and procedures must be consistent with the provisions of paragraph (a) of this section. These procedures must—

(i) Specify all facility approved interventions to manage inappropriate client behavior;

(ii) Designate these interventions on a hierarchy to be implemented, ranging from most positive or least intrusive, to least positive or most intrusive;

(iii) Insure, prior to the use of more restrictive techniques, that the client's record documents that programs incorporating the use of less intrusive or more positive techniques have been tried systematically and demonstrated to be ineffective; and

(iv) Address the following:

(A) The use of time-out rooms.

(B) The use of physical restraints.

(C) The use of drugs to manage inappropriate behavior.

(D) The application of painful or noxious stimuli.

(E) The staff members who may authorize the use of specified interventions.

(F) A mechanism for monitoring and controlling the use of such interventions.

(2) Interventions to manage inappropriate client behavior must be employed with sufficient safeguards and supervision to ensure that the safety, welfare and civil and human rights of clients are adequately protected.

(3) Techniques to manage inappropriate client behavior must never be used for disciplinary purposes, for the convenience of staff or as a substitute for an active treatment program.

(4) The use of systematic interventions to manage inappropriate client behavior must be incorporated into the client's individual program plan, in accordance with § 483.440(c) (4) and (5) of this subpart.

(5) Standing or as needed programs to control inappropriate behavior are not permitted.

(c) *Standard: Time-out rooms.* (1) A client may be placed in a room from which egress is prevented only if the following conditions are met:

(i) The placement is a part of an approved systematic time-out program as required by paragraph (b) of this section. (Thus, emergency placement of a client into a time-out room is not allowed.)

(ii) The client is under the direct constant visual supervision of designated staff.

(iii) The door to the room is held shut by staff or by a mechanism requiring constant physical pressure from a staff member to keep the mechanism engaged.

(2) Placement of a client in a time-out room must not exceed one hour.

(3) Clients placed in time-out rooms must be protected from hazardous conditions including, but not limited to, presence of sharp corners and objects, uncovered light fixtures, unprotected electrical outlets.

(4) A record of time-out activities must be kept.

(d) *Standard: Physical restraints.* (1) The facility may employ physical restraint only—

(i) As an integral part of an individual program plan that is intended to lead to less restrictive means of managing and eliminating the behavior for which the restraint is applied;

(ii) As an emergency measure, but only if absolutely necessary to protect the client or others from injury; or

(iii) As a health-related protection prescribed by a physician, but only if absolutely necessary during the conduct of a specific medical or surgical procedure, or only if absolutely necessary for client protection during the time that a medical condition exists.

(2) Authorizations to use or extend restraints as an emergency must be:

(i) In effect no longer than 12 consecutive hours; and

(ii) Obtained as soon as the client is restrained or stable.

(3) The facility must not issue orders for restraint on a standing or as needed basis.

(4) A client placed in restraint must be checked at least every 30 minutes by staff trained in the use of restraints, released from the restraint as quickly as possible, and a record of these checks and usage must be kept.

(5) Restraints must be designed and used so as not to cause physical injury to the client and so as to cause the least possible discomfort.

(6) Opportunity for motion and exercise must be provided for a period of not less than 10 minutes during each two hour period in which restraint is employed, and a record of such activity must be kept.

(7) Barred enclosures must not be more than three feet in height and must not have tops.

(e) *Standard: Drug usage.* (1) The facility must not use drugs in doses that interfere with the individual client's daily living activities.

(2) Drugs used for control of inappropriate behavior must be approved by the interdisciplinary team and be used only as an integral part of the client's individual program plan that is directed specifically towards the reduction of and eventual elimination of the behaviors for which the drugs are employed.

(3) Drugs used for control of inappropriate behavior must not be used until it can be justified that the harmful effects of the behavior clearly outweigh the potentially harmful effects of the drugs.

(4) Drugs used for control of inappropriate behavior must be—

(i) Monitored closely, in conjunction with the physician and the drug regimen review requirement at § 483.460(j), for desired responses and adverse consequences by facility staff; and

(ii) Gradually withdrawn at least annually in a carefully monitored program conducted in conjunction with the interdisciplinary team, unless clinical evidence justifies that this is contraindicated.

§ 483.460 Condition of participation: Health care services.

(a) *Standard: Physician services.*

(1) The facility must ensure the availability of physician services 24 hours a day.

(2) The physician must develop, in coordination with licensed nursing personnel, a medical care plan of treatment for a client if the physician determines that an individual client requires 24-hour licensed nursing care. This plan must be integrated in the individual program plan.

(3) The facility must provide or obtain preventive and general medical care as well as annual physical examinations of each client that at a minimum include the following:

(i) Evaluation of vision and hearing.

(ii) Immunizations, using as a guide the recommendations of the Public Health Service Advisory Commitee on Immunization Practices or of the Committee on the Control of Infectious Diseases of the American Academy of Pediatrics.

(iii) Routine screening laboratory examinations as determined necessary by the physician, and special studies when needed.

(iv) Tuberculosis control, appropriate to the facility's population, and in accordance with the recommendations of the American College of Chest Physicians or the section of diseases of the chest of the American Academy of Pediatrics, or both.

(4) To the extent permitted by State law, the facility may utilize physician assistants and nurse practitioners to provide physician services as described in this section.

(b) *Standard: Physician participation in the individual program plan.* A physician must participate in—

(1) The establishment of each newly admitted client's initial individual program plan as required by § 456.380 of this chapter that specified plan of care requirements for ICFs; and

(2) If appropriate, physicians must participate in the review and update of an individual program plan as part of the interdisciplinary team process either in person or through written report to the interdisciplinary team.

(c) *Standard: Nursing services.* The facility must provide clients with nursing services in accordance with their needs. These services must include—

(1) Participation as appropriate in the development, review, and update of an individual program plan as part of the interdisciplinary team process;

(2) The development, with a physician, of a medical care plan of treatment for a client when the physician has determined that an individual client requires such a plan;

(3) For those clients certified as not needing a medical care plan, a review of their health status which must—

(i) Be by a direct physical examination;

(ii) Be by a licensed nurse;

(iii) Be on a quarterly or more frequent basis depending on client need;

(iv) Be recorded in the client's record; and

(v) Result in any necessary action (including referral to a physician to address client health problems).

(4) Other nursing care as prescribed by the physician or as identified by client needs; and

(5) Implementing, with other members of the interdisciplinary team, appropriate protective and preventive health measures that include, but are not limited to—

(i) Training clients and staff as needed in appropriate health and hygiene methods;

(ii) control of communicable diseases and infections, including the instruction of other personnel in methods of infection control; and

(iii) Training direct care staff in detecting signs and symptoms of illness or dysfunction, first aid for accidents or illness, and basic skills required to meet the health needs of the clients.

(d) *Standard: Nursing staff.* (1) Nurses providing services in the facility must have a current license to practice in the State.

(2) The facility must employ or arrange for licensed nursing services sufficient to care for clients health needs including those clients with medical care plans.

(3) The facility must utilize registered nurses as appropriate and required by State law to perform the health services specified in this section.

(4) If the facility utilizes only licensed practical or vocational nurses to provide health services, it must have a formal arrangement with a registered nurse to be available for verbal or onsite consultation to the licensed practical or vocational nurse.

(5) Non-licensed nursing personnel who work with clients under a medical care plan must do so under the supervision of licensed persons.

(e) *Standard: Dental services.* (1) The facility must provide or make arrangements for comprehensive diagnostic and treatment services for each client from qualified personnel, including licensed dentists and dental

hygienists either through organized dental services in-house or through arrangement.

(2) If appropriate dental professionals must participate, in the development, review and update of an individual program plan as part of the interdisciplinary process either in person or through written report to the interdisciplinary team.

(3) The facility must provide education and training in the maintenance of oral health.

(f) *Standard: Comprehensive dental diagnostic services.* Comprehensive dental diagnostic services include—

(1) A complete extraoral and intraoral examination, using all diagnostic aids necessary to properly evaluate the client's oral condition, not later than one month after admission to the facility (unless the examination was completed within twelve months before admission);

(2) Periodic examination and diagnosis performed at least annually, including radiographs when indicated and detection of manifestations of systemic disease; and

(3) A review of the results of examination and entry of the results in the client's dental record.

(g) *Standard: Comprehensive dental treatment* The facility must ensure comprehensive dental treatment services that include—

(1) The availability for emergency dental treatment on a 24-hour-a-day basis by a licensed dentist; and

(2) Dental care needed for relief of pain and infections, restoration of teeth, and maintenance of dental health.

(h) *Standard: Documentation of dental services.* (1) If the facility maintains an in-house dental service, the facility must keep a permanent dental record for each client, with a dental summary maintained in the client's living unit.

(2) If the facility does not maintain an in-house dental service, the facility must obtain a dental summary of the results of dental visits and maintain the summary in the client's living unit.

(i) *Standard: Pharmacy services.* The facility must provide or make arrangements for the provision of routine and emergency drugs and biologicals to its clients. Drugs and biologicals may be obtained from community or contract pharmacists or the facility may maintain a licensed pharmacy

(j) *Standard: Drug regimen review.* (1) A pharmacist with input from the interdisciplinary team must review the drug regimen of each client at least quarterly.

(2) The pharmacist must report any irregularities in clients' drug regimens to the prescribing physician and interdisciplinary team.

(3) The pharmacist must prepare a record of each client's drug regimen reviews and the facility must maintain that record.

(4) An individual medication administration record must be maintained for each client.

(5) As appropriate the pharmacist must participate in the development, implementation, and review of each client's individual program plan either in person or through written report to the interdisciplinary team.

(k) *Standard: Drug administration.* The facility must have an organized system for drug administration that identifies each drug up to the point of administration. The system must assure that—

(1) All drugs are administered in compliance with the physician's orders;

(2) All drugs, including those that are self-administered, are administered without error;

(3) Unlicensed personnel are allowed to administer drugs only if State law permits;

(4) Clients are taught how to administer their own medications if the interdisciplinary team determines that self administration of medications is an appropriate objective, and if the physician does not specify otherwise;

(5) The client's physician is informed of the interdisciplinary team's decision that self-administration of medications is an objective for the client;

(6) No client self-administers medications until he or she demonstrates the competency to do so;

(7) Drugs used by clients while not under the direct care of the facility are packaged and labeled in accordance with State law; and

(8) Drug administration errors and adverse drug reactions are recorded and reported immediately to a physician.

(l) *Standard: Drug storage and recordkeeping.* (1) The facility must store drugs under proper conditions of sanitation, temperature, light, humidity, and security.

(2) The facility must keep all drugs and biologicals locked except when being prepared for administration. Only authorized persons may have access to the keys to the drug storage area. Clients who have been trained to self administer drugs in accordance with § 483.460(k)(4) may have access to keys to their individual drug supply.

(3) The facility must maintain records of the receipt and disposition of all controlled drugs.

(4) The facility must, on a sample basis, periodically reconcile the receipt and disposition of all controlled drugs in schedules II through IV (drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. 801 *et seq.*, as implemented by 21 CFR Part 308).

(5) If the facility maintains a licensed pharmacy, the facility must comply with the regulations for controlled drugs.

(m) *Standard: Drug labeling.* (1) Labeling of drugs and biologicals must—

(i) Be based on currently accepted professional principles and practices; and

(ii) Include the appropriate accessory and cautionary instructions, as well as the expiration date, if applicable.

(2) The facility must remove from use—

(i) Outdated drugs; and

(ii) Drug containers with worn, illegible, or missing labels.

(3) Drugs and biologicals packaged in containers designated for a particular client must be immediately removed from the client's current medication supply if discontinued by the physician.

(n) *Standard: Laboratory services.* (1) For purposes of this section, "laboratory" means an entity for the microbiological, serological, chemical, hematological, radiobioassay, cytological, immunohematological, pathological or other examination of materials derived from the human body, for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or assessment of a medical condition.

(2) If a facility chooses to provide laboratory services, the laboratory must—

(i) Meet the management requirements specified in § 405.1316 of this chapter; and

(ii) Provide personnel to direct and conduct the laboratory services.

(A) The laboratory director must be technically qualified to supervise the laboratory personnel and test performance and must meet licensing or other qualification standards established by the State with respect to directors of clinical laboratories. For those States that do not have licensure or qualification requirements pertaining to directors of clinical laboratories, the director must be either—

(*1*) A pathologist or other doctor of medicine or osteopathy with training and experience in clinical laboratory services; or

(*2*) A laboratory specialist with a doctoral degree in physical, chemical or biological sciences, and training and experience in clinical laboratory services.

(B) The laboratory director must provide adequate technical supervision

of the laboratory services and assure that tests, examinations and procedures are properly performed, recorded and reported.

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

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

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

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

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

(3) The laboratory must meet the proficiency testing requirements specified in § 405.1314(a) of this chapter.

(4) The laboratory must meet the quality control requirements specified in § 405.1317 of this chapter.

(5) If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory must be approved by the Medicare program either as a hospital or an independent laboratory.

§ 483.470 Condition of participation: Physical environment.

(a) *Standard: Client living environment.* (1) The facility must not house clients of grossly different ages, developmental levels, and social needs in close physical or social proximity unless the housing is planned to promote the growth and development of all those housed together.

(2) The facility must not segregate clients solely on the basis of their physical disabilities. It must integrate clients who have ambulation deficits or who are deaf, blind, or have seizure disorders, etc., with others of comparable social and intellectual development.

(b) *Standard: Client bedrooms.* (1) Bedrooms must—

(i) Be rooms that have at least one outside wall;

(ii) Be equipped with or located near toilet and bathing facilities;

(iii) Accommodate no more than four clients unless granted a variance under paragraph (b)(3) of this section;

(iv) Measure at least 60 square feet per client in multiple client bedrooms and at least 80 square feet in single client bedrooms; and

(v) In all facilities initially certified, or in buildings constructed or with major renovations or conversions on or after [*the effective date of these regulations*], have walls that extend from floor to ceiling.

(2) If a bedroom is below grade level, it must have a window that—

(i) Is usable as a second means of escape by the client(s) occupying the room; and

(ii) Is no more than 44 inches (measured to the window sill) above the floor unless the facility is surveyed under the Health Care Occupancy Chapter of the Life Safety Code, in which case the window must be no more than 36 inches (measured to the window sill) above the floor.

(3) The survey agency may grant a variance from the limit of four clients per room only if a physician who is a member of the interdisciplinary team and who is a qualified mental retardation professional—

(i) Certifies that each client to be placed in a bedroom housing more than four persons is so severely medically impaired as to require direct and continuous monitoring during sleeping hours; and

(ii) Documents the reasons why housing in a room of only four or fewer persons would not be medically feasible.

(4) The facility must provide each client with—

(i) A separate bed of proper size and height for the convenience of the client;

(ii) A clean, comfortable, mattress;

(iii) Bedding appropriate to the weather and climate; and

(iv) Functional furniture appropriate to the client's needs, and individual closet space in the client's bedroom with clothes racks and shelves accessible to the client.

(c) *Standard: Storage space in bedroom.* The facility must provide—

(1) Space and equipment for daily out-of-bed activity for all clients who are not yet mobile, except those who have a short-term illness or those few clients for whom out-of-bed activity is a threat to health and safety; and

(2) Suitable storage space, accessible to clients, for personal possessions, such as TVs, radios, prosthetic equipment and clothing.

(d) *Standard: Client bathrooms.* The facility must—

(1) Provide toilet and bathing facilities appropriate in number, size, and design to meet the needs of the clients;

(2) Provide for individual privacy in toilets, bathtubs, and showers; and

(3) In areas of the facility where clients who have not been trained to regulate water temperature are exposed to hot water, ensure that the temperature of the water does not exceed 110° Fahrenheit.

(e) *Standard: Heating and ventilation.* (1) Each client bedroom in the facility must have—

(i) At least one window to the outside; and

(ii) Direct outside ventilation by means of windows, air conditioning, or mechanical ventilation.

(2) The facility must—

(i) Maintain the temperature and humidity within a normal comfort range by heating, air conditioning or other means; and

(ii) Ensure that the heating apparatus does not constitute a burn or smoke hazard to clients.

(f) *Standard: Floors.* The facility must have—

(1) Floors that have a resilient, nonabrasive, and slip-resistant surface;

(2) Nonabrasive carpeting, if the area used by clients is carpeted and serves clients who lie on the floor or ambulate with parts of their bodies, other than feet, touching the floor; and

(3) Exposed floor surfaces and floor coverings that promote mobility in areas used by clients, and promote maintenance of sanitary conditions.

(g) *Standard: Space and equipment.* The facility must—

(1) Provide sufficient space and equipment in dining, living, health services, recreation, and program areas (including adequately equipped and sound treated areas for hearing and other evaluations if they are conducted in the facility) to enable staff to provide clients with needed services as required by this subpart and as identified in each client's individual program plan.

(2) Furnish, maintain in good repair, and teach clients to use and to make informed choices about the use of dentures, eyeglasses, hearing and other communications aids, braces, and other devices identified by the interdisciplinary team as needed by the client.

(3) Provide adequate clean linen and dirty linen storage areas.

(h) *Standard: Emergency plan and procedures.* (1) The facility must develop and implement detailed written plans and procedures to meet all potential emergencies and disasters such as fire, severe weather, and missing clients.

(2) The facility must communicate, periodically review, make the plan available, and provide training to the staff.

(i) *Standard: Evacuation drills.* (1) The facility must hold evacuation drills at least quarterly for each shift of personnel and under varied conditions to—

(i) Ensure that all personnel on all shifts are trained to perform assigned tasks;

(ii) Ensure that all personnel on all shifts are familiar with the use of the facility's fire protection features; and

(iii) Evaluate the effectiveness of emergency and disaster plans and procedures.

(2) The facility must—

(i) Actually evacuate clients during at least one drill each year on each shift;

(ii) Make special provisions for the evacuation of clients with physical disabilities;

(iii) File a report and evaluation on each evacuation drill;

(iv) Investigate all problems with evacuation drills, including accidents, and take corrective action; and

(v) During fire drills, clients may be evacuated to a safe area in facilities certified under the Health Care Occupancies Chapter of the Life Safety Code.

(3) Facilities must meet the requirements of paragraphs (i)(1) and (2) of this section for any live-in and relief staff they utilize.

(j) *Standard: Fire protection.* (1) *General.* (i) Except as specified in paragraph (j)(2) of this section, the facility must meet the applicable provisions of either the Health Care Occupancies Chapters or the Residential Board and Care Occupancies Chapter of the Life Safety Code (LSC) of the National Fire Protection Association, 1985 edition, which is incorporated by reference.[2]

(ii) The State survey agency may apply a single chapter of the LSC to the entire facility or may apply different chapters to different buildings or parts of buildings as permitted by the LSC.

(iii) A facility that meets the LSC definition of a residential board and care occupancy and that has 16 or fewer beds, must have its evacuation capability evaluated in accordance with the Evacuation Difficulty Index of the LSC (Appendix F).

(2) *Exceptions.* (i) For facilities that meet the LSC definition of a health care occupancy:

(A) The State survey agency may waive, for a period it considers appropriate, specific provisions of the LSC if—

(*1*) The waiver would not adversely affect the health and safety of the clients; and

(*2*) Rigid application of specific provisions would result in an unreasonable hardship for the facility.

(B) The State survey agency may apply the State's fire and safety code instead of the LSC if the Secretary finds that the State has a code imposed by State law that adequately protects a facility's clients.

(C) Compliance on November 26, 1982 with the 1967 edition of the LSC or compliance on April 18, 1986 with the 1981 edition of the LSC, with or without waivers, is considered to be compliance with this standard as long as the facility continues to remain in compliance with that edition of the Code.

(ii) For facilities that meet the LSC definition of a residential board and care occupancy and that have more than 16 beds, the State survey agency may apply the State's fire and safety code as specified in paragraph (j)(2)(B) of this section.

(k) *Standard: Paint.* The facility must—

(1) Use lead-free paint inside the facility; and

(2) Remove or cover interior paint or plaster containing lead so that it is not accessible to clients.

(l) *Standard: Infection control.*

(1) The facility must provide a sanitary environment to avoid sources and transmission of infections. There must be an active program for the prevention, control, and investigation of infection and communicable diseases.

(2) The facility must implement successful corrective action in affected problem areas.

(3) The facility must maintain a record of incidents and corrective actions related to infections.

(4) The facility must prohibit employees with symptoms or signs of a communicable disease from direct contact with clients and their food.

§ 483.480 Condition of participation: Dietetic services.

(a) *Standard: Food and nutrition services.*

(1) Each client must receive a nourishing, well-balanced diet including modified and specially-prescribed diets.

(2) A qualified dietitian must be employed either full-time, part-time, or on a consultant basis at the facility's discretion.

(3) If a qualified dietitian is not employed full-time, the facility must designate a person to serve as the director of food services.

(4) The client's interdisciplinary team, including a qualified dietitian and physician, must prescribe all modified and special diets including those used as a part of a program to manage inappropriate client behavior.

(5) Foods proposed for use as a primary reinforcement of adaptive behavior are evaluated in light of the client's nutritional status and needs.

(6) Unless otherwise specified by medical needs, the diet must be prepared at least in accordance with the latest edition of the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences, adjusted for age, sex, disability and activity.

(b) *Standard: Meal services.* (1) Each client must receive at least three meals daily, at regular times comparable to normal mealtimes in the community with—

(i) Not more than 14 hours between a substantial evening meal and breakfast of the following day, except on weekends and holidays when a nourishing snack is provided at bedtime, 16 hours may elapse between a substantial evening meal and breakfast; and

(ii) Not less than 10 hours between breakfast and the evening meal of the same day, except as provided under paragraph (b)(1)(i) of this section.

(2) Food must be served—

(i) In appropriate quantity;

(ii) At appropriate temperature;

(iii) In a form consistent with the developmental level of the client; and

(iv) With appropriate utensils.

(3) Food served to clients individually and uneaten must be discarded.

(c) *Standard: Menus.* (1) Menus must—

(i) Be prepared in advance;

(ii) Provide a variety of foods at each meal;

(iii) Be different for the same days of each week and adjusted for seasonal changes; and

(iv) Include the average portion sizes for menu items.

(2) Menus for food actually served must be kept on file for 30 days.

(d) *Standard: Dining areas and service.*

The facility must—

(1) Serve meals for all clients, including persons with ambulation deficits, in dining areas, unless otherwise specified by the interdisciplinary team or a physician;

---

[2] Incorporation of the 1985 edition of the National Fire Protection Association's Life Safety Code (published February 7, 1985; ANSI/NFPA 101) 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. The Code is available for inspection at the Office of the Federal Register Information Center, Room 8401, 1100 L Street NW., Washington, DC. Copies may be obtained from the National Fire Protection Association, Batterymarch Park, Quincy, Mass. 02269.

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

(2) Provide table service for all clients who can and will eat at a table, including clients in wheelchairs;

(3) Equip areas with tables, chairs, eating utensils, and dishes designed to meet the developmental needs of each client;

(4) Supervise and staff dining rooms adequately to direct self-help dining procedure, to assure that each client receives enough food and to assure that each client eats in a manner consistent with his or her developmental level: and

(5) Ensure that each client eats in an upright position, unless otherwise specified by the interdisciplinary team or a physician.

(Catalog of Federal Domestic Assistance Program No. 13.714 Medical Assistance Program)

Dated: September 4, 1987.

William L. Roper,

Administrator, Health Care Financing Administration.

Approved: March 31, 1988.

Otis R. Bowen,

Secretary.

[FR Doc. 88-12250 Filed 6-2-88; 8:45 am]

BILLING CODE 4120-01-M