assessment of civil money penalties) against certain insured banks or officers, directors, employees, agents or other persons participating in the conduct of the affairs thereof:

Names or persons and names and locations of banks authorized to be exempt from disclosure pursuant to the provisions of subsections (c)(6), (c)(8), and (c)(9)(A)(ii) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(6), (c)(8), and (c)(9)(A)(ii)).

Note.—Some matters falling within this category may be placed on the discussion agenda without further public notice if it becomes likely that substantive discussion of those matters will occur at the meeting.

Discussion Agenda:

Application for consent to purchase assets and assume liabilities:

Metropolitan Bank St. Paul, St. Paul, Minnesota, an insured State nonmember bank, for consent to purchase the assets of and assume the liabilty to pay deposits made in Metro Thrift Company, Inc., St. Paul, Minnesota, a non-FDIC-insured institution

Memorandum regard liquidation activities.

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)).

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

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: February 28, 1986.

Federal Deposit Insurance Corporation.

Margaret M. Olsen,

Deputy Executive Secretary.

[FR Doc. 86–4778 Filed 2–28–86; 3:27 pm]

BILLING CODE 6714–01–M

4

FEDERAL RESERVE SYSTEM; BOARD OF GOVERNORS

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: Notice forwarded to Federal Register on February 26, 1986.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 10:00 a.m., Wednesday, March 5, 1986.

CHANGES IN THE MEETING: The open meeting has been cancelled.

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

Dated: February 28, 1986.

William W. Wiles,

Secretary of the Board.

[FR Doc. 86–4700 Filed 2–28–86; 10:35 am]

BILLING CODE 6210–01–M

5

FEDERAL RESERVE SYSTEM; BOARD OF GOVERNORS

TIME AND DATE: 11:00 a.m., Monday, March 10, 1986.

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

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Proposals regarding fees for directors of the Federal Reserve Bank and members of advisory panels of the Federal Reserve System.
2. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
3. Any items carried forward from a previously announced meeting.

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

Dated: February 28, 1986.

William W. Wiles,

Secretary of the Board.

[FR Doc. 86–4788 Filed 2–28–86; 3:53 pm]

BILLING CODE 6210–01–M

6

INTERNATIONAL TRADE COMMISSION

[USITC SE–86–8]

TIME AND DATE: Monday, March 10, 1986 at 2:00 p.m.

PLACE: Room 117, 701 E Street, NW., Washington, D.C. 20436.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agenda.
2. Minutes.
3. Ratification List.
4. Petitions and Complaints.
   a. Certain dynamic random access memories, components thereof, and products containing same (Docket No. 1283).
5. Any items left over from previous agenda.

CONTACT PERSON FOR MORE INFORMATION: Kenneth R. Mason, Secretary (202) 523–0161.

Kenneth R. Mason,

Secretary.

February 27, 1986.

[FR Doc. 86–4775 Filed 2–28–86; 3:17 pm]

BILLING CODE 7020–02–M

7

INTERNATIONAL TRADE COMMISSION

[USITC SE–86–9]

TIME AND DATE: Friday, March 14, 1986 at 11:00 a.m.

PLACE: Room 117, 701 E Street, NW., Washington, D.C. 20436.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Petitions and Complaints.
   a. Certain luggage products (Docket No. 1284).

CONTACT PERSON FOR MORE INFORMATION: Kenneth R. Mason, Secretary (202) 523–0161.

Kenneth R. Mason,

Secretary.

February 27, 1986.

[FR Doc. 86–4776 Filed 2–28–86; 3:18 pm]

BILLING CODE 7020–02–M

8

LEGAL SERVICES CORPORATION

Committee on Audit and Appropriations

TIME AND DATE: Meeting will commence at 12:00 p.m., Thursday, March 13, 1986, and continue until 4:30 p.m. or until all official business is completed.

PLACE: Mississippi Band of Choctaw Indians, Tribal Office Building, Route 7, Philadelphia, Mississippi 39350.

STATUS OF MEETING: Open.

MATTERS TO BE CONSIDERED:

1. Approval of Agenda
2. Approval of Draft Minutes January 30, 1986
3. FY 1986 Consolidated Operating Budget

CONTACT PERSON FOR MORE INFORMATION: Joel Thimell, Policy Development, (202) 863–1842.

Dated Issued: February 27, 1986.

Timothy H. Baker,

Secretary.

[FR Doc. 86–4680 Filed 2–27–86; 4:55 pm]

BILLING CODE 6820–35–M

9

LEGAL SERVICES CORPORATION

Operations and Regulations Committee Meeting

TIME AND DATE: The meeting will commence at 6:30 p.m., Wednesday, March 12, 1986, and continue until all official business is completed.

PLACE: Holiday Inn North, Spanish Oaks Room I and II, I–55 North Frontage Road, Jackson, Mississippi 39206.

STATUS OF MEETING: Open.

MATTERS TO BE CONSIDERED:

1. Approval of Agenda
2. Denial of Refunding—45 CFR 1625
   —Report from the Office of General Counsel
   —Public comment
   —Recommendations to Board
3. Other Regulations Adopted after April 27, 1984

CONTACT PERSON FOR MORE INFORMATION: Thomas A. Bovard, Counsel, Division of Policy Development, (202) 863–1842.

Date Issued: February 27, 1986.

Timothy H. Baker,

Secretary.

[FR Doc. 86–4681 Filed 2–27–86; 4:55 pm]

BILLING CODE 6820–35–M

10

NUCLEAR REGULATORY COMMISSION

DATE: Weeks of March 3, 10, 17, and 24, 1986.

PLACE: Commissioners' Conference Room, 1717 H Street, NW., Washington, DC.

STATUS: Open and Closed.

MATTERS TO BE CONSIDERED:

Week of March 3

Wednesday, March 5

11:30 a.m.
Affirmation Meeting (Public Meeting) (if needed)

Week of March 10—Tentative

Tuesday, March 11

10:00 a.m.
Briefing by TVA on Status, Plans and Schedules (Public Meeting)
2:00 p.m.
Briefing by DOE on R&D Results from TMI–2 Cleanup (Public Meeting)

Wednesday, March 12

2:00 p.m.
Status Briefing on Fermi (Open/Portion may be Closed—Ex. 5 & 7)

Thursday, March 13

10:00 a.m.
Briefing by Staff and Licensee on Status of Kerr McGee Sequoyah Fuel Facility (Public Meeting)
11:30 a.m.
Affirmation Meeting (Public Meeting) (if needed)

Friday, March 14

10:00 a.m.
Periodic Meeting with Advisory Committee on Reactor Safeguards (Public Meeting)

Week of March 17—Tentative

Tuesday, March 18

2:00 p.m.
Briefing by Southern California Edison Co. on San Onofre-1 (Public Meeting)

Wednesday, March 19

10:00 a.m.
Periodic Briefing by Regional Administrators (Public Meeting)
2:00 p.m.
Status of Pending Investigations (Closed—Ex. 5 & 7)

Thursday, March 20

2:00 p.m.
Discussion of Management-Organization and Internal Personnel Matters (Closed—Ex. 2 & 6)
3:30 p.m.
Affirmation Meeting (Public Meeting) (if needed)

Week of March 24—Tentative

Wednesday, March 26

10:00 a.m.
Quarterly Source Term Briefing (Public Meeting)
2:00 p.m.
Periodic Briefing by Regional Administrators (Public Meeting)

Thursday, March 27

10:00 a.m.
Discussion/Possible Vote on Palo Verde-2 Full Power Operating License (Public Meeting)
2:00 p.m.
Affirmation Meeting (Public Meeting) (if needed)

Friday, March 28

10:00 a.m.
Advisory Committee on Reactor Safeguards (ACRS) Meeting on Safety Goals (Public Meeting)

ADDITIONAL INFORMATION: Affirmation of "Review of ALAB–819 (In the Matter of Philadelphia Electric Company)" scheduled for February 27, *postponed.*

TO VERIFY THE STATUS OF MEETINGS CALL (RECORDING): (202) 634–1498.

CONTACT PERSON FOR MORE INFORMATION: Julia Corrado (202) 634–1410.

Julia Corrado,

Office of the Secretary.

February 27, 1986.

[FR Doc. 86–4793 Filed 2–28–86; 3:56 pm]

BILLING CODE 7590–01–M

11

TENNESSEE VALLEY AUTHORITY

[Meeting No. 1364]

TIME AND DATE: 10:30 a.m. (e.s.t.), Thursday, March. 6, 1986.

PLACE: TVA West Tower Auditorium, 400 West Summit Hill Drive, Knoxville, TN.

STATUS: Open.

Agenda

Approval of minutes of meeting held on February 14, 1986.

Action Items

Old Business Items

1. Recommendation regarding program for compliance with Environmental Protection Agency's stack height regulation at Colbert, Johnsonville, Shawnee, and Widows Creek fossil plants.

New Business Items

B—Purchase Awards

B1. Invitation NQ–835085—Steam generator blowdown demineralizers for Watts Bar Nuclear Plant.

B2. Negotiation GF–453861—Dry fly ash facility for John Sevier Fossil Plant.

F—Unclassified

F1. Supplement to Agreement No. TV–61214A with Oak Ridge Operations, U.S. Department of Energy (DOE) providing for TVA to continue performing mapping services for DOE.

F2. Supplement to Contract No. TV–60035A with Environmental Protection Agency covering arrangements for TVA to continue the long-term water quality monitoring program of selected reservoirs in the Tennessee Valley region in order to evaluate their acid sensitivity.

F3. Contract No. TV–69143A among State of Alabama Community Colleges in Gadsden, the University of Alabama, the City of Gadsden, Alabama, and TVA to establish a joint research and training center to serve as a focal point for economic development as well as industrial development and training in advanced technologies.

CONTACT PERSON FOR MORE INFORMATION: Craven H. Crowell, Jr., Director of Information, or a member of his staff can respond to requests for information about this meeting. Call (615) 632–8000, Knoxville, Tennessee. Information is also available at TVA's Washington Office (202) 245–0101.

Dated: February 27, 1986.

W.F. Willis,

General Manager.

[FR Doc. 86–4731 Filed 2–28–86; 12:24 pm]

BILLING CODE 8120–01–M

federal register

Tuesday
March 4, 1986

Part II

Department of Health and Human Services

Health Care Financing Administration

42 CFR Parts 435 and 442
Medicaid Program; Standards for Intermediate Care Facilities for the Mentally Retarded; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 435 and 442

[BERC-266-P]

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

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

ACTION: Proposed rule.

SUMMARY: We are proposing a general revision 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. This proposed rule is 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 proposed regulations would be to align Federal standards with contemporary care practices for residential care services for persons with mental retardation or other developmental disabilities. We are also proposing to make several technical changes and cross-references to achieve consistency with other existing regulations.

DATES: To be considered, comments must be mailed or delivered to the appropriate address, as provided below, and must be received by 5:00 p.m. on May 5, 1986.

ADDRESS: Mail Comments to the following address:

Health Care Financing Administration, Department of Health and Human Services, Attention: BERC-266-P, P.O. Box 26676, Baltimore, Maryland 21207

In addition, please address a copy of your comments on the information collection requirements to:

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, DC 20503, Attention: Fay Iudicello.

If your prefer, you may deliver your comments to one of the following addresses:

Room 309-G Hubert H. Humphrey Building 200 Independence Ave., SW., Washington, DC or

Room 132, East High Rise Building, 6325, Security Boulevard, Baltimore, Maryland

In commenting, please refer to file code BERC-266-P. Comments will be available for public inspection as they are received, beginning approximately three weeks after publication of this document, in Room 309-G of the Department's offices at 200 Independence Ave., SW., Washington, DC 20201, on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (202-245-7890).

FOR FURTHER INFORMATION CONTACT: Samuel Kidder (301) 597-5909.

SUPPLEMENTARY INFORMATION:

I. Background

General

Section 1905(c) of the Social Security 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) 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 140,000 individuals in over 2,911 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 for Services to Mentally Retarded and Other Developmentally Disabled Persons (AC MRDD). 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 large 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. We are proposing a general revision of the standards 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 Regulations

A. General Approach

In revising these standards, we have based our proposals primarily on the accreditation standards published in 1983 by the Accreditation Council for Services to Mentally Retarded and Other Developmentally Disabled Persons (AC MRDD), particularly in the Active Treatment Services section of our proposed standards. We have 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 the mentally retarded 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 revisions to the standards are as follows:

- We are proposing 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.
- We are proposing to revise most 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 would retain appropriate detail in the areas of needed client protections.

- We would reword much of the language contained in the current regulations to reflect contemporary terminology in the field of developmental disabilities. For example, we have substituted the term "client" for "resident" throughout the standards.
- We would retain necessary emphasis on health services, but we would revise the regulations to reflect the wide diversity in health care delivery systems utilized by ICFs/MR.
- The proposed standards emphasize the development of the individual client in defining the active treatment process. We have used the AC MRDD standards for active treatment as a guide and would tie professional qualifications and duties to the active treatment process.
- We would clarify numerous existing standards that have created problems for providers and reviewers (e.g., 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).

We believe that the proposed modifications to the current regulations would result in an improved set of standards for ICFs/MR. Although not proposed in this notice, we are also considering using a "condition of participation" format for these regulations, and invite public comment on this approach.This change would make the regulations for ICFs/MR consistent with the organization of the Medicare and Medicaid regulations for skilled nursing facilities (SNFs). Under this format, requirements are characteristically grouped as conditions of participation, each of which contains standards that are used to assess compliance with the condition.

Although we have not used the conditions format at this time, we believe the standards could easily be organized into conditions of participation in the final regulations. For example, the standards could be organized into conditions of participation in the following way:

1. A condition of participation entitled "Administration and Management" could be structured to cover the proposed standards that involve overall policy direction and administrative requirements for the ICF/MR.

2. A condition of participation on client protections could encompass the proposed standards that require facilities to afford clients their legal and civil rights, including financial arrangements and staff treatment of clients.

3. We could establish a condition of participation on facility staffing to include all personnel qualifications, staff licensure and training requirements, and the direct care staff ratios. This would also include professional program services, because we believe that the qualifications and sufficiency of professional program staff directly impact on the facility's ability to provide the required active treatment services for their clients.

4. We could establish a condition of participation on behavior modification programs to cover all the standards that deal with this issue, including drug usage.

5. There could be a separate condition of participation on active treatment services to incorporate all the proposed standards that comprise an individual's active treatment program. This could include client assessment requirements for admissions, transfers, release, and the establishment and modification of a client's individual program plan.

6. There could be one condition of participation on health care services to cover the proposed standards on physician, nursing, dental, pharmacy, and laboratory services.

7. We could have a condition entitled "Physical Environment" that would regulate client living areas, space and equipment in other areas of the facility, and would include the standards on fire safety, building accessibility and use, and sanitation.

8. We could have one condition on all facets of dietary services.

Under such an approach, State agencies would survey for compliance with the conditions of participation and if a facility is found to meet *all* the proposed requirements at the condition level, it would be eligible for Medicaid certification. Facilities with deficiencies at the standard level could have up to 12 months to effectuate a corrective plan of action. We are particularly requesting public comments on the use of conditions and is potential impact on facility participation in the Medicaid ICF/MR program.

Although we are considering the use of the condition of participation format, we believe that the proposed regulations using standards also would ensure that clients are provided with quality care while at the same time recognizing the needs of facilities of widely differing characteristics. These changes are discussed in detail below.

B. Proposed Revisions to the Standards for ICFs/MR

Protection of Clients' Rights

Current regulations at 42 CFR 442.403 and 442.404 identify the rights of clients in ICFs/MR, including a residents' bill of rights. These standards were taken directly from the standards for general ICFs and contain detailed descriptions of clients' rights that are also stated in other sections of the standards. For example, § 442.404(f) of the existing regulations describes in detail a client's rights regarding the use of restraints. However, §§ 442.437 and 442.438 duplicate and overlap with the provisions of § 442.404(f). To eliminate this duplication, we are proposing to create a new section (see proposed § 442.401) entitled "Protection of Clients' Rights". This section would specify clients' rights and what the facility must do to assure that clients' rights are protected. The specific details relating to these rights have been retained in appropriate sections of these proposed regulations.

Throughout the standards, we use the terms "client, parents (if the clients are minors) or guardians" in recognition of the three persons who can act in a client's behalf unless otherwise determined by the State. By doing so, we do not intend to limit the State's authority to decide who can represent the client; rather, by using a consistent term denoting who must be informed, give permission, etc., we hope to minimize confusion. We are also proposing to eliminate the provision that allowed a qualified mental retardation professional to determine whether or not a client could understand his or her rights, which may have had the unintended effect of appearing to change the client's legal status without proper State adjudication.

Administrative Services

1. Client Finances: Current regulations at 42 CFR 442.406 contain the duties of the facility with regard to the protection of the finances of each client. We would retain this standard, but would simplify the language and include language from section 1861(j)(14) of the Act, referred to in section 1905(c) of the Act, which would require that the facility maintain a system that assures a complete accounting of clients' personal funds. (See proposed § 442.410.)

2. Governing Body: Current regulations (42 CFR 442.409 and 442.410) specify the duties of the governing body and set the qualifications for the chief executive officer. We would simplify and combine these standards. Proposed

regulations at § 442.412 would specify that the facility must have a governing body that exercises general direction over the facility, and sets the qualifications for and appoints the administrator of the facility. We would also require that the administrator possess knowledge of developmental disabilities.

3. Commnication With Clients, Parents, and Guardians: Current regulations at 42 CFR 442.414 specify the facility's responsibility to have an active program of communication with clients, parents, and guardians. We are proposing to retain this standard, with some minor modifications in language. We would add new requirements explicitly allowing family, clients and friends to participate in the active treatment process and clearly permitting leave for visits, trips and vacations in recognition of the importance of their continued involvement. (See proposed § 442.414.)

4. Compliance with Federal, State and Local Laws: Current regulations at 42 CFR 442.415 require that facilities meet all applicable Federal, State and local laws, regulations and codes pertaining to health and safety. We would retain this standard but would add a reference to civil rights laws (that is, section 504 of the Rehabilitation Act of 1973 (Pub. L. 93–112), Title VI of the Civil Rights Act of 1964 (Pub. L. 88–352), the Age Discrimination Act of 1975 (Pub. L. 94–135) and all regulations issued under the authority of these Acts). This means that the State's ICF/MR program must be in compliance with these laws and regulations, and each facility must be in compliance with those provisions of the laws and regulations which apply on a facility-specific basis. We would also eliminate other references throughout the standards which specify requirements already contained in State laws. Thus, facilities would continue to be required to meet all applicable laws, but surveyors would not have to duplicate the monitoring activities of other agencies. (See proposed § 442.416.)

5. Provision of Needed Services: We would clarify in the proposed regulations at 42 CFR 442.418(a) that, at a minimum, facilities are required to furnish directly the following:

- The services of a qualified mental retardation professional.
- The services of direct care staff.
- The development and monitoring of active treatment programs.
- Nursing services for clients with medical care plans.
- Living quarters.

Other services, such as physician, dental, pharmacy and food services, can be arranged for through outside resources (e.g., outside agencies or individuals who provide programs and services to the facility).

However, in all cases, the facility must assume responsibility for the provision of services. Current regulations at 42 CFR 442.417, 442.455 and 442.476 discuss the arrangements facilities may have with outside resources in order to furnish required services to their clients. We propose to consolidate these three sections into one standard (see proposed § 442.418(b)) that would specify that if the facility cannot furnish a needed service, it must have a written agreement with an outside resource to furnish the service. Under the proposed rules, the agreement would be required to contain the responsibilities of both parties and ensure that all standards contained in this subpart are met. The facility would be responsible for assuring that the outside services meet the needs of each client.

6. Personnel Policies: Current regulations at 42 CFR 442.427 discuss written personnel policies. We would retain the essential elements of this standard, however, we would not require the policies to be written. Additionally, we would add a provision to prohibit a facility from employing individuals with a history of child or client abuse, neglect or exploitation. (See proposed § 442.420.) As revised, this section would require that the facility:

- Develop and implement personnel policies that are available to all staff;
- Make job descriptions available for all positions;
- Prohibit employees with signs of symptoms of a communicable disease from working;
- Prohibit the employment of individuals with a history of child or client abuse, neglect or exploitation.

7. Licensure and Professional Standards: We propose to retain the standard on licensure and professional standards currently found at 42 CFR 442.428. We would, however, eliminate the requirement that the facility take into account the standards of professional conduct developed by professional societies because the licensure or certification itself carries with it applicable standards of conduct. (See proposed § 442.422.)

8. Staff Treatment of Clients: Treatment of clients by facility staff is currently discussed at 42 CFR 442.430. We are proposing to retain this standard as § 442.424, with some minor wording changes. The regulations would specify that the facility must develop policies and procedures to prohibit mistreatment, neglect, or abuse of clients, assure that alleged violations are reported immediately, and have evidence that all violations are reported and investigated promptly within 5 working days, and an appropriate penalty imposed.

9. Facility Staffing: Current regulations found at 42 CFR 442.431, 442.433, 442.445 and 442.473 address appropriate staffing of facilities, including the size and duties of the staff. We are proposing (see § 442.426) to combine these standards and also add new requirements for support staff. We would modify the current standards as follows:

a. We have retained the requirement that prohibits the facility from depending upon clients or volunteers to meet requirements for client care or support services. This provision is necessary to assure that volunteers supplement services but are not the sole providers of services.

b. We would prohibit direct care staff from being required to provide housekeeping or other support services to the extent that these duties interfere with the exercise of their primary direct care duties.

c. We would retain the requirement currently found in § 442.445 that in any unit housing more than 16 persons, there must be staff on duty *and awake*, when clients are present. This on duty and awake standard is especially important at night when clients are usually present and usually asleep. We would also retain the requirement that in units housing 16 or fewer clients, a responsible direct care staff person be immediately accessible to clients 24 hours a day. Among other concerns, these requirements would ensure the safe evacuation of clients in case of a fire or adverse weather conditions.

d. We would require that all facilities employ a qualified dietitian on either a full-time, part-time, or consultant basis, regardless of the size of the facility. We have not specified the frequency of this consultation and invite public comments on this issue. Additionally, under the proposed rule, a facility that does not employ a full-time dietitian would be required to designate a person to serve as the director of food services. Current regulations at § 442.473 contain different standards depending on the size of the facility, but do not require facilities serving fewer than 20 persons to employ a registered dietitian. These revisions would assure that all clients, not just those in large facilities, receive adequate dietary monitoring and menu planning.

10. Direct Care (Residential Living Unit) Staff: Current regulations at 42

CFR 442.445 contain the requirements regarding the ratio of direct care staff to clients. We would retain requirements for staff to client ratios with modifications (see proposed § 442.428). We would change the ratios to reflect present and on-duty staff rather than overall staff as specified in existing regulations. (The term "overall staff" attempts to account for present and on-duty staff, as well as for staff on leave and for vacant positions.) The proposed ratios reflect the existing ratios calculated without including staff on leave or vacant positions. In addition, in the proposed § 442.428(a) we have raised the age for children from six to twelve years because there are few young children in facilities today and because we believe children under age 12 require close staff involvement and supervision.

The proposed staff to client ratios for a 24-hour period follow below. These ratios would be considered the minimum requirements that a facility must meet and could be exceeded. Additionally, we have noted per shift ratios that have been applied through ICF/MR guidelines throughout the history of the program.

a. For each living unit serving children under 12 years or serving severely impaired clients, the present and on-duty staff to client ratio would be 1 to 3.2. On a shift basis, we would expect this ratio to equate to the following present and on-duty staff to client ratios:

- One to eight for the day shift.
- One to eight for the evening shift.
- One to sixteen for the night shift.

b. For each living unit serving moderately retarded clients, the present and on-duty staff to client ratio would be one to four. On a shift basis, we would expect this ratio to equate to the following present and on-duty staff to client ratios:

- One to eight for the day shift.
- One to sixteen for the evening shift.
- One to sixteen for the night shift.

We note that the day and evening shift ratios could be reversed at the discretion of the facility and based on client need.

c. For living units serving mildly retarded clients, the present and on-duty staff to client ratio would be 1 to 6.4. On a shift basis, we would expect this ratio to equate to the following present and on-duty staff to client ratios:

- One to sixteen for the day shift.
- One to sixteen for the evening shift.
- One to thirty-two for the night shift.

11. Staff Training Program: Current regulations at 42 CFR 442.432 require the facility to have a program for the continuing training of staff. We would revise this standard to emphasize the need for training of staff who work directly with clients to focus on skills directed toward clients' developmental and behavioral needs. In addition, we would require that staff members be able to demonstrate practical skills and techniques necessary to implement the individual program plans for each client under their care. This represents a major new focus on staff performance rather than only on process. (See proposed § 442.430.)

12. Client records: Current regulations at 42 CFR 442.499 to 442.504 contain the requirements a facility must follow with regard to client records. These sections contain many details regarding recordkeeping requirements that are duplicated in other areas of the current standards. We are proposing to consolidate general requirements regarding client records in § 442.432 which requires that the facility develop and maintain a comprehensive recordkeeping system that assures the confidentiality of records. While we would continue to identify specific records that must be kept regarding particular facets of care where appropriate, most notably in the active treatment section, in general we believe that the facility is able to determine the type of recordkeeping structure that best fits its needs.

13. Emergencies or Death of a Client: Current regulations at 42 CFR 442.426 require facilities to notify a client's parents or guardian of any significant incidents including illness, accident or death. We would delete certain requirements concerning autopsies since State laws address this issue. (See proposed § 442.434.)

14. Infection Control: In recognition of our continued concern for the safeguarding of client and staff health, we are proposing to add a new section (see proposed § 442.436) to require the facility to engage in an active program for the prevention, control and investigation of infection or communicable diseases.

Active Treatment Services

1. Active Treatment: We are proposing to create a new section in the standards on active treatment services. Section 1905(d) of the Social Security Act provides that payment may be made for services in an ICF/MR if the individual in the facility is receiving active treatment. Although the regulations are based on this statutory requirement, the specific requirements in the regulations related to it are scattered throughout the current ICF/MR standards. However, there is a definition of active treatment found in 42 CFR 435.1009 that we are also proposing to revise. In proposed § 442.440, we would require the facility to provide an active treatment program for each client that is directed toward either: (1) The acquisition of the skills necessary for the client's maximum possible independence, or (2) the prevention of regression or loss of current functional status in dependent clients where no further positive growth is demonstrable. We would also emphasize that active treatment must not include the maintenance of generally independent clients who function with little supervision or who require few if any significant active treatment services. The revised regulations will, for the first time, enable the surveyor to make a judgment about whether or not the facility is providing active treatment services for each client by specifically describing the process involved in the delivery of the active treatment program.

2. Admissions, Transfers, and Discharge: Current regulations at 42 CFR 442.418, 442.421, 442.424, and 442.425 discuss the process for admission, release, and transfer of clients. We would retain these provisions (see proposed § 442.442) with the following changes:

a. We would modify the language to require that facilities admit only those clients who are in need of active treatment services.

b. We would eliminate the provision that permits a facility to admit a client when the facility has determined that admission is not the best plan for the client. Under the statute, the facility can only receive Medicaid payment for those persons in need of and receiving active treatment.

c. We would permit admission evaluations to be based either on evaluations made by the facility or by outside sources. We would also require that a preadmission evaluation be completed or updated no more than 90 days before admission.

d. We would require that admission decisions be made by an interdisciplinary team based on a comprehensive evaluation of the client.

e. We would require a physician to participate in establishing the newly admitted client's individual program plan. This would ensure that these regulations are consistent with current Medicaid utilization control requirements at 42 CFR 456.380 that specify plan of care requirements for intermediate care facilities.

f. We would require that if a client is to be transferred or discharged, the facility must provide documentation that the client was transferred for good cause (e.g., medical reasons or the

facility or staff are unable to provide necessary services). The facility must also provide a final summary of the client's status at the time of transfer or discharge.

g. We would retain requirements dealing with planning for a client's discharge and adjustments to a new environment.

3. Individual Program Plan (IPP): In the proposed § 442.444, we would require that an interdisciplinary team representing the professions, disciplines or service areas relevant to each client's needs, develop an IPP for each client that states specific intervention objectives. Current regulations at § 442.421 require the facility to review the pre-admission evaluation within one month after admission. We would retain this requirement but make the focus client-oriented rather than facility-oriented, by requiring the participation of the client and the client's family, if obtainable and appropriate, in the development of an IPP for each client. We would require that the IPP outline specific objectives that are related to the client's developmental and behavioral management needs and: (1) Stated separately in terms of single behavioral outcomes, (2) assigned projected completion dates, (3) expressed in behavioral terms that provide measureable indices of progress, (4) organized to reflect a developmental progression appropriate to the individual, (5) assigned priorities and (6) specific to the programs and strategies to be used. We would also require that the IPP emphasize personal care skills essential for privacy and independence (including, but not limited to, toilet training, personal hygiene, dental hygiene, self-feeding, bathing, dressing and grooming), until these skills are either accomplished or demonstrated to be developmentally unavailable to the client. We would also eliminate the word "prognosis" from this requirement, as this is essentially a medical term that lends itself to numerous interpretations inappropriate in this setting.

4. Program Implementation: Current regulations at 42 CFR 442.435 require the facility to develop an activity schedule for each resident that details how his or her time is to be spent, including the provision that there can be no more than 3 continuous hours of unscheduled activity. We would revise this section to require facilities to implement a continuous active treatment program for each client, consisting of the interventions and services needed to carry out the objectives identified in the IPP (see proposed § 442.446). We would retain the requirement that multi-handicapped, non-ambulatory clients spend a major portion of each waking day out of bed and outside of the bedroom area although this requirement would be included in the proposed standard relating to the IPP. (See proposed § 442.444(f).)

5. Program Documentation: There are numerous sections in the current standards that discuss program documentation and recordkeeping. We would consolidate these into one section (proposed § 442.448) that requires the facility to document, in measurable terms, the client's performance in relationship to the objectives contained in the IPP and to account for other major incidents related to the client's developmental, social, and behavioral status. Other programmatic recordkeeping to be performed will be left to the discretion of the facility.

6. *Program Monitoring and Change:* Current regulations at 42 CFR 442.422 require that the status of each resident be reviewed at least annually by the interdisciplinary team. We would retain this requirement, but would require that the review repeat the same initial process outlined in § 442.442. We would require that each client's program be coordinated and monitored by a qualified mental retardation professional who is employed by the facility. We would define a qualified mental retardation professional as a physician, a registered nurse, or an individual who holds at least a bachelor's degree in one of the professions defined in § 442.460 of these proposed standards and has at least one year of experience working directly with persons with mental retardation or other developmental disability. This would increase the number of persons qualified to serve as a qualified mental retardation professional. We considered numerous suggestions and proposals for changes in the requirements for the qualified mental retardation professional and we have received support of our approach from groups and individuals in the field. However, in recognition of the wide diversity of views about qualified mental retardation professional qualifications, we especially invite comments on this important client monitoring function.

We would also require that the facility establish a specially constituted committee to review, monitor, and approve individual behavior management and other programs. The committee would also review, monitor, and provide consultation to the administrator concerning facility-wide programs in behavior management, drug usage, etc. The committee would not have the authority to approve facility practices, but would serve to aid in client protection and act as a consultant for the administrator. (See proposed § 442.450.)

7. *Behavior Management:* Current regulations at 42 CFR 442.437–442.441 contain the requirements for behavior management. We are proposing to retain these requirements and update them by incorporating the current language of the voluntary standards of the Accreditation Council for Facilities for the Mentally Retarded and Developmentally Disabled (1983 edition). We would revise the current standards as follows:

a. We would require the facility to have written policies and procedures for the behavioral management of clients, to allow clients to participate in the development of these procedures, and to prohibit the use of coercion or abuse. We would prohibit the placement of a client alone in a room from which egress is not prossible, except when done as part of an organized behavior modification program. However, we are concerned that by permitting clients to be locked in a room, a new fire safety issue is raised. The fire safety standards that we have proposed (see 50 FR 45921, November 5, 1985, for details) include a new chapter 21 of the National Fire Protection Association's Life Safety Code entitiled "Residential Board and Care Occupancies" and its equivalency system, the Fire Safety Evaluation System for Board and Care Homes. These fire safety standards place a great emphasis on the client's own ability to remove him or herself from fire hazards and less emphasis on physical plant features. Thus, we specifically invite comments on the advisability of permitting clients to be in locked rooms and, if this practice is advisable, how can clients be protected from fire hazards. (See proposed § 442.452.)

b. We would require the facility to develop detailed behavior modification programs that are included in the client's IPPs, approved in writing by the facility's review committee and conducted only with the written consent of the client, parents, or legal guardian. (See proposed § 442.454.)

c. We would require that the facility have written procedures that contain specific details on who may use restraints, how they may be used, and a system for monitoring their use. The facility would be permitted to use physical restraints only if necessary to protect the client from injury to himself or herself or to others, or as part of an approved behavior modification program. (See proposed § 442.456.)

d. We would require that drugs used for behavior management be utilized only as a integral part of the client's IPP and be directed toward the reduction of, and eventually the elimination of, the behavior for which the drugs are used. We would eliminate the use of the term "chemical restraint" as this term has been used to refer to the application of any medication that was designed to alter or control behavior. A drug that facilitates needed (or appropriate) responses from the client is not a chemical restraint and any drug that is applied inappropriately can be a restraint. (See proposed § 442.458.)

8. *Professional Program Services:* The current standards for ICFs/MR specify the qualifications for the professional staff by cross-reference to the skilled nursing facility (SNF) definitions contained in 42 CFR 405.1101. Since few facility administrators have access to SNF regulations, we are proposing to consolidate these requirements into one standard (see proposed § 442.460) and to list the qualifications of each profession following the approach contained in the AC MRDD standards, section 4.7 of the 1983 edition.

We have discussed personnel qualifications with the relevant professional groups in order to bring the proposed requirements in line with contemporary practice. We are not proposing any changes in qualifications except where professional requirements have been modified by the relevant professional certifying or accrediting organization.

We propose adding qualifications for a new professional category. This is a general qualification standard for persons with at least a bachelor's degree in a human services field, in recognition of the fact that there are other disciplines not specified in this section that provide services to clients in ICFs/MR (for example, rehabilitation counselors). We propose to eliminate all sub-professional qualifications, but would not restrict a facility from hiring these individuals.

It is our desire that these proposed standards protect client safety and ensure appropriate treatment without imposing undue costs or restrictions on facility operations. We, therefore, encourage comments on the question of the need for identifying specific professional program staff and their qualifications (as well as the level of qualifications specified) and whether and to what extent facilities should have discretion in determining the need for and qualifications of such personnel. We also encourage comments as to alternative methods for ensuring appropriate treatment and protecting client safety, such as approaches which would focus on successful implementation of the client's IPP, rather than on the use of professional staff meeting particular qualifications.

9. Physician Services: Current regulations at 42 CFR 442.474 to 442.477 set forth the requirements for physician services. These standards were directed primarily toward organized health service departments in large institutions. We would revise the current requirements that are based on the size of the institution and focus instead on the needs of the clients. The regulations, as revised, would reflect the growing awareness that there are various ways facilities acquire health services for their clients and that not all clients require a medical care plan (i.e., a formalized plan for the provision of physician and related medical care services). We propose the following:

a. The facility would be required to provide physician services on a 24-hour a day basis. The facility would be allowed to use physician assistants and nurse practitioners to provide physician services to the extent permitted by State law. The facility would be responsible for providing or arranging for the provision or services to meet the client's full range of health needs, even if the client does not require a medical care plan but requires more than simple quarterly health review. (See proposed § 442.462.)

b. The physician would participate in the development and update of the client's IPP, and the development of a medical care plan of treatment if one is required. (See proposed § 442.464.)

c. The facility would be required to have a formal arrangement for providing each client with medical care that includes preventive health services as well as the provision of emergency treatment. (See proposed § 442.466). We would eliminate the requirement that the facility designate a physician to be responsible for maintaining the health conditions and practices of the facility, as this is the proper role for administrators and other responsible staff.

10. Nursing Services: Nursing services are discussed in current regulations at 42 CFR 442.478 to 442.481. We would revise these requirements as follows:

a. We would require the facility to provide nursing services in accordance with client needs. These services would include—

- Developing the IPP;
- If ordered by a physician, developing a medical care plan of treatment for a client;
- Surveillance of a client's health status at least quarterly, that is, an in-person, direct, physician observation of the client to detect signs and symptoms of health problems and poor hygiene practices; and
- Implementing preventive health measures (See proposed § 442.468).

b. To assure that each client's nursing needs are met, we would require that the facility have enough nursing staff to carry out the various nursing duties, including a licensed nurse on duty on one full shift seven days a week to supervise the nursing services provided to clients under a medical care plan. We would require that the facility utilize registered nurses as appropriate and as required by State law to perform the services described in this section, but other licensed nursing personnel may also be utilized. We would eliminate the specific qualifications for practical and vocational nurses because we believe that State and local laws adequately regulate the profession. We would require those facilities that employ only licensed practical or vocational nurses to have a formal arrangement with a registered nurse to serve on a consultant basis. (See proposed § 442.470.) We have not specified the frequency of this consultation and invite public comment on the issue.

1. Dental Services: The requirements for the provision of dental services to clients of ICFs/MR are currently found at 42 CFR 442.457 to 442.462. In order to assure that all clients receive necessary dental services we would revise the regulations as follows:

a. We would require that the facility provide or make arrangements for comprehensive dental diagnostic and treatment services for each client, and that dental professionals participate, as appropriate, in the development of the IPP as part of the interdisciplinary process. (See proposed § 442.472.)

b. We would retain the current requirement that comprehensive diagnostic services include a complete initial examination, periodic followup examinations, and entry of the results in clients' dental records. (See proposed § 442.474.)

c. We would require that comprehensive dental treatment include provisions for emergency treatment 24-hours a day and routine dental care as needed. (See proposed § 442.476.)

d. We would require that if the facility maintains an in-house dental service, a permanent record be kept for each client. If the facility does not maintain a service, it would be required to obtain a summary of the results of dental visits and maintain this in the client's record. (See proposed § 442.478.)

12. Pharmacy Services: Current regulations at 42 CFR 442.482 to 442.485 set forth the requirements for the provision of pharmacy services. We would revise many of the present requirements of these sections, while continuing to ensure proper storage, labeling, packaging, and review of drugs. We would also revise the regulations to take into account the fact that many facilities do not have in-house pharmacy services. We would revise the regulations as follows:

a. We would require the facility to provide drugs and biologicals, either from an in-house pharmacy or through outside sources. (See proposed § 442.480.)

b. We would revise the regulations to stress the importance of the pharmacist's involvement in the drug regimen reviews, even when the RN is doing the actual review. (See proposed § 442.482.)

c. We would require the facility to have an organized system for drug administration that assures that drugs are properly administered, without error, including those that are self administered. We would require that, where unlicensed personnel are allowed by State law to administer drugs, a licensed nurse participate in the training of these personnel in facility-specific drug administration procedures apart from and in addition to any State program. We would also require that drugs that are to be administered to clients while they are not under the direct care of the facility be packaged and labeled by a pharmacist. (See proposed § 442.484.)

d. We would require that the facility store drugs under lock and key except when they are being prepared for administration. We would also require that drugs be stored under proper conditions of sanitation, temperature, light, humidity, and security. The facility would be required to maintain records of the receipt and disposition of all controlled drugs and, on a sample basis, periodically reconscile the receipt and disposition of all controlled substances. (See proposed § 442.486.)

e. We would require that drugs be labeled in accordance with accepted professional principles and practices and that the facility not maintain outdated drugs or drug containers with worn, illegible, or missing labels. (See proposed § 442.488.)

13. Laboratory Services: Current Medicaid regulations at 42 CFR 440.30 require that independent laboratory services be provided by a laboratory that meets the requirements for participation in Medicare. 42 CFR 405.1310 through 405.1317 contain the conditions for coverage of services of independent laboratories. However, many large public ICFs/MR operate their own laboratories. In order to assure the health and safety of clients served by these laboratories, we are proposing to add a new section 442.489 which would contain the standards that the ICF/MR must meet if it elects to provide direct laboratory services on a routine basis. We propose the following:

a. We would include a general definition of laboratory services, specifying some of the services that could be supplied by such a laboratory.

b. We would require that the laboratory must either be licensed or approved as a laboratory according to State law (if it is located in a State that provides for licensing or approval of laboratories), or must meet the requirement specified in paragraph (c) through (f) of this section.

c. We would require that the laboratory meet the management requirements specified in 42 CFR 405.1316. Section 405.1316 requires, generally, that the laboratory maintain records and meet professionally acceptable standards.

d. We would require that the laboratory director 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. We specifically invite comments on these educational requirements for the laboratory director.

e. Under this proposal, we would require that the laboratory director provide adequate technical supervision of the laboratory services and ensure that staff have appropriate education and experience, are sufficient in numbers, and receive appropriate in-service training.

f. We would also require that laboratory technologists be technically competent to perform test procedures and report test results.

g. We would require that the laboratory meet the proficiency testing requirements specified in § 405.1314(a) and the quality control requirements specified in § 405.1317.

Physical Environment

We are proposing to consolidate all of the disparate sections of the regulations dealing with the physical plant of the facility, while retaining the essential client protection and living environment features of the existing standards. We would revise many of the requirements, recognizing the many types of facilities operating in the ICF/MR program. We propose to revise the regulations regarding the physical environment as follows:

1. Living Environment: We would continue to require that clients be housed appropriately, according to age, development and social needs. We also would continue to prohibit the segregation of residents based on physical handicap. (See proposed § 442.500.)

2. Bedrooms: We would revise the standard on client bedrooms to require floor to ceiling walls in newly certified facilities. The exception for existing facilities is necessary because many facilities have partial walls. To complete these walls would be expensive, especially when one considers possible modifications to ventilating systems. We would also revise the standard to allow bedrooms to be below ground level under certain circumstances. We would continue the prohibition against more than four clients to a bedroom unless a variance is granted. We would clarify the conditions for granting such a variance to indicate that a variance may be granted only when clients are so health-impaired as to require constant supervision. The variance was never intended to justify the continued use of open wards. We would continue to require that the facility provide each client with a separate bed and appropriate bedding and furniture. (See proposed § 442.502)

3. Storage Space: We would require that clients have adequate space for equipment and suitable storage space for personal possessions, including clothing. (See proposed § 442.504.)

4. Bathrooms: We would require that bathrooms provide adequate toilet and bathing facilities and provide for individual privacy. We would also require that if clients have not been trained to regulate water temperature, the temperature of the water not exceed 110° Fahrenheit. (See proposed § 442.506.)

5. Heating and Ventilation: We would retain the provision requiring each bedroom to have at least one window and direct outside ventilation. We would also require the facility to maintain the temperature and humidity within a normal range and ensure that the heating apparatus is not a burn or smoke hazard to clients. (See proposed § 442.508.)

6. Floors: We would retain the provision that the floors have either a resilient nonabrasive, nonslip surface or nonabrasive carpeting in units where clients crawl. (See proposed § 442.510.)

7. Space and Equipment: We are proposing to consolidate several existing standards and create a new standard to require that the facility provide sufficient space and equipment in dining, health services, and program areas to enable staff to provide clients with needed services. We would also require the facility to furnish, maintain, and encourage the use of dentures, eyeglasses, hearing aids, and other devices required by the client. (See proposed § 442.512.)

Safety and Sanitation

Current regulations at 42 CFR 442.505 to 442.512 set forth requirements for various aspects of safety and sanitation. We propose to revise these standards as follows:

1. Emergency Plans: We would require that the facility have detailed written plans and procedures to meet all potential emergencies and that the plan be available to all staff. We have eliminated the requirement that these procedures be posted, since we do not believe that posting is as useful as ensuring that staff are adequately trained. (See proposed § 442.550.)

2. Evacuation Drills: We have revised the standard on evacuation drills to stress the participation of those individuals capable both physically and mentally of cooperating in their own evacuation from a building. Thus, we would emphasize the importance of training those clients able to do so, to respond in their own behalf to an emergency. We would revise the rules to require facilities to hold drills at least quarterly for each shift of personnel (assuming three shifts, this amounts to 12 drills per year) and to actually evacuate those clients who can cooperate during each of these drills. For those clients who cannot cooperate, we would require actual evacuation during at least one drill a year on each shift (assuming three shifts, this amounts to three drills per year). (See proposed § 442.552.)

3. Fire Protection: Because we have proposed revisions to the current regulations on fire protection in a separate regulations document, "Fire Safety Standards for ICFs/MR" (see 50 FR 45921, November 5, 1985, for details on the proposal), we have not addressed them here. We would, however, reserve § 442.554 for the placement of the fire protection standards after the proposal is finalized.

4. Paint: We would retain the requirement that the facility use lead-free paint and remove or cover old paint or plaster containing lead. (See proposed § 442.556.)

5. Building Accessibility: ICF/MR programs must be accessible to the handicapped. By requiring compliance with civil rights laws (see § 442.416 of the proposed regulations), we propose that the facility meet Department-wide regulations establishing accessibility standards for all recipients of federal financial assistance. It should be noted that under these standards each facility need not necessarily make structural changes but they must make their programs and activities, when viewed as a whole, readily accessible to handicapped persons.

Food and Nutrition Service

Food and nutrition requirements are addressed in current regulations at 42 CFR 442.465 to 442.471. These standards are directed toward large facilities that operate their own institutional food services. We would revise the regulations to change many of the requirements that are not applicable for the smaller group homes that operate their own kitchens. We would revise the regulations as follows:

1. Diet: We would require that the facility provide each client with a diet prepared 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. (See proposed § 442.558.)

2. Meal Service: We would retain the standard on meal services that requires the facility to serve at least three meals a day at regular times, at the appropriate temperature, form (e.g., pureed, ground, chopped) and with the proper utensils. (See proposed § 442.560.)

3. Menus: We would continue to require that menus be prepared in advance, be different for the same days of each week, be adjusted for seasonal changes, be kept on file for 30 days and include the average portion sizes for menu items. We would eliminate the requirement that the facility keep a record of food that is purchased because this burdensome requirement does not assure that clients achieve adequate diets or that they receive adequate nutrition. (See proposed § 442.562.)

4. Dining Areas: We would continue to require that facilities serve meals in dining areas, provide table service for all clients who can and will eat at a table, and equip areas with appropriate tables, chairs, utensils and dishes. (See proposed § 442.564.)

C. Other Proposed Revisions

1. Active Treatment

Current regulations at 42 CFR 435.1009 contain the definition of "active treatment". We propose to revise this definition to bring it into conformance with the revisions we are proposing to the active treatment section in the standards. The revised definition would clarify that the active treatment program is directed toward either the acquisition of the skills necessary for the client's maximum possible development, or the prevention of regression or loss of the client's current functional status.

2. Exemption From Certain Nursing Home Standards

Current regulations at 42 CFR 442.252 specify that an ICF must meet State requirements for nursing home safety and sanitation. Many ICFs/MR have found the standard at § 442.502 to be in conflict with the nature of an ICF/MR, particularly in small facilities. Examples of these nursing home requirements are a nurse call system and a licensed nursing home administrator. We are proposing to revise this section of the regulations by exempting ICFs/MR from this requirement. We would continue to require that the ICF/MR be in compliance with all applicable Federal, State and local laws, regulations and codes, such as health, safety, sanitation, research, and civil rights laws and accessibility laws for the handicapped. (See proposed § 442.416.)

III. Regulatory Impact Statement

Executive Order 12291

Executive Order 12291 requires us to prepare and publish a regulatory impact analysis for any regulations that are likely to have an annual economic impact of $100 million or more, cause a major increase in costs or prices, or meet other thresholds specified in section 1(b) of the Order.

As noted elsewhere in the preamble, we are proposing to revise the ICF/MR standards with the twofold purpose of: (1) Ensuring that clients are provided quality care; and (2) relieving facilities of the duplicative requirements contained in the current regulations and thus reducing their operating costs. As the focus shifts from the institution to the client, we believe that because of these proposed changes, State surveyors will be in a better position to determine whether active treatment is actually occurring for each client. This determination is important to ensure that those who work with clients deliver accountable, habilitative services that result in the client's growth and

development and that result in more effective expenditure of Medicaid dollars in the ICF/MR setting.

While we believe that the regulation would accomplish these results, for several reasons we are not able to determine the economic impact. First, current cost reporting requirements do not provide data broken down by cost centers that would allow us to determine the extent of our present or future 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.

In conclusion, even though we can not develop a precise estimate, our best available data indicate that the economic impact of this regulation would not exceed $100 million, nor would it meet the other thresholds specified in the Executive Order. Therefore, we have not prepared a regulatory impact analysis. We also believe that these proposed regulations would maximize net benefits by reducing facility operating costs, ensuring more administrative flexibility, and reducing paperwork burden. Clients should benefit from the stronger focus on definable outcomes related to the care provided to them.

Regulatory Flexibility Act

Consistent with the Regulatory Flexibility Act, we prepare and publish a regulatory flexibility analysis for any regulation that is likely to have a significant impact on a substantial number of small entities. A small entity is a small business, a nonprofit enterprise, or a government jurisdiction with a population of less than 50,000. The purpose of the analysis would be to anticipate the potential impact and to seek alternatives that would have a less significant effect.

As of September 9, 1985, there are about 2,911 certified ICFs/MR ranging in size from 4 to more than 1500 beds. The composition of these ICFs/MR is as follows:

Number of beds	Number of ICFs/MR	Percent of total
4-16	2,078	71
17-50	322	11
51-100	220	7
101-300	166	5
301-500	48	1
501-750	47	1
751-	30	1

Public ICFs/MR comprise about 31 percent of certified ICFs/MR and private facilities represent the remaining 69 percent.

We believe that all of these facilities would benefit by the new standards because of the reduced paperwork burdens and costs, and the increased administrative flexibility provided to facilities in the proposal. We also expect that some individual facilities may be significantly affected by these proposals. For example, we understand that the public ICFs/MR currently commit as much as 20 percent of their fiscal and staff resources to the preparation of paperwork under the present standards (as estimated by the National Association of Superintendents of Public Residential Facilities for the Mentally Retarded). While some of this 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 proposed regulations' emphasis on staff and client performance rather than paper compliance, could reduce the production of paper by a third in these facilities. However, State licensing requirements and internal facility policies and practices would also affect the extent of real savings which could occur under these standards by retaining some of the same requirements.

We believe that facilities with fewer than 16 beds would be affected less significantly by our new standards because these facilities are now subject to interpretive guidelines especially designed for surveying small facilities. While these facilities would 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.

Other provisions which may significantly impact individual facilities include:

1. *Physician services*—We are proposing to allow physician assistants (PAs) and nurse practitioners (NPs) to perform physician functions to the extent allowed by State law. We anticipate that this provision could result in significant savings for those facilities that can use PAs and NPs for routine health care.

2. *Nursing services*—For those facilities that serve 15 or fewer persons who do not now require professional nursing services, the proposed standards would result in the necessity to arrange for nursing personnel to conduct an in-person health review of each client *at least* quarterly. This could represent an increased cost over present requirements for affected facilities, although we cannot determine whether these costs would be significant to these affected facilities because we cannot calculate the expected offset in savings that would occur under these standards. However, this requirement would 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, would not need a licensed nurse on duty.

3. *Staff to client ratios*—We are proposing to revise the method used in determining staff to client ratios. Instead of counting total employees, we would count numbers of employees on duty during a 24-hour period. We believe that this would provide a more accurate measure of manpower actually spent caring for clients. It should not have a significant impact on facility staffing levels because the proposed ratios were derived from current ratios factoring out the estimated numbers of employees not actually on duty at a given time. It also reflects surveyor guideline practices that have been used since the beginning of the program.

4. *Dental services*—Our proposed standards would require that each client's dental needs be addressed, including dental care needed for relief of pain and infections, restoration of teeth, and maintenance of dental health. Current standards require comprehensive dental treatment including emergency care and annual check-ups. We believe that our proposed language makes explicit that which was always intended in the current standards, namely that the client's dental care needs be met. Whether this proposal represents an increase in cost to affected facilities depends on the extent to which they are meeting existing standards as we intended them to be applied.

5. *Client bedrooms (floor to ceiling walls)*—We are proposing to require, for newly certified facilities, that walls must extend from the floor to the ceiling between living quarters. Clients would benefit by increased privacy and a slight degree of increased safety by the containment of possible spreading fires. The economic impact of this requirement would be negligible because there are very few new facilities coming into the program that do not already meet this requirement.

6. *Client bedrooms (variance to the four-to-a-bedroom rule)*—Our proposal limits the conditions under which a facility can claim a variance to our long-

standing rule that no more than four persons may be allowed per bedroom. We would limit this arrangement to 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 new provision may represent significant increased capital expenditures, or the buildings affected could face the loss of certification in the ICF/MR program. We believe that the existing provision allowing for more than four persons per bedroom was never intended to serve as a vehicle for the perpetuation of open ward housing arrangements for clients who could successfully live in more private space. Thus, this proposal actually supports those States and facilities that have committed the necessary resources to comply with the intent of the original standards. This provision would not affect most ICFs/MR with fewer than 16 beds because they typically use housing with normal size bedrooms and usually house fewer than four persons per bedroom.

7. *Evacuation drills*—We are proposing to revise the requirement for evacuation drills to focus more attention on the mobility and responsiveness of various clients to a possible life-threatening situation. We believe that the proposed change will have no economic impact.

8. *Laboratory services*—We are also proposing certain health and safety standards for those ICFs/MR that choose to provide in-house laboratory services (ICFs/MR that have arrangements with independent laboratories may contract only with laboratories that meet the requirements for participation in Medicare (42 CFR 440.30)). We have identified 110 public (but no private) ICFs/MR that currently use in-house labs. Of this total, only 38 are currently State licensed. We are proposing that the remaining unlicensed facilities meet the requirements of proposed § 442.489, unless they become State licensed.

The requirements detailed in proposed § 442.489(c), (d), (e) and (f) are basically standard norms for laboratories and should not impose any additional requirements beyond these accepted standards. Further, as most of these laboratories are now operating near the level of those provisions, they should, again, not incur great costs in complying with our requirements.

We believe that any costs incurred by affected ICFs/MR would be offset by the health and safety benefits inherent in these provisions. As a result of a recent survey, we have determined that although laboratory services are incorporated in facilities' per diem rates, in most instances there was no quality control over these services. Including these laboratory requirements would allow State surveyors and Federal authorities to monitor the quality of this vital service in those ICFs/MR that choose to provide laboratory services. Quality control is especially important in larger, public ICFs/MR, which now house the most severely handicapped clients. These facilities use laboratory services extensively and routinely for drug levels, fluid analyses, tissue and waste analyses, and for infection control. Thus, we believe that all ICF/MR clients will benefit from the incremental improvements in the services received from their laboratories.

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 proposed revisions. Overall, we believe that most facilities will be able to improve performance at lower cost. 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 many smaller facilities will be affected both significantly and beneficially.

In our view, the Regulatory Flexibility Act does not require an analysis unless the impact is adverse. However, because of this significant beneficial impact, we have voluntarily prepared the analysis above, which, when taken together with the remainder of the preamble, constitutes a regulatory flexibility analysis

Paperwork Reduction Act of 1980

Sections 442.410 (a) and (b), 442.418(b)(1), 442.432 (a), (e) and (f), 442.436(c), 442.442 (b)(2)(i), (c)(1) and (c)(3), 442.444 (a), (c), (d) and (e), 442.446 (c) and (d), 442.448 (a) and (b), 442.450(d), 442.452(a), 442.454 (a) and (b), 442.456(b), 442.468(b), 442.478 (a), (b) and (c), 442.482 (b), (c) and (d), 442.484(i), 442.486 (c) and (d), 442.489(d)(2), 442.502(c)(2), 442.550(a), 442.552(b)(4) and 442.562 contain information collection requirements which require approval from the Office of Management and Budget under the Paperwork Reduction Act of 1980. We have submitted a copy of this proposed rule to the Office of Management and Budget (OMB) for its review of these information collection requirements. Other organizations and individuals desiring to submit comments on the information collection requirements should direct them to the agency official designated for this purpose whose name appears in this preamble, and to the Office of Information and Regulatory Affairs, OMB, New Executive Office Building, (Room 3208), Washington, DC 20503, Attn: Fay Iudicello.

IV. Response to Comments

Because of the large number of pieces of correspondence we normally receive on proposed regulations, we cannot acknowledge or respond to them individually. However, we will consider all comments that are received by the end of the comment period and, if we proceed with a final rule, we will respond to those comments in the preamble to that rule.

List of Subjects

42 CFR Part 435

Aid to families with dependent children, Aliens, Categorically needy, Contracts (Agreements—State Plan), Eligibility, Grant-in-Aid program—health, Health facilities, Medicaid, Medically needy, Reporting and recordkeeping requirements, Spend-down, Supplemental security income (SSI).

42 CFR Part 442

Certification of intermediate care facilities (ICFs), Certification of skilled nursing facilities (SNFs), Contracts (Agreements), Disabled, Grant-in-Aid program—health, Health facilities, Health professions, Health records, Information (Disclosure), Medicaid, Mental health centers, Nursing homes, Nutrition, Privacy, Safety.

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

PART 435—ELIGIBILITY IN THE STATES, DISTRICT OF COLUMBIA AND THE NORTHERN MARIANA ISLANDS

The authority citation for Part 435 continues to read as follows:

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

A. Section 435.1009 is amended by revising the definition of "active treatment in intermediate care facilities for the mentally retarded" to read 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" requires the following:

(a) The provision of an active treatment program for each client that is directed toward—

(1) The acquisition of developmental, behavioral, and social skills necessary for the client's maximum possible individual independence; or

(2) For dependent clients where no further positive growth is reasonably considered possible, the prevention of regression or loss of current optimal functional status.

(b) Active treatment does not include the 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.

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PART 442—STANDARDS FOR PAYMENT FOR SKILLED NURSING AND INTERMEDIATE CARE FACILITY SERVICES

B. Part 442 is amended as set forth below:

1. The table of contents for Subpart G and the authority citation for Part 442 are revised to read as follows:

Subpart G—Standards for Intermediate Care Facilities for the Mentally Retarded

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

Subpart E—Intermediate Care Facility Requirements; All Facilities

2. Subpart E is amended by revising § 442.252 to read as follows:

§ 442.252 State safety and sanitation standards.

An ICF other than an ICF/MR must meet State safety and sanitation standards for nursing homes.

3. Subpart G is revised to read as follows:

Subpart G—Standards for Intermediate Care Facilities for the Mentally Retarded

§ 442.400 Basis and purpose.

This subpart implements section 1905 (c) and (d) of the Act which gives the Secretary authority to prescribe standards for intermediate care facility services in facilities for the mentally retarded or persons with related conditions.

§ 442.401 Protection of clients' rights.

The facility must ensure the rights of all clients. Therefore, the facility must—

(a) Inform each client, parent (if the client is a minor), or guardian (if applicable), of the client's rights and the rules of the facility;

(b) Inform each client, parent or guardian of the client's medical condition, developmental and behavioral status, attendant risks of treatment, and of the right to refuse treatment;

(c) Allow and encourage each client to exercise his or her rights as a client of the facility, and as a citizen of the United States, including the right to file complaints;

(d) Allow each client to manage his or her financial affairs and teach him or her to do so to the extent of the client's capabilities;

(e) Ensure that clients are not subjected to physical or psychological abuse;

(f) Ensure that clients are free from unnecessary drugs and physical restraints and are provided habilitation to reduce dependency on drugs and physical restraints;

(g) Provide each client with the opportunity for personal privacy;

(h) 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;

(i) Permit clients to communicate, associate and meet privately with individuals of their choice, and to send and receive mail;

(j) Permit clients to participate in social, religious, and community group activities; and

(k) Permit clients to retain and use personal possessions and appropriate clothing, and ensure that each client is dressed in his or her own clothing each day unless confined to bed by a physician.

Administrative Services

§ 442.410 Client finances.

The facility must establish and maintain a system that assures a full and complete accounting of the clients' personal funds.

(a) The system must include the use of a separate account for funds to preclude any commingling of client funds with facility funds or with the funds of any person other than another client.

(b) The facility must maintain a current, written financial record for each client that includes the management of all funds handled by the facility on behalf of the client.

(c) The financial record must be available on request to the client and his or her parents or guardian.

§ 442.412 Governing body.

The facility must identify an individual or individuals to constitute the governing body of the facility. The governing body must—

(a) Exercise general policy, budget, and operating direction over the facility;

(b) Set the qualifications (in addition to those already set by State law, if any) for the administrator of the facility, which must include knowledge in the field of developmental disabilities; and

(c) Appoint the administrator of the facility.

§ 442.414 Communications with clients, parents, and guardians.

The facility must have an active program of communication with the client, parents, and guardian. The facility must—

(a) Permit participation of parents and guardians in the client's active treatment process specified in § 442.440 unless their participation is unobtainable or inappropriate;

(b) Answer communications from clients' families and friends promptly and appropriately;

(c) Permit individuals with a relationship to the client (such as family, close friends, and advocates) to visit at any reasonable hour, without prior notice, unless and interdisciplinary team determines that this would not be appropriate;

(d) Permit parents or guardians to visit any area of the facility that provides direct client care services to the client; and

(e) Permit frequent and informal leaves from the facility for visits, trips, or vacations.

§ 442.416 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, sanitation, research and civil rights.

§ 442.418 Provision of needed services.

(a) *Services provided directly.* At a minimum, the following must be provided directly by the facility:

(1) The services of a qualified mental retardation professional.

(2) The services of direct care staff.

(3) The development and monitoring of active treatment programs.

(4) Nursing services for clients with medical care plans.

(5) Living quarters as specified in §§ 442.500 through 442.512, which set forth the standards for the physical environment of an ICF/MR.

(b) *Services provided through outside arrangements.* (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) Assure that the outside services meet the standards for quality of services contained in this subpart.

(3) The facility must assure that the quality of outside services meets the needs of each client.

§ 442.420 Personnel policies.

The facility must—

(a) Develop and implement personnel policies that are available to all employees;

(b) Make job descriptions available for all positions; and

(c) Prohibit employees with symptoms or signs of a communicable disease from working; and

(d) Prohibit the employment of individuals with a history of child or client abuse, neglect or exploitation.

§ 442.422 Licensure and professional standards.

The facility must require compliance with the same licensure or certification standards for positions in the facility as are required for comparable positions in community practice.

§ 442.424 Staff treatment of clients.

(a) The facility must develop and implement policies and procedures that prohibit mistreatment, neglect or abuse of the client by an employee of the facility.

(b) The facility must ensure that all alleged violations of policies are reported immediately through established procedures.

(c) The facility must have evidence that—

(1) It investigates thoroughly all alleged violations;

(2) The results of the investigation are reported to the administrator or his designated representative within 5 working days of the incident; and

(3) If the alleged violation is verified, the administrator takes appropriate corrective action.

§ 442.426 Facility staffing.

(a) The facility must not depend upon clients or volunteers to perform direct care services for the facility.

(b) 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.

(c) In each defined 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.

(d) 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 (when clients are present) to respond to injuries and symptoms of illness, and to handle emergencies.

(e) 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.

(f) The facility must employ a qualified dietitian who is registered or eligible for registration by the American Dietetics Association either full-time, part-time, or on a consultant basis.

(g) If a qualified dietitian is not employed full-time, the facility must designate a person to serve as the director of food services.

§ 442.428 Direct care (residential living unit) staff.

Direct care staff are defined as the present on-duty staff-per-clients calculated over all shifts in a 24 hour period for each defined residential living unit. Direct care staff must be provided by the facility in the following minimal ratios:

(a) For each defined residential living unit serving children under the age of 12, severely and profoundly retarded clients, severely physically handicapped clients, 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.

(b) For each defined residential living unit serving moderately retarded clients, the staff to client ratio is 1 to 4.

(c) 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.

§ 442.430 Staff training program.

(a) 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.

(b) For employees who work with clients, training must focus on skills and competencies directed toward clients' developmental, behavioral, and health needs.

(c) Staff must be able to demonstrate skills and techniques necessary to implement the individual program plans for each client under their care.

§ 442.432 Client records.

(a) 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.

(b) The facility must keep confidential all information contained in the clients' records, regardless of the form or storage method of the records.

(c) The facility must develop and implement policies and procedures governing the release of any client information, including consents necessary from the client, or his or her parents or legal guardian.

(d) Any individual who makes an entry in a client's record must make it legibly, date it, and sign it.

(e) The facility must provide a legend to explain any symbol or abbreviation used in a client's record.

(f) The facility must provide each identified residential living unit with appropriate aspects of each client's record.

§ 442.434 Emergencies or death of a client.

The facility must notify promptly the client's parents or guardian of any significant incidents, including serious illness, accident or death, and autopsy findings if requested.

§ 442.436 Infection control.

(a) 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.

(b) The facility must implement successful corrective action in affected problem areas.

(c) The facility must maintain a log of incidents and corrective actions related to infections.

Active Treatment Services

§ 442.440 Active treatment.

(a) The facility must provide an active treatment program for each client that is directed toward—

(1) The acquisition of developmental, behavioral, and social skills necessary for the client's maximum possible individual independence; or

(2) For dependent clients where no further positive growth is demonstrable, the prevention of regression or loss of current optimal functional status.

(b) Active treatment does not include the 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 these standards.

§ 442.442 Admissions, transfers, and discharge.

(a) The facility must admit only those individuals who are in need of active treatment services as described in this subpart and for whom the facility can provide needed services.

(b) Admission decisions must be made by an interdisciplinary team, based on a comprehensive evaluation of the client that is conducted or updated by the facility or made by outside sources.

(1) A comprehensive evaluation must contain background information and a comprehensive functional assessment of current developmental, behavioral, social and health 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.

(2) A preadmission evaluation must be completed or updated no more than 90 days before the date of admission.

(3) At the time of admission, a physician must participate in the establishment of the client's individual program plan as required by § 456.380 of this chapter that specifies plan of care requirements for ICFs.

(c) If a client is to be either transferred or discharged, the facility must—

(1) Have documentation in the client's record that the client was transferred or discharged for good cause;

(2) Provide a reasonable time to prepare the client and his or her parents or guardian for the transfer or discharge (except in emergencies);

(3) Provide a final summary of the client's developmental, behavioral, social, and health status at the time of the discharge that is available for release to authorized persons and agencies, with the consent of the client, parents or guardian; and

(4) Provide a post-discharge plan of care that will assist the client to adjust to his or her new living environment.

§ 442.444 Individual program plan.

(a) The facility must develop an individual program plan (IPP) for each client. An interdisciplinary team representing the professions, disciplines, or service areas that are relevant to each client's needs, as identified by comprehensive functional assessments described in § 442.442(b), must be used to develop the plan.

(b) Appropriate facility staff must participate in interdisciplinary team meetings. Participation by other agencies involved in serving the client is encouraged. Participation by the client or the client's parents or guardian is required unless their participation is unobtainable or inappropriate.

(c) Within 30 days after admission, the interdisciplinary team must perform assessments or re-assessments as needed to supplement pre-admission data. The assessment must—

(1) Identify the presenting problems and disabilities and, where possible, their causes;

(2) Identify the client's specific developmental strengths;

(3) Identify the client's developmental and behavioral management needs;

(4) Identify the client's need for services without regard to the actual availability of the services needed; and

(5) Include, as applicable, physical development and health, sensorimotor development, affective development, speech and language development and auditory functioning, cognitive development, vocational skills and adaptive behaviors or independent-living skills necessary for the client to be able to function in the community.

(d) Within 30 days after admission, the interdisciplinary team must prepare, for each client, an IPP that states specific objectives for individual needs. These objectives must—

(1) Be stated separately, in terms of a single behavioral outcome;

(2) Be assigned projected completion dates;

(3) Be expressed in behavioral terms that provide measurable indices of performance;

(4) Be organized to reflect a developmental progression appropriate to the individual;

(5) Be assigned priorities; and

(6) Include the programs and strategies to be used.

(e) The IPP must emphasize personal care skills essential for privacy and independence (including, but not limited to, toilet training, personal hygiene, dental hygiene, self-feeding, bathing, dressing, and grooming), until the client has acquired these skills or it has been demonstrated that he or she is developmentally incapable of acquiring them.

(f) The IPP must provide that multi-handicapped and non-ambulatory

clients 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.

(g) A copy of each client's IPP must be made available to all relevant staff, including staffs of other agencies who work with the client, and to the client's parents or guardian.

§ 442.446 Program implementation.

(a) As soon as the interdisciplinary team has formulated a client's IPP, the facility must implement a continuous active treatment program for each client.

(b) The program must consist of needed interventions and services in sufficient number and frequency to carry out the objectives identified in the IPP.

(c) The facility must develop an active treatment schedule that outlines the active treatment program and is attached to and distributed with the IPP.

(d) Each client's IPP must be implemented by all staff who work with the client, including professional, paraprofessional and nonprofessional staff.

§ 442.448 Program documentation.

(a) The facility must document, in measurable terms, the client's performance in relationship to the objectives contained in the IPP.

(b) The facility must document that significant developmental, behavioral and social objectives identified in the client's IPP have taken place.

§ 442.450 Program monitoring and change.

(a) Each client's active treatment program must be integrated, coordinated and monitored by an qualified mental retardation professional who—

(1) Is employed by the facility;

(2) Has at least one year of experience working directly with persons with mental retardation or other developmental disability; and

(3) Is one of the following:

(i) A physician.

(ii) A registered nurse.

(iii) An individual who holds at least a bachelor's degree in a professional category included in § 442.460.

(b) A client's active treatment program must be reviewed and revised as necessary, if—

(1) The client has successfully completed an objective or objectives identified in the IPP;

(2) The client is regressing or losing skills already gained; or

(3) The client is failing to progress toward identified objectives after reasonable efforts have been made.

(c) The facility must develop procedures for revising plans between regularly scheduled reviews that include at least—

(1) Participation of and approval by the interdisciplinary team for any changes in the individual objectives of a client's IPP; and

(2) Approval of changes in implementation strategies for objectives by the qualified mental retardation professional and a professional member of the interdisciplinary team associated with the area of planned change.

(d) At least annually, the facility must reassess and revise the IPP, repeating the process set forth in § 442.444.

(e) The facility must establish and use a specially constituted committee or committees consisting of members from facility staff, parents, clients (if possible), and persons with no ownership or control interest in the facility, to—

(1) Review, approve, and monitor those individual behavior management and other programs that, in the opinion of the committee, involve risks to client protections; and

(2) Review, monitor and make suggestions about facility practices and programs as they relate to drug usage, physical restraints, behavior modification programs, protection of client rights and funds, and any other areas that the committee feels need to be addressed.

(f) The provisions of paragraph (e) of this section may be modified only if, in the judgment of the survey agency, State law or regulations provide for equivalent client protection and consultation.

§ 442.452 Behavior management—policies and procedures.

(a) The facility must have written policies and procedures for the behavioral management of clients. Those policies and procedures must be available to and implemented by all staff, and be available to parents, guardians, and if possible, clients.

(b) To the extent possible, clients must participate in the formulation of behavior management policies and procedures.

(c) Staff of the facility must not use corporal punishment, or verbal, physical, or sexual abuse.

(d) Staff must not place a client unobserved in a room or other area from which egress is prevented except as part of a systematic time-out program that meets all applicable standards.

(e) Clients must not discipline other clients, except as part of an organized self-government that is conducted in accordance with the behavior management policies and procedures specified in paragraph (a) of this section.

(f) Staff must not punish a client by withholding food that contributes to a nutritionally adequate diet.

§ 442.454 Behavior modification programs.

(a) The facility must formulate and implement written policies and procedures that govern the use of behavior modification programs, specify the staff members who may authorize their use, and describe a mechanism for monitoring and controlling their use.

(b) Each written behavior modification program (including aversive techniques), physical restraint program, and program for the use of drugs for behavior modification purposes must be a part of each client's IPP and specify—

(1) The behavioral objectives of the program;

(2) The methods to be used;

(3) The schedule for the use of the method;

(4) The persons responsible for the program; and

(5) The data to be collected to assess progress toward the desired objectives.

(c) For purposes of this subpart, a "time out" device is a procedure designed to improve behavior by placing the client where there is no opportunity for positive reinforcement of his or her undesirable behavior.

(d) Removal from a situation for time-out purposes must not be for longer than one hour, except in extraordinary instances that are approved by a professional member of the client's interdisciplinary team.

(e) Each behavior modification program that involves the use of aversive conditioning or time-out devices must be—

(1) Approved in writing by the facility's review committee, as required by § 442.450(e); and

(2) Conducted only with the written consent of the client or his or her parents or legal guardian, if available.

(f) Except in response to emergency situations, less restrictive methods of behavior management must be attempted and documented to have failed before more restrictive methods are employed.

§ 442.456 Physical restraints.

(a) The facility may employ physical restraint only—

(1) As a time out device that is an integral part of an IPP and that is intended to lead to less restrictive means of managing and eliminating the bahavior for which the restraint is applied; or

(2) As an emergency measure, but only if absolutely necessary to protect the client or others from injury.

(b) The facility must have written policies and procedures that define the use of restraints, the staff members who may authorize their use, and a mechanism for monitoring and controlling their use.

(c) Written authorization for restraints not used as part of an integrated behavior modification program must not be in effect longer than 12 consecutive hours.

(d) The facility must not issue orders for restraints on a standing or as needed basis.

(e) An individual placed in restraint must be checked at least every thirty minutes by staff trained in the use of restraints and a record of these checks must be kept.

(f) Restraints must be designed and used so as not to cause physical injury to the individual and so as to cause the least possible discomfort.

(g) The facility must not employ physical restraints as punishment, for the convenience of staff, or as a substitute for an active treatment program.

(h) Opportunity for motion and exercise must be provided for a period of not less than 10 minutes during each two hours in which restraint is employed, and a record of such activity must be kept.

(i) Totally enclosed cribs are considered restraints and their use must be governed by the standards in this section.

(j) Barred enclosures other than cribs must not be more than three feet in height and must not have tops.

(k) A physical restraint used as a time-out device must be used only during behavior modification exercises and only in the presence of staff trained to implement the program.

§ 442.458 Drug usage.

(a) The facility must not use drugs as a punishment, for the convenience of staff, as a substitute for an active treatment program, or in doses that interfere with an individual's IPP.

(b) Drugs used for behavior management must be used only as an integral part of the client's IPP that is directed toward the reduction of, and eventual elimination of, the behaviors for which the drugs are employed.

§ 442.460 Professional program services.

(a) The facility must provide professional program services to implement the active treatment program defined by each client's IPP. Professional program staff must work directly with the clients and with other professionals and the paraprofessional and nonprofessional staffs who work with clients.

(b) The facility must have available enough qualified professional staff and support personnel to carry out the various professional services in accordance with the stated goals and objectives of every IPP.

(c) Professional program staff must participate as members of the interdisciplinary team in relevant aspects of the active treatment process.

(d) 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.

(e) Professional program staff must meet the following qualifications:

(1) An occupational therapist must be—

(i) Eligible for certification as an occupational therapist by the American Occupational Therapy Association; or

(ii) A graduate of an occupational therapist educational program accredited jointly by the American Occupational Therapy Association and the committee on Allied Health Education and Accreditation of the American Medical Association.

(2) An occupational therapy assistant must be—

(i) Eligible for certification as a certified occupational therapy assistant by the American Occupational Therapy Association; or

(ii) A graduate of an occupational therapy assistant program accredited by the American Occupational Therapy Association.

(3) A physical therapist must be licensed as a physical therapist by the State in which he or she practices.

(4) A physical therapy assistant must be a graduate of a two year college-level program approved by the American Physical Therapy Association.

(5) A psychologist must have at least a master's degree in psychology from an accredited program.

(6) A social worker must—

(i) Be licensed, if applicable, by the State in which he or she is practicing;

(ii) Hold a graduate degree from a school of social work accredited or approved by the Council on Social Work Education; or

(iii) Hold a Bachelor of Social Work degree from a college or university accredited or approved by the Council on Social Work Education.

(7) A speech and language pathologist or audiologist must be licensed, if applicable, by the State in which he or she is practicing and—

(i) Be eligible for a certificate of clinical competence in speech and language pathology or audiology granted by the American Speech, Language, and Hearing Association under its requirements in effect on the publication of this provision; or

(ii) Meet the educational requirements for certification and be in the process of accumulating the supervised experience required for certification.

(8) A professional recreation staff member must have a bachelor's degree in recreation or in a specialty area such as art, dance, music or physical education, or recreation therapy.

(9) A human services professional must have at least a bachelor's degree in a human services field other than those mentioned in paragraphs (e)(1) through (e)(8) of this section (such as sociology, special education, rehabilitation counseling).

§ 442.462 Physician services.

(a) The facility must provide or arrange for the provision of physician services 24 hours a day, including treatment, medications, diet, and any other medical service prescribed or planned for the client.

(b) 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.

§ 442.464 Physician participation.

(a) A physician must participate in—

(1) The establishment of the newly admitted client's IPP as required by § 456.380 of this chapter that specifies plan of care requirements for ICFs; and

(2) The development of a medical care plan of treatment (i.e., a formalized plan for the provision of physician and related medical care services) for a client if the physician determines that an individual client requires such a plan for the medical management of specific serious health problems. This plan must be integrated in the overall IPP, as appropriate.

(b) If appropriate, physicians must participate in the review and update of an IPP as part of the interdisciplinary team process either in person or through written report to the interdisciplinary team.

§ 442.466 Comprehensive health services.

The facility must—

(a) Have a formal arrangement for providing each client with medical care that includes care for medical emergencies on a 24 hours a day basis as well as general preventive health services; and

(b) Provide annual physical examinations that include the following:

(1) Examination of vision and hearing.

(2) Routine immunizations and tuberculosis control.

(3) Screening laboratory examinations as determined necessary by the physician, and special studies, if needed.

§ 442.468 Nursing services.

The facility must provide clients with nursing services in accordance with their needs. These services must include—

(a) The development, review, and update of an IPP as part of the interdisciplinary team process;

(b) 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;

(c) A determination of clients' health status by an onsite, direct physical review at least quarterly of those residents certified by a physician as not in need of a medical care plan of treatment. Based on the nurse's recorded findings, the nurse must take necessary action (including referral to a physician if necessary) to address the health problems of clients;

(d) Other nursing care as prescribed by the physician or as identified by client needs; and

(e) Implementing, with other members of the interdisciplinary team, appropriate protective and preventive health measures that include, but are not limited to—

(1) Training clients and staff as needed in appropriate health and hygiene methods;

(2) Control of communicable diseases and infections, including the instruction of other personnel in methods of infection control; and

(3) 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.

§ 442.470 Nursing staff

(a) Nurses providing services in the facility must have a current license to practice in the State.

(b) The facility must have available enough nursing staff and other support personnel to carry out the various nursing services.

(c) The facility must employ a licensed nurse on one full shift 7 days a week to supervise the health services for clients for whom the physician has ordered a medical care plan.

(d) In facilities with clients who have been determined by the physician not to require a medical care plan, the facility must arrange for licensed nursing personnel to conduct health surveillance of each client on a quarterly basis.

(e) The facility must utilize registered nurses as appropriate and required by State law to perform the health services specified in this section.

(f) 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 consult with the licensed practical or vocational nurses.

(g) Non-licensed personnel who work with clients under a medical care plan must do so under the supervision of licensed persons.

§ 442.472 Dental services.

(a) 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.

(b) Dental professionals must participate, as appropriate, in the development, review and update of an IPP as part of the interdisciplinary process.

§ 442.474 Comprehensive dental diagnostic services.

Comprehensive dental diagnostic services included—

(a) 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 6 months before admission);

(b) Periodic examination and diagnosis performed at least annually, including radiographs when indicated and detection of manifestations of systemic disease; and

(c) A review of the results of examination and entry of the results in the client's dental record.

§ 442.476 Comprehensive dental treatment.

Comprehensive dental treatment services include—

(a) Provision of emergency dental treatment on a 24-hour-a-day basis by a licensed dentist; and

(b) Dental care needed for relief of pain and infections, restoration of teeth, and maintenance of dental health.

§ 442.478 Documentation.

(a) 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.

(b) 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 maintained in the client's living unit.

(c) The facility must 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.

§ 442.480 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.

§ 442.482 Drug regimen review.

[a] A pharmacist or registered nurse must review the drug regimen of each client at least quarterly.

(b) The pharmacist or nurse must report any irregularities in clients' drug regimens to the prescribing physician.

(c) The pharmacist or nurse must prepare a record of each client's drug regimen reviews and the facility must maintain that record.

(d) An individual medication administration record must be maintained for each client.

(e) The pharmacist must participate, as appropriate, in the development, implementation, and review of each client's IPP.

§ 442.484 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—

(a) All drugs are administered in compliance with the physician's orders;

(b) All drugs are administered without error, including those that are self-administered;

(c) If unlicensed personnel are allowed by State law to administer drugs, a licensed nurse participates in the training of these personnel in facility-specific drug administration procedures apart from and in addition to any State program;

(d) 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;

(e) The client's physician is informed of the interdisciplinary team's decision

that self-administration of medications is an objective for the client;

(f) No client self-administers medications until he or she demonstrates the competency to do so;

(g) Drugs used by clients while not under the direct care of the facility are packaged and labeled by a pharmacist;

(h) There is an automatic stop order for those drugs not limited by the prescription in time or quantity; and

(i) Drug administration errors and adverse drug reactions are recorded and reported immediately to a physician or registered nurse.

§ 442.486 Storage and recordkeeping.

(a) The facility must store drugs under proper conditions of sanitation, temperature, light, humidity, and security.

(b) The facility must keep all drugs and biologicals locked except when being prepared for administration. Only authorized personnel may have access to the keys to the drug storage area.

(c) The facility must maintain records of the receipt and disposition of all controlled drugs.

(d) The facility must, on a sample basis, periodically reconcile the receipt and disposition of all controlled drugs in schedules II through IV (as identified in 21 U.S.C. 812).

(e) If the facility maintains a licensed pharmacy, the facility must comply with the regulations for controlled drugs (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).

§ 442.488 Labeling.

(a) Labeling of drugs and biologicals must—

(1) Be based on currently accepted professional principles and practices; and

(2) Include the appropriate accessory and cautionary instructions, as well as the expiration date, if applicable.

(b) The facility must not retain—

(1) Outdated drugs; and

(2) Drug containers with worn, illegible, or missing labels.

(c) Drugs and biologicals packaged in containers designated for a particular client and that have been discontinued by the physician must not be available for administration.

§ 442.489 Laboratory services.

(a) For purposes for this section, "laboratory" means a facility 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.

(b) If an ICF/MR that meets the requirements of this subpart operates its own laboratory, the laboratory must either—

(1) Be licensed or approved according to State law if it is located in a State that provides for the licensing or approval of laboratories; or

(2) Meet the requirements of paragraphs (c) through (f) of this section.

(c) The laboratory must meet the management requirements specified in § 405.1316 of this chapter.

(d) The facility must provide personnel to direct and conduct the laboratory services.

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

(i) A pathologist or other doctor of medicine or osteopathy with training and experience in clinical laboratory services; or

(ii) A laboratory specialist with a doctoral degree in physical, chemical or biological sciences, and training and experience in clinical laboratory services.

(2) 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.

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

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

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

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

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

(e) The laboratory must meet the proficiency testing requirements specified in § 405.1314(a) of this chapter.

(f) The laboratory must meet the quality control requirements specified in § 405.1317 of this chapter.

Physical Environment

§ 442.500 Client living environment.

(a) 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.

(b) The facility must not segregate clients on the basis of their physical handicaps. It must integrate clients with ambulation deficits or who are deaf, blind, epileptic, etc., with others of comparable social and intellectual development.

§ 442.502 Client bedrooms.

(a) Bedrooms must—(1) Be rooms that have at least one outside wall;

(2) Be equipped with or located near toilet and bathing facilities;

(3) Accommodate no more than four clients unless granted a variance under paragraph (c) of this section;

(4) Measure at least 60 square feet per client in multiple client bedrooms and at least 80 square feet in single client bedrooms; and

(5) In all newly certified facilities, have walls that extend from floor to ceiling.

(b) If a bedroom is below grade level, it must have a window that is no more than 44 inches from the floor and must be usable as a second means of escape. If the facility is surveyed under the Health Care Occupancy Chapter of the Life Safety Code, the window must be no more than 36 inches above the ground.

(c) The survey agency may grant a variance from the limit of four clients per room only if a physician or psychologist who is a member of the interdisciplinary team and who is a qualified mental retardation professional—

(1) 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

(2) Documents the reasons why housing in a room of only four or fewer persons would not be feasible.

(d) The facility must provide each client with—

(1) A separate bed of proper size and height for the convenience of the client;

(2) A clean, comfortable, fire safe mattress;

(3) Bedding appropriate to the weather and climate; and

(4) Appropriate furniture, such as a chest of drawers, a table or desk, and an individual closet with clothes racks and shelves accessible to the client.

§ 442.504 Storage space in living units.

The facility must provide—(a) Space for 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;

(b) Suitable storage space, accessible to clients, for personal possessions, such as TVs, radios, prosthetic equipment and clothing; and

(c) Adequate clean linen and dirty linen storage areas for each living unit.

§ 442.506 Client bathrooms.

The facility must—(a) Provide toilet and bathing facilities appropriate in number, size, and design to meet the needs of the clients;

(b) Provide for individual privacy in toilets, bathtubs, and showers unless specifically contraindicated by the client's physical, behavioral, or developmental needs; and

(c) 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.

§ 442.508 Heating and ventilation in living units.

(a) Each client bedroom in the facility must have—(1) At least one window to the outside; and

(2) Direct outside ventilation by means of windows, air conditioning, or mechanical ventilation.

(b) The facility must—(1) Maintain the temperature and humidity within a normal comfort range by heating, air conditioning or other means; and

(2) Ensure that the heating apparatus does not constitute a burn or smoke hazard to clients.

§ 442.510 Floors in living units.

The facility must have—(a) Floors that have a resilient, nonabrasive, and slip-resistant surface; and

(b) Nonabrasive carpeting, if the living unit is carpeted and serves clients who crawl.

§ 442.512 Space and equipment in dining, health services, and program areas.

(a) The facility must provide sufficient space and equipment in dining, health services, 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 these standards and as identified in each client's IPP.

(b) The facility must furnish, maintain in good repair, and encourage the use of, dentures, eyeglasses, hearing and other communications aids, braces, and other devices identified by appropriate specialists or the interdisciplinary team as needed by the client.

Safety and Sanitation

§ 442.550 Emergency plan and procedures.

(a) The facility must have detailed written plans and procedures to meet all potential emergencies and disasters such as fire, severe weather, and missing clients.

(b) The facility must communicate, periodically review, make the plan available, and provide training to the staff.

§ 442.552 Evacuation drills.

(a) The facility must hold evacuation drills at least quarterly for each shift of personnel and under varied conditions to—

(1) Ensure that all personnel on all shifts are trained to perform assigned tasks;

(2) Ensure that all personnel on all shifts are familiar with the use of the facility's fire protection features; and

(3) Evaluate the effectiveness of emergency and disaster plans and procedures.

(b) The facility must—

(1) Actually evacuate clients who cannot cooperate in an evacuation, during at least one drill a year on each shift;

(2) Actually evacuate clients who can cooperate in an evacuation, during at least one drill each quarter on each shift;

(3) Make special provisions for the evacuation of the physically handicapped;

(4) File a report and evaluation on each evacuation drill; and

(5) Investigate all problems with evacuation drills, including accidents, and take corrective action.

(c) Facilities must meet the requirements of paragraphs (a) and (b) of this section for any live-in and relief staff they utilize.

§ 442.554 [Reserved]

§ 442.556 Paint.

The facility must— (a) Use lead-free paint inside the facility; and

(b) Remove or cover interior paint or plaster containing lead so that it is not accessible to clients.

§ 442.558 Food and nutrition services.

(a) The facility must provide each client with a nourishing, well-balanced diet including modified and specially-prescribed diets.

(b) A qualified dietitian and a physician must participate in decisions about modified and special diets, including modifications and changes to special and modified diets.

(c) Unless otherwise specified by medical needs the diet must be prepared 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.

§ 442.560 Meal services.

(a) The facility must serve at least three meals daily, at regular times comparable to normal mealtimes in the community with—

(1) Not more than 14 hours between a substantial evening meal and breakfast of the following day; and

(2) Not less than 10 hours between breakfast and the evening meal of the same day.

(b) Food must be served—(1) In appropriate quanitity;

(2) At appropriate temperature;

(3) In a form consistent with the developmental level of the client; and

(4) With appropriate utensils.

(c) Food served and uneaten must be discarded.

§ 442.562 Menus.

Menus must—(a) Be prepared in advance;

(b) Provide a variety of foods at each meal;

(c) Be different for the same days of each week and adjusted for seasonal changes;

(d) Be kept on file for 30 days; and

(e) Include the average portion sizes for menu items.

§442.564 Dining areas and service.

The facility must—(a) Serve meals for all clients, including persons with ambulation deficits, in dining areas, unless otherwise specified by the interdisciplinary team or a physician;

(b) Provide table service for all clients who can and will eat at a table, includng clients in wheelchairs;

(c) Equip areas with tables, chairs, eating utensils, and dishes designed to meet the developmental needs of each client; and

(d) Supervise and staff dining rooms adequately to direct self-help dining procedures and to assure that each client receives enough food.

(Catalog of Federal Domestic Assistance Program No. 13.714 Medical Assistance Program)

Dated: February 10, 1986.

Henry R. Desmarais,

Acting Administrator, Health Care Financing Administration.

Approved: February 26, 1986.

Otis R. Bowen,

Secretary

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Part III

Environmental Protection Agency

40 CFR Part 271

State Hazardous Waste Programs; Procedures for Approving Revisions; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[SW-FRL-2943-7]

State Hazardous Waste Programs; Procedures for Approving Revisions

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency is today promulgating amendments to the procedures in 40 CFR 271.21 for processing revisions to State hazardous waste programs. The final rule is designed to streamline and improve the revision process for the States by eliminating the distinction between substantial and non-substantial revisions and making other changes to the approval procedures. The new process offers increased public participation by providing an opportunity to comment on all, rather than only substantial, program revisions.

DATES: These regulations shall be promulgated for purposes of judicial review at 1:00 p.m. eastern time on March 18, 1986. These regulations shall become effective on March 18, 1986.

FOR FURTHER INFORMATION CONTACT: The RCRA hotline, toll-free at (800) 424–9346 or in Washington, DC at (202) 382–3000, or Frank McAlister, State Programs Branch, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. Telephone: (202) 382–2210.

SUPPLEMENTARY INFORMATION:

I. Background

States with final authorization under section 3006(b) of the Resource Conservation and Recovery Act ("RCRA" or "the Act"), 42 U.S.C. 6926(b), have a continuing obligation to maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than the Federal hazardous waste program. In addition, as an interim measure, the Hazardous and Solid Waste Amendments of 1984 (Pub. L. 98–616, November 8, 1984, hereinafter "HSWA") allow States to revise their programs to become substantially equivalent instead of equivalent to RCRA requirements promulgated under HSWA authority. States exercising the latter option receive "interim authorization" for the HSWA requirements under section 3006(g) of RCRA, 42 U.S.C. 6926(g), and later apply for final authorization for the HSWA requirements.

Revisions to State hazardous waste programs are necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most commonly, State program revisions are necessitated by changes to EPA's regulations in 40 CFR Parts 260–266 and 270–271. 40 CFR 271.21(b) requires States to submit their proposed program revisions to EPA for approval. The rule, prior to today's amendment, also specified two types of EPA approval procedures for program revisions.

For substantial program revisions, EPA was required to issue a public notice in the **Federal Register**, in the major newspapers in the State, and via mail to interested persons. The notice had to summarize the proposed revisions, provide for a comment period of at least 30 days, and provide for an opportunity for public hearing if there was significant public interest. After the comment period and a determination by the Agency that the proposed revisions were in compliance with the requirements of the Act, a notice of approval was published in the **Federal Register**. The same procedures did not apply to non-substantial program revisions. Rather, notice of approval of non-substantial program revisions could have been given simply by a letter from the Administrator to the State Governor or his designee.

EPA was concerned that the procedures for processing substantial program revisions might have been too time-consuming and resource-intensive for both the States and EPA. The time element is particularly critical; until a State receives authorization to implement a permitting requirement imposed by HSWA, the State cannot issue a RCRA permit to a facility within its borders. Instead, it must issue a joint permit with EPA whereby EPA adds the HSWA requirements that the State is not authorized to implement. We also were concerned that the public did not have an opportunity to comment on non-substantial program revisions.

To simplify and expedite the State revision process, EPA proposed on June 10, 1985 (50 FR 24362–24364) to streamline the procedures for approval of State hazardous waste program revisions. The proposal also sought to expand the opportunity for public involvement to include all State program revisions. EPA strongly encourages full public participation in all its State authorization decisions.

To accomplish these objectives, we proposed to eliminate the distinction between substantial and non-substantial program revisions and to substitute two alternative procedures for approving revisions: (1) Standard rulemaking, or (2) immediate final rulemaking. Under the first alternative, a proposed approval or disapproval would have been published in the **Federal Register** with at least a 30-day public comment period. EPA would have reviewed the public comments and responded to them in a final rule approving or disapproving the proposed revision. Under the second alternative, EPA would have published an immediate final rule in the **Federal Register** indicating that the State revision was approved or disapproved. EPA's decision would have taken effect 45 days after the date of publication unless EPA received a negative comment within the 30-day comment period. Under this proposed option, if EPA received a negative comment, EPA would have notified the State of the comment and published a new **Federal Register** action withdrawing the immediate final rule. The **Federal Register** publication would have identified the objection and proposed the approval or disapproval of the revision with a new comment period. The standard rulemaking alternative discussed above would have then been followed until a final decision was reached.

It should be noted that on January 6, 1986, EPA proposed additional changes to 40 CFR 271.21 (see 51 FR 496–504). The purpose of the January 6 proposal is to facilitate authorization of hazardous waste programs by defining *when* State program modifications must be completed. In contrast, today's final rule identifies *how* the State revisions will be processed. Regardless of the outcome of the January 6 proposal, today's rule will have a beneficial effect in streamlining State program approval procedures.

II. Provisions of the final rule

A. General

Although few comments were received on the proposal, all commenters supported the concept of streamlining the approval process for State program revisions. Indeed, most commenters suggested providing less opportunity for public comment than EPA proposed. As will be discussed in EPA's response to comments, those suggestions were rejected.

In analyzing the proposed rule, EPA realized there was no reason why receipt of adverse comments should automatically result in withdrawal of its decision. Normally EPA responds to public comments and does not provide a new comment period on comments that are received. We concluded that automatic withdrawal of the immediate

final rule and reproposal of EPA's decision would serve no practical purpose and only delay resolution of the issues raised by the comments. EPA was persuaded that a more efficient process could be devised. Thus, the final rule adopts the following approach.

The rule provides that if no adverse comments are received on EPA's decision to approve a State program revision, the decision will take effect 60 days after the date of publication. A second **Federal Register** notice would not be published. This aspect of the rule is the same as proposed, except that the proposal provided for an effective date 45 days after the date of publication. The Agency found it necessary to extend the effective date from 45 to 60 days since the proposal would have allowed an insufficient amount of time (a maximum of only 15 days after the close of the comment period) for the Agency to address adverse comments in accordance with the alternatives provided in the final rule, as discussed below. In addition, EPA wishes to clarify that the immediate final rule will be published in the final rule section of the **Federal Register** but will be cross-referenced in the proposed rule section of the **Federal Register** as well.

If adverse comments are received, a second **Federal Register** notice will be published before the time the immediate final rule takes effect. Unlike the proposal, however, the second notice may or may not withdraw the immediate final rule. If the Administrator disagrees with the public comments, he may publish a second **Federal Register** notice prior to the effective date of his decision which identifies the issues raised, responds to these comments and affirms that the immediate final rule will take effect as scheduled.

If the Administrator agrees with the public comments and decides to reverse his decision, he may do one of two things. He may publish a final rule before the effective date of his decision reflecting his changed position and explaining his reasoning. Alternatively, if he believes the change in position warrants a new round of public comment, he may withdraw the immediate final rule prior to its effective date and simultaneously propose his new decision.

Finally, if the comments raise issues that the Administrator cannot resolve before the effective date of the immediate final rule, he will withdraw the rule prior to its effective date. At a later date, he may publish a final rule which responds to comments and contains his decision or he may provide a new round of comment. This option assures that EPA will have whatever amount of time is necessary to consider all comments fully.

In short, the final rule provides the Administrator with several procedural options for making decisions on program revisions, including following standard rulemaking procedures. The common denominator of all the approaches is that no decision to approve or disapprove a State program will be made without an opportunity for public comment or before EPA has the opportunity to consider and respond to public comments. At the same time EPA retains the flexibility to choose the quickest and most effective approach for each situation, thereby reducing the administrative burdens and time delays for the States and EPA.

B. Use of Standard Rulemaking and Immediate Final Rulemaking

While either standard rulemaking or immediate final rulemaking procedures may be used to approve State program revisions, the Agency is more likely to use the standard rulemaking procedure in some circumstances. For example, if a State submitted a program revision for a large number of changes at the same time and the Agency expected the revision to generate public interest (e.g., there is a history of public comments on authorization decisions affecting the State), we would follow the standard rulemaking procedures. Further, EPA would normally use standard rulemaking procedures if the Agency were planning to disapprove a State program revision since more public comment would be likely.

On the other hand, the immediate final approach most likely would be used if the State has a history of little or no public interest in previous authorization decisions. For example, if no comments had been received on the State's initial application for final authorization or on recent program revisions, then subsequent revisions would ordinarily be processed using the immediate final rulemaking.

C. Elimination of Public Hearing Requirement

As discussed in the proposal, the new procedures do not require public hearings to be held in conjunction with EPA's authorization decisions. Since there is no legal requirement to provide for hearings on revision decisions and little public interest has been shown to date in attending hearings on initial authorization of State programs, we think the opportunity to provide written comments is adequate. Only one comment was received on the elimination of routine public hearings, and that comment favored the rule change. However, while the regulatory requirement is deleted, a Regional Administrator, in his discretion, could decide to hold a hearing.

III. Response to Comments

Several commentors suggested that comments on EPA's decision to approve or disapprove a State program revision which are inconsequential, insignificant or trivial may unnecessarily hinder the streamlining process and, therefore, EPA should only respond to significant comments. EPA does not believe that it is practical or desirable to rate the significance of public comments. Unless a comment is not germane to the program revision or is unsupported, EPA will respond to it in a second **Federal Register** notice. By "germane" EPA means that it would not publish a response where, for example, the comment concerned the State's permit program whereas the program revision concerned manifest requirements. Similarly, EPA would not publish a response where a person objected to EPA's decision but gave no reason.

One commentor suggested that EPA retain flexibility in how the Agency responds to adverse comments by allowing the option of either responding to the comments in the **Federal Register** or extending the public comment period. We agree that adverse comments should not result in automatic withdrawal of EPA's decision and have changed the rule as discussed above.

One commentor suggested that, where EPA withdraws an immediate final rule, the Agency should provide a specific response in the **Federal Register** which details what must be changed by the State, how the change must be made, and to what extent the change must be made. EPA agrees that, if time allows, such discussion would be appropriate; however, an overriding concern is the timely withdrawal of the rule (see section II A above). If not explained in the **Federal Register**, EPA will provide a detailed letter to the State which will be publicly available.

Several commentors, suggested that EPA retain the non-substantial revision process. We have rejected this comment because, as stated in the proposal, we believe that the public should be able to comment on all program revisions. Further, what EPA views as a non-substantial revision may be considered substantial by the public. Indeed, the concept of distinguishing between substantial and non-substantial program revisions is problematic. We also disagree with the comment that non-substantial revisions are essentially clerical revisions.

Two commentors opposed the use of standard rulemaking procedures for State authorization decisions. We believe it is important to retain the option of standard rulemaking procedures. We can think of no legal or practical reason for limiting EPA's discretion to use standard rulemaking procedures.

One commentor requested guidance on when EPA would use standard rulemaking procedures versus immediate final rules. Section II.*B* of the preamble provides discussion on this subject.

Two commentors opposed increasing the opportunity for public involvement in State program revisions. The Agency disagrees. We believe it is sound public policy to provide all parties the opportunity to review and comment on all EPA State authorization decisions, irrespective of whether or not one particular party may view a proposed revision as non-substantial or trivial, as discussed above. Further, EPA does not have to establish a basis for allowing public comment. Also, while we recognize the public has the opportunity to comment at State proceedings (e.g., at State hearings on the adoption of their regulations), the public does not have the opportunity to advise EPA at that time on whether each State program revision meets the Federal requirements for authorization.

IV. Regulatory Impact

Under Executive Order 12291 (46 FR 12193, February 19, 1981), EPA must judge whether a regulation is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. This regulation is not major because it will not result in an annual effect on the economy of $100 million or more, nor will it result in an increase in costs or prices to industry. There will be no adverse impact on the ability of the U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. The regulation merely streamlines procedures for approving State RCRA program revisions. The Office of Management and Budget has exempted this rulemaking from Executive Order 12291.

V. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, EPA is required to determine whether a regulation will have a significant impact on a substantial number of small entities so as to require a regulatory flexibility analysis. No regulatory flexibility analysis is required where the head of an agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

The amendments adopted here merely streamline the procedures for approving State hazardous waste program revisions and do not affect the compliance burdens of the regulated community.

Therefore, pursuant to 5 U.S.C. 601(b), I certify that this regulation will not have a significant economic impact on a substantial number of small entities.

VI. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, EPA must estimate the paperwork burden created by any information collection request contained in a proposed or final rule. Because there are no information collection activities created by this rulemaking, the requirements of the Paperwork Reduction Act do not apply.

Information collection requirements contained elsewhere in 40 CFR Part 271 have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act and have been assigned OMB control number 2000–0041.

List of Subjects in 40 CFR Part 271

Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Indian lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Water pollution control, Water supply.

Dated: February 21, 1986.

Lee M. Thomas,

Administrator.

For the reasons set out in the preamble, 40 CFR Part 271 is revised as follows:

PART 271—REQUIREMENTS FOR AUTHORIZATION OF STATE HAZARDOUS WASTE PROGRAMS

1. The authority for Part 271 continues to read as follows:

Authority: Secs. 1006, 2002(a), and 3006, Solid Waste Disposal Act as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6905, 6912(a), and 6926).

§ 271.1 [Amended]

2. In § 271.21, paragraphs (b)(2)–(4) are revised to read as follows:

* * * * *

(b) * * *

(2) The Administrator shall approve or disapprove program revisions based on the requirements of this part and of the Act. In approving or disapproving program revisions, the Administrator shall follow the procedures of paragraph (b)(3) or (4) of this section.

(3) The procedures for an immediate final publication of the Administrator's decision are as follows:

(i) The Administrator shall issue public notice of his approval or disapproval of a State program revision:

(A) In the **Federal Register;**

(B) In enough of the largest newspapers in the State to attract Statewide attention; and

(C) By mailing to persons on the State agency mailing list and to any other persons whom the agency has reason to believe are interested.

(ii) The public notice shall summarize the State program revision, indicate whether EPA intends to approve or disapprove the revision and provide for an opportunity to comment for a period of 30 days.

(iii) Approval or disapproval of a State program revision shall become effective 60 days after the date of publication in the **Federal Register** in accordance with paragraph (b)(3)(i) of this section, unless an adverse comment pertaining to the State revision discussed in the notice is received by the end of the comment period. If an adverse comment is received the Administrator shall so notify the State and shall, within 60 days after the date of publication, publish in the **Federal Register** either:

(A) A withdrawal of the immediate final decision; or

(B) A notice containing a response to comments and which either affirms that the immediate final decision takes effect or reverses the decision.

(4) The procedures for proposed and final publication of the Administrator's decision are as follows:

(i) The Administrator shall issue public notice of his proposed approval or disapproval of a State program revision:

(A) In the **Federal Register;**

(B) In enough of the largest newspapers in the State to attract Statewide attention; and

(C) By mailing to persons on the State agency mailing list and to any other persons whom the agency has reason to believe are interested.

(ii) The public notice shall summarize the State program revision, indicate whether EPA intends to approve or disapprove the revision and provide for an opportunity to comment for a period of at least 30 days.

(iii) A State program revision shall become effective when the Administrator's final approval is published in the **Federal Register.**

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