DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 87F-0416]

Pfizer Central Research, Pfizer, Inc.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to future filing, of a petition (FAP 8A4048) proposing that the food additive regulations be amended to provide for the safe use of a genetically modified *Escherichia coli* K-12 (*E. coli* K-12) as a source of chymosin for use in food.

FOR FURTHER INFORMATION CONTACT: Eric L. Flamm, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-426-8950.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 9, 1988 (53 FR 3792), FDA published a notice that it had filed a petition (FAP 8A4048) from Pfizer Central Research, Pfizer, Inc., 235 East 42d St., New York, NY 10017, that proposed to amend the food additive regulations to provide for the safe use of a genetically modified *E. coli* K-12 as a source of prochymosin.

The prochymosin preparation obtained by fermentation of the modified *E. coli* K-12 is processed to yield chymosin for use in food. Pfizer Central Research, Pfizer, Inc., has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7). Published elsewhere in this issue of the **Federal Register** is a final rule (Docket No. 87G-0418) affirming that the use of chymosin preparation derived from *E. coli* K-12 is generally recognized as safe.

Dated: March 14, 1990.

Alan L. Hoeting,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 90-6599 Filed 3-22-90; 8:45 am]

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Friday
March 23, 1990

Part V

Department of Health and Human Services

Health Care Financing Administration

42 CFR Part 405 et al.

Medicare and Medicaid Programs; Nurse Aide Training and Competency Evaluation Programs and Preadmission Screening and Annual Resident Review; Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 431, 433 and 483

RIN 0938-AE50

[BPD-662-P]

Medicare and Medicaid Programs; Nurse Aide Training and Competency Evaluation Programs

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

ACTION: Proposed rule.

SUMMARY: This rule proposes Federal requirements that States have competency evaluation programs and training and competency evaluation programs for nurse aides employed by Medicare and Medicaid participating nursing facilities and also have a nurse aide registry.

The purpose of these provisions is to ensure that nurse aides have the education, practical knowledge, and skills needed to care for residents of nursing facilities. These requirements would implement, in part, sections 4201(a) and 4211(a) of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) and section 6901(b) of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89).

DATES: To assure consideration, comments must be submitted to the appropriate address, as provided below, and should be received no later than 5:00 p.m. on May 22, 1990.

ADDRESSES: Mail comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD-662-P, P.O. Box 26676, Baltimore, Maryland 21207.

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

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

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

Due to staffing and resource limitations, we cannot accept facsimile (FAX) copies of comments.

In commenting, please refer to file code BPD-662-P. Comments received timely will be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, in Room 309-G of the Department's offices at 200 Independence Avenue SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: 202-245-7890).

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

SUPPLEMENTARY INFORMATION:

I. Background

Overview

Facilities under the Medicare and Medicaid programs can be any of several different facilities providing a wide variation of patient care services. A nursing facility that is a Medicare skilled nursing facility (SNF) is primarily engaged in providing skilled nursing care and related services or rehabilitation services for the rehabilitation of injured, disabled, or sick persons.

A nursing facility under the Medicaid program is an institution or distinct part of an institution that is primarily engaged in providing skilled nursing care and related services; rehabilitation services for the rehabilitation of injured, disabled, or sick persons; or on a regular basis, health-related care and services above the level of room and board, to individuals who, because of their mental or physical condition, require care and services that are only available through an institution.

Nursing facilities participating in the Medicare and Medicaid programs agree to comply with the requirements included in our regulations at 42 CFR parts 405 and 442. Extensive revisions to those rules at 42 CFR part 483 become effective October 1, 1990, as discussed below.

Compliance with the requirements is assessed by means of an onsite survey, usually performed by a State survey agency, that measures adherence to Federally established guidelines.

Requirements for Long Term Care Facilities

On February 2, 1989, we published in the **Federal Register** (54 FR 5316) final regulations with a comment period which specified new and revised requirements that long-term care facilities (SNFs and intermediate care facilities (ICFs), both of which, effective October 1, 1990, will be considered nursing facilities (NFs) under Medicaid and SNFs under Medicare) must meet in order to receive Federal funds for the care of residents who are Medicare beneficiaries or Medicaid recipients. We issued the regulations following a notice of proposed rulemaking (NPRM) to refocus the requirements for participation in both programs to actual facility performance in meeting residents' needs in a safe and healthful environment. The previous set of requirements had focused on the capacity of the facility to provide appropriate care. In addition, we needed to simplify Federal enforcement procedures by using a single set of requirements that apply to all activities common to SNFs, ICFs, and NFs.

Many of the requirements in the February 2 regulations included detailed, self-implementing provisions of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) (Pub. L. 100-203). OBRA '87 was enacted after we issued the NPRM for the final regulations. An effective date of August 1, 1989 was specified for the regulations, except for those requirements that require a later effective date.

The revision of the nursing home regulations was the most extensive set of Federal regulatory changes in this area of the health care industry in 15 years. Because of these major revisions, we had to rewrite significantly the survey guidelines for conducting inspections of nursing homes, and we have had to conduct extensive training of individuals who will conduct the inspections to determine facility compliance with Federal requirements.

On July 14, 1989 we published a rule in the **Federal Register** (54 FR 29717) announcing that we believed it would be beneficial to all affected parties, including beneficiaries and recipients, to delay the effective date of the regulations until January 1, 1990. This delay was intended to allow opportunity for further improvement of surveyor skills and allow facilities additional lead time to become more familiar with these requirements and to make needed changes. In the long run, the delay was expected to enhance the quality of care provided to residents of the facilities and our ability to measure accurately and uniformly that quality among participating facilities.

Therefore, we changed the effective date of the February 2 regulations to January 1, 1990. Those parts of the regulations that are to be effective on October 1, 1990, were unaffected by this change.

On December 19, 1989, the Omnibus Budget Reconciliation Act of 1989 (OBRA '89) (Pub. L. 101-239) was enacted. Section 6901(a) of OBRA '89 further delays the effective date of the February 2, 1989 regulations to October 1, 1990, and we confirmed this in a final rule on December 29, 1989, 54 FR 53611. The statutory delay in the effective date of our substantial revision of nursing home requirements presents us with a paradox: the legislation and the provisions of this proposal concern, in part, proposed modifications to

regulations that presently are not in effect. We intend to deal with this paradox in two ways. First, we are proposing, where necessary, to modify the text of the February 2, 1989 rule. We are doing this because the OBRA '87 requirements concerning nurse aide training and registry were codified by the February 2, 1989 rule and are not otherwise a part of the Code of Federal Regulations. Second, we anticipate that the effective date of this proposal would not be before October 1, 1990, the effective date of the February 2, 1989 rule.

II. Proposed Rule

Nurse Aide Training and Competency Evaluation

Prior to the enactment of OBRA '87, there were no Federal requirements concerning training and competency evaluation of nurse aides. Rather, conditions for Medicare at § 405.1121(h) and for Medicaid at § 442.314 required all staff be suitably and appropriately trained. New sections 1819(e)(1), 1819(f)(2), 1919(e)(1) and 1919(f)(2) of the Social Security Act (the Act), added by OBRA '87, require the Secretary to establish standards for training and competency of nurse aides and authorize States to grant approvals of competency evaluation programs and training and competency evaluation programs only in accordance with those standards. Sections 1819(e)(1) and 1919(e)(1) of the Act require that the State review and approve nurse aide competency evaluation programs and training and competency evaluation programs. Some of the provisions of OBRA '87 have been modified by OBRA '89; these proposed regulations reflect the modifications.

To implement the OBRA '87 provisions, we would amend Part 431, State Organization and General Administration, to add a new § 431.120, State requirements with respect to nursing facilities. We would require that the State plan provide that the requirements under a new subpart D of part 483 (discussed below) are met. That subpart would contain requirements for States and State agencies concerning nurse aide training and competency evaluation. The State plan must specify the rules and procedures the State follows in carrying out the requirements, including review and approval of State-operated programs and interagency agreements where the State delegates responsibilities to other agencies. We would cite sections 1919 (e)(1) and (e)(2) as the basis of these requirements.

Section 6901(b)(5) of OBRA '89 amended section 1903(a)(2)(B) of the Act to clarify that temporary enhanced funding is available for nurse aide competency evaluation programs and training and competency evaluation programs. We would implement this section in new § 433.15(b)(8) which indicates that Federal financial participation (FFP) for nurse aide competency evaluation programs and training and competency evaluation programs is available in the following amounts: for calendar quarters beginning on or after July 1, 1988 and before July 1, 1990, the lesser of 90 percent or the Federal medical assistance percentage (FMAP) plus 25 percentage points; for calendar quarters beginning after July 1, 1990, 50 percent.

In our February 2, 1989 rule we established a new § 483.75, Level A Requirement: Administration. We require that a facility be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident. Section 483.75(g), contains requirements for training of nurse aides that incorporated the training and competency evaluation requirements added by OBRA '87. (See 54 FR 5349) Nurse aides subject to the training and competency evaluation programs are defined in § 483.75(g)(6) as any individuals providing nursing or nursing-related services to residents in a facility, excluding volunteers who provide such services without pay. We would like to clarify that the definition of a nurse aide at § 483.75(g)(6) includes any person, regardless of job title or gender, who provides nursing or nursing-related services but is not a volunteer or a licensed health professional. For example, this definition could include orderlies and psychiatric technicians, depending on the services they provide to residents in the nursing facility. We noted that the OBRA '87 provisions are essentially self-executing due to their explicit requirements.

Section 6901 of OBRA '89 contains a number of provisions affecting the content of the February 2, 1989 rule. As noted earlier, section 6901(a) establishes that the rule not be effective before October 1, 1990, and we issued a regulation on December 29, 1989 to implement this requirement. Section 6901(b)(1) delays the effective date of sections 1819(b)(5)(A) and 1919(b)(5)(A) of the Act from January 1, 1990 to October 1, 1990. These sections state that a facility must not use any individual working in a facility as a nurse aide for more than 4 months, on a full-time, temporary, per diem, or other basis, unless that individual has completed a training and competency evaluation program or a competency evaluation program approved by the State, and that individual is competent to provide nursing and nursing related services.

Section 6901(b)(4) provides for a delay and a transition in the nurse aide training requirement. Section 6901(b)(1) also modifies sections l819(b)(5)(B) and 1919(b)(5)(B) by delaying from January 1, 1990 to October 1, 1990 the date by which a facility must provide a competency evaluation program approved by the State and preparation necessary for completion of the evaluation for individuals used by the facility as of January 1, 1990 (delayed from July 1, 1989 by OBRA '89). We would revise the effective dates of § 483.75(g) to reflect the statutory changes. We would implement this provision in § 483.150, as discussed below, but would incorporate it by reference in § 483.75(g).

We also would amend Part 483, Requirements for States and Long Term Care Facilities, by redesignating existing subpart D, which concerns intermediate care facilities for the mentally retarded, as subpart I. We would then establish a new Subpart D entitled, Requirements That Must Be Met by States and States Agencies: Nurse Aide Training and Competency Evaluation. The subpart would include requirements that must be met by States in addition to those that must be met by the State Medicaid agency. The subpart includes State review and approval requirements, including curriculum requirements, and provides for a State registry of nurse aides.

Following is an explanation of our proposed requirements.

In new § 483.150, Role of States in nurse aide training, we would propose three exceptions to the requirement that all aides complete a training and competency evaluation program or competency evaluation program approved by the State. Specifically, we would incorporate the requirements of sections 6901(b)(4) (B), (C), and (D) of OBRA '89. Sections 6901(b)(4) (B) and (C) allow an individual to be considered to meet the requirements of sections 1819(b)(5)(A) and 1919(b)(5)(A) of the Act (of completing a training and competency evaluation program approved by the State under sections 1819(e)(1)(A) or 1919(e)(1)(A) of the Act) if—

- The aide would have satisfied the requirement as of July 1, 1989, if a number of hours (not less than 60 hours) were substituted for "75 hours" in

sections 1819(f)(2) and 1919(f)(2) of the Act, respectively, and if the aide had received, before July 1, 1989, at least the difference in the number of hours in the course and 75 hours in supervised practical nurse aide training or in regular in-service nurse aide education; or

• The aide was found competent (whether or not by the State), before July 1, 1989, after the completion of a course of nurse aide training of at least 100 hours duration.

Section 6901(b)(4)(D) of OBRA '89 indicates that a State may waive the requirement for an individual to complete a competency evaluation program approved by the State if that individual can prove to the satisfaction of the State that he or she has served as a nurse aide at one or more facilities of the same employer in the State for at least 24 consecutive months before December 19, 1989.

New § 483.151, State review and approval of nurse aide training and competency evaluation programs, contains requirements for: State review and administration; approval of programs not offered by the State; timely action on requests for approval; length of the approval period; and withdrawal of approval. In § 483.151(a), we propose to require that the State do either or both of the following:

• Offer a nurse aide training and competency evaluation program that meets the requirements of new § 483.152 (discussed below) and/or a competency evaluation program that meets the requirements of new § 483.154 (discussed below); or

• Specify nurse aide training and competency evaluation programs not offered by the State that the State approves as meeting the requirements of § 483.152 and/or competency evaluation programs not offered by the State that the State approves as meeting the requirements of § 483.154.

These requirements are necessary to implement sections 1819(e)(1) and 1919(e)(1) of the Act, which require States to specify nurse aide training and competency evaluation programs and competency evaluation programs that comply with requirements established by the Secretary. We would specify that a State may offer a nurse aide training and competency evaluation program or a competency evaluation program, or both, to clarify that the State may choose either option to meet the statutory requirement that it specify programs it approves as meeting the standards.

Under our proposal a State may subcontract or delegate the operation of a program it offers, but the State would be required to review and approve programs against the requirements of these regulations and to determine if the requirements were met before approving a program or programs. The State may not delegate or subcontract the approval of nurse aide training and competency evaluation programs or nurse aide competency evaluation programs to an entity outside of the State government. A delegation or subcontract would be contrary to the requirement of sections 1819(e)(1) and 1919(e)(1), which require that these determinations be made by the State.

We propose that, if the State does not choose to offer one or both of the programs specified in this section, the State survey agency or another State government entity must review and approve or disapprove nurse aide training and competency evaluation programs and nurse aide competency evaluation programs when requested to do so by a Medicare participating skilled nursing facility or a Medicaid participating nursing facility. Sections 1819(b)(5) and 1919(b)(5) of the Act require a facility to use only nurse aides who have successfully completed a State approved nurse aide training and competency evaluation program or a State approved competency evaluation program. Since the facility is restricted to using nurse aides who have successfully completed a State approved program, the facility should be able to request the State to provide a judgment on a program about which the facility has a question if the State chooses to approve non-State nurse aide competency evaluation programs and training and competency evaluation programs.

We propose that the State survey agency, in the course of all surveys, determine whether the nurse aide training and competency evaluation requirements of § 483.75(g) are met. (We note that the effective date for § 483.75(g) has been delayed until October 1, 1990 by section 6901(a) of OBRA '89. We expect that our final revision of § 483.151(a)(4) would not be effective until that date.) Specifically, the State would be required, in the course of all surveys, to determine whether the facility used only nurse aides who had successfully completed a nurse aide competency evaluation program or a training and competency evaluation program approved by the State under this paragraph.

In § 483.151(b), we propose to require that before a State approves a nurse aide training and competency evaluation program or a nurse aide competency evaluation program, the State must—

• Make at least one onsite visit to the entity providing the training or performing the competency evaluation;

• Determine whether the nurse aide training and competency evaluation program meets the course requirements of § 483.152 for nurse aide training and competency evaluation programs;

• Determine whether the nurse aide competency evaluation program meets the requirements of § 483.154 for nurse aide competency evaluation programs; and

• Not approve a nurse aide training and competency evaluation program performed by a skilled nursing facility or nursing facility that has been out of compliance with any requirement for participation within any of the 24 consecutive months prior to the State's review of the facility based program.

We believe the State must make at least one onsite visit to the entity offering the training if it is to ensure that the program being offered meets its written description and that facilities exist for the skills demonstration portion of the training and competency evaluation.

Our proposal that the State not be permitted to approve a program offered by a facility that has been out of compliance with any requirement for participation within the previous 24 consecutive months is derived from sections 1819(f)(2)(B)(iii)(I) and 1919(f)(2)(B)(iii)(I) of the Act, which impose that prohibition.

In § 483.151(c), we would require that the State respond to the requestor with either a notice of the action taken on the request or a request for additional information within 90 days of the date of the facility's request for review and approval of a nurse aide training and competency evaluation program or competency evaluation program or within 90 days of the receipt of additional information requested by the State. We believe that 90 days is a reasonable period within which the State should be expected to act on a facility's request. However, we would welcome public comment on the reasonableness of this time period.

In § 483.151(d), we would specify that the State may not grant approval of a program for a period longer than 2 years. Sections 1819(f)(2)(A)(iii) and 1919(f)(2)(A)(iii) of the Act require that the regulations specify the frequency and methodology for a State's review of the nurse aide training and competency evaluation program and nurse aide competency evaluation programs it approves. Because these entities may

have no other governmental oversight, we believe review at least every 2 years to determine if they can be reapproved is reasonable. We welcome comments on the frequency of these reviews.

In § 483.151(e), we address the State requirements for withdrawing approval of a nurse aide training and competency evaluation program or competency evaluation program. We are proposing that the State must withdraw approval of a facility-based nurse aide training and competency evaluation program when it makes a determination that the facility is out of compliance with a requirement for participation, as specified in part 483, subpart B as a skilled nursing facility or as a nursing facility. (We note that the effective date for subpart B of part 483 has been delayed until October 1, 1990 by section 6901(a) of OBRA '89. We expect that our final revision of § 483.151(e)(1) would not be effective until that date.) As we indicated earlier, we are prohibited by sections 1819(f)(2)(B)(iii)(I) and 1919(f)(2)(B)(iii)(I) of the Act from permitting a State to approve a nurse aide training and competency evaluation program that is performed by a facility that is out of compliance with a requirement for participation. Thus, we would require that a State withdraw its approval from a program when it becomes aware that the program would no longer meet the requirements for approval.

In this section we also propose that the State may withdraw approval of a nurse aide training and competency evaluation program or a nurse aide competency evaluation program if the State determines that the programs fail to meet any one of the applicable requirements of §§ 483.152 or 483.154. We do not believe that it is appropriate for a program to continue operating if the State knows it has ceased to comply with the requirements for approval.

We propose to require that the State withdraw approval of a nurse aide training and competency evaluation program or nurse aide competency evaluation program if the entity providing the program does not agree to permit unannounced visits by the State to review the program. We believe that unannounced visits to review and assess programs as they operate would enable States to ensure that the requirements for approval are met. It has been our policy to make unannounced visits to nursing homes to verify ongoing compliance with certification requirements, and this policy has a proven record of allowing accurate assessments.

In § 483.152 we propose to specify the requirements that must be met by a nurse aide training and competency evaluation program that is offered by or approved by a State. To be approved, a nurse aide training and competency evaluation program must meet the course structure, format, content, and fee requirements discussed below. Exceptions are also provided to reflect requirements added by section 6901(b)(3)(D) of OBRA '89.

In § 483.152(a), as specifically required by sections 1819(f)(2)(A)(i) and 1919(f)(2)(A)(i) of the Act, we require a training and competency evaluation program to consist of at least 75 hours of initial training and to contain as a minimum the subjects specified in § 483.152(b).

We would require that the nurse aide training and competency evaluation program provide for at least 16 hours of supervised practical training, which we propose to define as training in a clinical setting in which the trainee demonstrates knowledge while performing tasks on an individual under the direct supervision of a registered nurse (RN) or a licensed practical nurse (LPN). This requirement can only be met by hands-on training directly supervised by an individual qualified to perform the tasks as discussed below. We believe that at least 16 hours of training is essential for an individual to learn the range of techniques necessary to care for a resident properly, and we encourage comment on the suitability of this time frame. Although we would require that the program contain at least 16 hours of such training to be approved, States would be able to require more than 16 hours of training if they choose to do so.

As noted above, we propose to require that nurse aide training and competency evaluation programs meet specified requirements for qualified personnel. We propose in § 483.152(a)(4)(i) and (ii) that the training of nurse aides be performed by or under the general supervision of an RN who has a minimum of 2 years of nursing experience, at least 1 year of which must be in the provision of long term care services. We believe that this level of education and experience is necessary to ensure that the training and competency evaluation program meets its objectives of providing the education and knowledge needed for individuals to function competently as nurse aides in nursing facilities.

In a nursing facility based program, the training of nurse aides may be performed by or under the supervision of the director of nursing for the facility. We recognize that in facility-based programs the director of nursing may be the most competent person to manage the training and competency evaluation program and that there is no reason that he or she should not be permitted to supervise the program.

We would permit other personnel from the health professions and other related fields to be used to supplement the instructor. These individuals may include, but are not limited to registered nurses, licensed practical/vocational nurses, pharmacists, dieticians, social workers, sanitarians, fire safety experts, nursing home administrators, gerontologists, psychologists, physical and occupational therapists, activities specialists, speech, language/hearing therapists, and resident rights experts. We believe that individuals from these varied fields can make significant contributions to the education of nurse aides. Nurse aides have the most significant impact on the quality of life of residents of nursing facilities and therefore need a broad range of knowledge beyond the ability to perform specific tasks properly. We believe that instruction supplemental to nursing instruction would be beneficial to them.

We are considering whether to permit an LPN with long term care experience to conduct or supervise the training of nurse aides in a facility-based program, while requiring that an RN with long term care facility experience conduct or supervise the training in a non facility-based program. Although this provision is not contained in these proposed regulations, it was in the State Operations Manual instructions issued to State survey agencies and HCFA regional offices in April 1989, and it has generated many comments. Commenters objected to the restrictions, pointing out that an LPN is as capable of running a non facility-based program as of running a facility-based program. Therefore, we are soliciting public comments on the question of whether an LPN may conduct or supervise the training in facility-based and/or non facility-based programs.

We propose in § 483.152(a)(5) to require that a nurse aide training and competency evaluation program contain competency evaluation procedures that are specified in § 483.154. We believe that it is appropriate for the competency evaluation requirements that must be met for a nurse aide competency evaluation program to be approved by the State also to be required for a nurse aide training and competency evaluation program to be approved by the State.

In § 483.152(b), we propose the minimum curriculum that the nurse aide training and competency evaluation program must meet to be approved by

the State. The minimum curriculum is an expansion upon the minimum content requirement of sections 1819(f)(2)(A)(i) and 1919(f)(2)(A)(i) of the Act. In developing our proposed minimum curriculum, we considered the content requirements of pre-existing nurse aide training programs such as the Job Corps program curriculum of the Department of Labor and the curriculum of the American Red Cross, and we are interested in commenters' views of the curriculum.

To be approved by the State, we would require that the curriculum of the nurse aide training program include at least the following subjects:

• At least 16 hours of training in the following areas prior to any direct contact with a resident:

—Communication and interpersonal skills;
—Infection control;
—Safety/emergency procedures;
—Promoting residents' independence; and
—Respecting residents' rights.

The remainder of the 75 hours of training must include:

• Basic nursing skills:

—Taking and recording vital signs;
—Measuring and recording height and weight;
—Caring for the residents' environment;
—Recognizing abnormal signs and symptoms of common diseases and conditions; and
—Caring for residents when death is imminent.

• Personal care skills, including, but not limited to:

—Bathing;
—Grooming, including mouth care;
—Dressing;
—Toileting;
—Assisting with eating and hydration;
—Proper feeding techniques;
—Skin care; and
—Transfers, positioning, and turning.

• Mental health and social service needs.

—Modifying aide's behavior in response to residents' behavior;
—Identifying developmental tasks associated with the aging process;
—Behavior management by reinforcing appropriate behavior and reducing or eliminating inappropriate behavior;
—Allowing the resident to make personal choices, providing and reinforcing other behavior consistent with the resident's dignity; and
—Using the resident's family as a source of emotional support.

• Care of cognitively impaired residents

—Techniques for addressing the unique needs and behaviors of individuals with dementia (Alzheimer's and others);
—Communicating with cognitively impaired residents;
—Understanding the behavior of cognitively impaired residents;
—Appropriate responses to the behavior of cognitively impaired residents; and
—Methods of reducing the effects of cognitive impairments.

• Basic restorative services.

—Training the resident in self care according to the resident's abilities;
—Use of assistive devices in transferring, ambulation, eating, and dressing;
—Maintenance of range of motion;
—Proper turning and positioning in bed and chair;
—Bowel and bladder training; and
—Care and use of prosthetic and orthotic devices.

• Residents' Rights

—Providing privacy and maintenance of confidentiality;
—Promoting the residents' right to make personal choices to accommodate their needs;
—Giving assistance in resolving grievances and disputes;
—Providing needed assistance in getting to and participating in resident and family groups and other activities;
—Maintaining care and security of residents' personal possessions;
—Providing care which maintains the resident free from abuse, mistreatment, and neglect, and the need to report any such instance to appropriate facility staff; and
—Maintaining the resident's environment and care to avoid the need for restraints.

We propose to require that each of these subject areas be covered because we believe that they are necessary to ensure the health and safety of residents, since most of the care that is provided to residents of skilled nursing facilities and nursing facilities is provided by nurse aides. They are essentially the same as the guidelines specified in the State Operations Manual at section 4121, which we issued in April 1989.

We considered whether or not to require, under course content requirements in § 483.152(b)(1)(iii), that safety and emergency procedures include cardio-pulmonary resuscitation (CPR). In the guidance we provided to States in the Medicare State Operations Manual (rev. 223, April 1989) and the Medicaid State Manual (rev. 62, April 1989), we did include CPR in the minimum curriculum, and since then, we have received numerous objections from nurses, aides, and facilities. Their objections focused on the cost of such a requirement and the advisability of devoting so many hours of training to a seldom used skill. The manual instructions were intended as guidance to States, and in the absence of Federal regulations, such items as CPR that are not specifically identified in sections 1819(f)(2) and 1919(f)(2) of the Act are not required to be included in a training program in order for the State to approve it.

In these proposed regulations, we are not specifically requiring that CPR be included in nurse aide training of safety and emergency procedures, but we are interested in receiving further public comment on this issue.

In § 483.152(c), we propose that no nurse aide may be charged for any portion of a nurse aide training and competency evaluation program including any fees for textbooks or other required course materials. This provision is mandated by section 6901(b)(3)(D) of OBRA '89.

We propose to include at § 483.154 the requirements for nurse aide competency evaluation programs to be offered or approved by the State. In this section, we would address the content of the competency evaluation program, administration of the competency evaluation, nursing facility proctoring of the competency evaluation, and actions that follow both successful and unsuccessful completion of the program.

We would require that the State inform any individual who takes the competency evaluation in advance that a record of the successful completion of the evaluation will be included in the State's nurse aide registry established under § 483.156. We propose to include this requirement because we believe that the individual should be advised that successful completion of the program will result in his or her name being entered in a State registry.

In § 483.154(b), we propose that the competency evaluation must—

• Allow an aide, at his or her option, to establish competency through methods other than passing a written examination;

• Address each course requirement specified in § 483.152(b) (the minimum curriculum requirements for nurse aide training and competency evaluation programs);

• Be developed from a pool of test questions, only a portion of which is used in any one examination; and

• Use a system that maintains the integrity of both the pool of questions and the individual examinations.

We are proposing, as required by section 6901(b)(3)(D) of OBRA '89, that

the competency evaluation must allow an aide, at his or her option, to establish competency through methods other than passing a written examination.

We would require that the competency evaluation address each topic in § 483.152(b), the minimum curriculum for nurse aide training and competency evaluation programs to be approved by the State. We chose to make the areas of evaluation identical to the minimum areas for training because the Act specifies identical areas for training and competency evaluation programs in sections 1819(f)(2)(A)(i) and 1919(f)(2)(A)(i) and for competency evaluation programs in sections 1819(f)(2)(A)(ii) and 1919(f)(2)(A)(ii) of the Act.

The examination must be developed from a pool of test questions, only a portion of which is to be used in any one examination. Also, the examination must use a system that prevents disclosure of both the pool of questions and the individual examinations. We are proposing these requirements because we believe that they are necessary to preserve the integrity of the examinations. Preservation of the integrity of the examinations is necessary to ensure that the individuals who are found competent on the basis of test results to function as nurse aides have been accurately evaluated in all areas of concern.

In § 483.154(b)(2), we propose to require that the competency evaluation include a demonstration of the tasks that the individual will be expected to perform as part of his or her function as a nurse aide. We believe that a demonstration of skills is essential to any determination of whether an individual is competent to function as a nurse aide since the proper performance of these tasks has such a great bearing on the health and welfare of the resident. The demonstration would have to include any task that the individual would be permitted to perform as a nurse aide.

In § 483.154(c), we propose requirements that govern the administration of the competency evaluation. Specifically, we propose to require that the competency evaluation be administered and evaluated only by the State directly or by a State approved entity which is neither a skilled nursing facility that participates in Medicare nor a nursing facility that participates in Medicaid. The State maintains responsibility for assuring that individuals meet the competency evaluation requirements. This restriction on who may perform competency evaluation programs is based upon sections 1819(f)(2)(B)(iii)(II) and 1919(f)(2)(B)(iii)(II) of the Act, which require that the regulations prohibit States from delegating the State responsibility for competency evaluations to facilities. We also propose that no charges for the competency evaluation may be imposed on any nurse aide. This implements section 6901(b)(3)(D) of OBRA '89.

We would require that the skills demonstration part of the evaluation be performed in a facility or laboratory setting comparable to the setting in which the individual will function as a nurse aide and that the skills demonstration part be administered and evaluated by a registered nurse with at least one year's experience in providing care of the elderly or the chronically ill of any age. We believe that observation of an individual in a facility-like setting by a registered nurse who is experienced in the care of the nursing home population is necessary to determine if an individual is competent to provide care to residents. The tasks that will be evaluated are essential to the health and welfare of the residents, who have physical and medical problems that require proper care to prevent deterioration in their health status or to enable them to achieve the most improvement possible. We believe that requiring a registered nurse with this level and type of experience increases the likelihood that aides will be able to provide care that approaches these goals.

In § 483.154(d), we address State authority to permit nursing facility proctoring of competency evaluation. We propose that nurse aides may be permitted to have the competency evaluation performed at the facility in which they are or will be employed unless the facility is out of compliance with any of the requirements of participation within any of the 24 months prior to the evaluation. This is required by section 6901(b)(3)(D) of OBRA '89. We would authorize the State to permit the examination to be proctored by facility personnel if the State finds that the procedure adopted by the facility ensures that the competency evaluation program is secure from tampering; is standardized and scored by a testing, educational, or other organization approved by the State; and requires no scoring by the facility personnel. We believe that a properly secured standardized examination could be administered by the facility without conflict and that proctoring presents a practical and efficient way of performing competency evaluations for many individuals.

We are considering whether to allow facility personnel to read objective or multiple choice questions to an aide as part of an oral examination. We request public comment on this potential requirement.

We propose that the State must not permit facility personnel to proctor the skills demonstration portion of the evaluation. We considered allowing proctoring of the skills demonstration, but were unable to think of a method for documenting individual performance without a subjective determination by the facility. We welcome public comment on this requirement.

We would require the State to retract the right to proctor nurse aide competency evaluations from facilities in which the State finds any evidence of impropriety, including evidence of tampering by facility staff. Clearly, in such circumstances, the facility's proctoring of the competency evaluation can no longer be trusted as a valid representation of an individual's competency to function as a nurse aide.

In § 483.154(e), we propose requirements regarding what can be considered successful completion of the competency evaluation program. The State must establish the overall standard for satisfactory completion of its approved competency evaluation program. However, we require that at a minimum, the State must require the individual to complete successfully all of the personal care skills specified in § 483.152(b)(3) and any others they would be permitted to perform in the facility. We propose this minimum standard for satisfactory completion of a competency evaluation program because we believe that the personal care skills identified in that section are the most important aspect of competency to be evaluated since improper performance of any one of them could result in deterioration of a resident's health status. Of course, the State would be able to add more skills that the individual would have to demonstrate properly and would also be able to add other minimal requirements.

We would require that a record of successful completion of the competency evaluation be included in the nurse aide registry established under § 483.156 within 30 days of the date the individual is found to be competent. We are imposing a time frame upon States because we believe that a time frame is necessary to prevent unreasonable delays in the inclusion of the data in the registry. We propose the 30 day time frame because we believe that it is a reasonable standard.

In § 483.154(f), we propose that if the individual fails to complete the examination satisfactorily, he or she

must be advised of the areas of inadequacy and that he or she has at least 3 opportunities to take the evaluation. The State may impose a maximum (but no less than 3) upon the number of times an individual may attempt to complete the competency evaluation successfully. We are proposing these requirements to ensure that individuals who want to function as nurse aides will have a reasonable opportunity to complete the competency evaluation program successfully. We do not want the competency evaluation process required by the statute to have the undesirable effect of reducing the numbers of persons who will choose to work as nurse aides. By advising individuals who have not successfully completed the competency evaluation program of the areas of weakness and that they have several attempts to complete it successfully, we hope that they will be able to complete it successfully on a subsequent attempt. We have proposed that States permit prospective aides to take the test a minimum of three times. However, we wish to balance the interests of aides with the interest of the States that operate the testing programs. Therefore, we are especially interested in comments on the issue of how many times a retest must be permitted.

Although not addressed in the proposed rule, we wish to solicit public comments on the question of whether private duty nurse aides (also called "sitters") who are hired by residents or their families to provide care to residents of nursing facilities should be required to complete a State approved nurse aide training and competency evaluation program or a State approved competency evaluation program (or meet the OBRA '89 requirements for waiver of that requirement) and be placed on the registry as a condition of being used to provide care in participating skilled nursing facilities and nursing facilities. Under sections 1819(b)(5)(F) and 1919(b)(5)(F), nurse aides (or "sitters") who provide nurse aide services on a voluntary basis without monetary compensation are not required to complete a nurse aide training and competency evaluation program or competency evaluation program.

Specifically, we believe that the law does not necessarily preclude our taking either of the two following positions on the issue:

• We could revise the requirements for participation for skilled nursing facilities and nursing facilities to require that facilities only permit private duty nurse aides to provide care to residents in the facility if they have successfully completed a State approved nurse aide training and competency evaluation program or a State approved competency evaluation program (or meet the OBRA '89 requirements for waiver of that requirement) and have been added to the registry. Sections 1819(b)(5)(C) and 1919(b)(5)(C) of the Act would support this requirement because these sections require that a facility "* * * must not permit an individual other than in a training and competency evaluation program approved by the State, to serve as a nurse aide * * *" Moreover, the definition of a "nurse aide" at sections 1819(b)(5)(F) and 1919(b)(5)(F) of the Act defines a "nurse aide" as meaning "* * * any individual providing nursing or nursing-related services to residents * * *." Hence, these sections could be read together to prohibit a facility from permitting an individual who has not successfully completed a nurse aide training and competency evaluation program or a competency evaluation program to provide services in the facility unless he or she is a volunteer.

• Alternatively, sections 1819(b)(5)(A) and 1919(b)(5)(A) of the Act state that the facility "* * * must not use * * *" any individual as a nurse aide unless he or she has met the training and competency evaluation or competency evaluation requirements of that section. Since the private duty nurse is neither "used by the facility," nor paid by the facility (either directly or through a contract for services), the law does not appear to require that these private duty aides meet the requirements that a nurse aide used by the facility would have to meet.

Because we believe that we are not necessarily precluded from taking either position, we are requesting public comment and discussion of this issue. We have received a significant number of inquiries from residents, facilities, and States on this issue, and we expect to address it in the final regulation.

Nurse Aide Registry

Sections 1819(e)(2) and 1919(e)(2) of the Act require that States maintain a nurse aide registry that must include individuals who have successfully completed the competency evaluation for nurse aides. We propose to implement this requirement of the Act in § 483.156, which sets forth requirements concerning registry establishment, operation and content. It also sets forth requirements for disclosure of information from the registry to facilities and other interested parties.

In § 483.156(a) we would require that the State establish and maintain a registry of nurse aides that meets the requirements of this section. The registry would be required to include at a minimum the information contained in paragraph (c) of this section, registry content (addressed separately below).

We propose that the registry be accessible to the public and health providers on a fixed schedule set by the State of at least 6 hours per day between the hours of 7:00 a.m. and 6:00 p.m., local time, Monday through Friday, except for State and Federal holidays, and notify facilities in advance of changes in the hours of operation. We believe that this range of service is necessary to meet the needs of providers and the public for information from the registry. Turnover of nurse aides is significant, and we believe that the registry will be required to handle a sufficiently large volume of inquiries that the hours and days of operation are justified. However, we request public comment on this issue.

If the State chooses, the registry may also include home health aides who have successfully completed a home health aide competency evaluation program approved by the State. We are proposing that States may include home health aides in this registry because we recognize that there is often significant movement of nurse aides to home health agencies and vice versa. Should States choose to add home health aides to the registry and to use only home health aides who are on the registry, home health agencies would become aware if applicants had been found to have abused, neglected, or misappropriated property as nurse aides. Moreover, home health agencies could rely upon the registry as proof of completion of a certain level of training and competency for new employees. If a State wishes, it could establish home health aide training and competency evaluation requirements that individuals would need to meet before being placed on the home health aide registry.

We would require the registry to respond timely to written and telephone inquiries that request information from the registry. Facilities will need timely responses to be able to hire staff promptly.

We also propose that when the registry responds to an inquiry and reports that an aide has been found by the State survey and certification agency to have neglected or abused a resident or misappropriated property, the registry must also include any statement made by the nurse aide disputing the finding (as provided under paragraph (a)(5)). The inclusion of the aide's statement is required by sections

1819(e)(2)(B) and 1919(e)(2)(B) of the Act.

In § 483.156(b) we propose that the State may contract the daily operation and maintenance of the registry to a non-State entity. However, the State must maintain accountability for overall operation of the registry and compliance with these regulations. Moreover, we propose to require in this section that only the State survey and certification agency may place on the registry findings of abuse, neglect, or misappropriation of property.

We recognize that a State may determine that the most efficient means of managing a registry of this size would be for the State to subcontract it to a private entity. We also recognize that States may find it efficient to delegate the maintenance and operation of a registry to another entity in the State, for example, the component of the State that maintains the registry of licensed nurses. Should the State delegate or subcontract the registry outside the State government, the State continues to be responsible to the Secretary for compliance with all applicable requirements of these regulations.

We would provide that the only registry related function that cannot be subcontracted to a private entity or delegated to another entity of the State is the placement of findings of complaints of abuse, neglect, or misappropriation of property on the registry. The State survey and certification agency must, but other agencies may perform these investigations and only that agency of the State can place these findings on the registry. These investigations are performed under the authority of sections 1819(g)(1)(C) and 1919(g)(1)(C) of the Act, which clearly specify that they will be performed "* * * through the agency responsible for surveys and certification of nursing facilities under this subsection * * *." We believe that it is appropriate to make one agency responsible for placing adverse findings on the registry.

In § 483.156(b)(3), we propose to require that the State renew a nurse aide's registration at least once every 2 years on a schedule set by the State. We are proposing this requirement because we believe that permitting longer periods of registration would make it virtually impossible for the State to detect individuals who have not functioned as a nurse aide for compensation for 24 consecutive months. As we indicated above, sections 1819(b)(5)(D) and 1919(b)(5)(D) of the Act preclude such individuals from functioning as nurse aides unless they have successfully completed another training and competency evaluation program. Therefore, if the State becomes aware that an individual who is renewing his or her registration has not functioned as a nurse aide for compensation for 24 consecutive months, or longer, the State must deny registration until he or she successfully completes or demonstrates that he or she completed another training and competency evaluation program.

We propose that the State may charge registration fees from individuals listed in the registry. We recognize that registration fees are commonly charged for registered or licensed individuals outside of the health professions as well as in them (e.g. licensed nurses, barbers, steam engineers), and we have no authority to prohibit States from charging registration fees to nurse aides. We acknowledge that section 6901(b)(3)(D) prohibits charging nurse aides for training and competency evaluation programs. However, registration is not a part of those programs. Therefore, registration fees may be charged.

Proposed § 483.156(c) would contain the minimum content of the registry. We would require that the State include the individual's full name, maiden name and any other surnames used, last known home address, and date of birth. Maiden names and previously used surnames and birth dates would enable the registry to differentiate more easily between individuals with the same names. The address is necessary so that the State can mail the notice of reregistration to the individual when reregistration is appropriate. We are requiring the individual's last employer, date of hiring, and data of termination because we believe it is impossible for States to determine if an individual has not worked as a nurse aide for 24 consecutive months without this information.

We would require that the State include the date that the individual passed the competency evaluation and the date of the expiration of the individual's current registration. The date of successful completion is necessary evidence of completion, and it may be useful to a facility that is deciding whether to hire an individual. We also believe that the date of the expiration of the current registration is necessary so that the State can send the reregistration application timely. In addition, the State would be required to include the individual's last known employer and the date of hiring by that employer. This information is essential to ensure that the nurse aide has not had 24 consecutive months during which he or she has not functioned as a nurse aide. We believe that this information is necessary to be able to determine if the individual's registration would have to be revoked, pending successful completion of another training and competency evaluation.

We would require that the State assign a registration number to an individual when he or she successfully completes the competency evaluation program or is determined exempt from that requirement based on section 6901 of OBRA '89. We also propose that the registration number must include a modifier which indicates the type of registration. We propose to require the use of a registration number as a means of ensuring that the individual is qualified to function as a nurse aide and as a means of safeguarding the registry from misuse.

We would also require that a State include the name and address of the entity that administered the competency evaluation and any control or identification number if the State chooses to assign such a number. This information is necessary to ensure that the competency evaluation, if not performed by the State, was performed by an entity that was approved by the State, or was waived. Moreover, the information may be useful to facilities who are deciding whether to employ an individual. We are not requiring that the State assign control or identification numbers to entities that it has approved to perform competency evaluations. However, if the State chooses to do so, the number should be part of the identification in the registry.

In accordance with sections 1819(e)(2)(B) and 1919(e)(2)(B) of the Act, we also propose to require in § 483.156(c)(1)(ix) that the State include the following information on any finding by the State of abuse, neglect, or misappropriation of property by an individual nurse aide:

- Documentation of the State's investigation, including the nature of the allegation and the evidence that led the State to conclude that the allegation was valid;
- The date of the hearing, if the individual chose to have one, and its outcome; and
- A statement by the individual disputing the allegation, if he or she chooses to make one.

Although not explicitly stated in the regulation, we would expect States to determine if adverse findings from other States exist before adding an individual to the registry. We welcome, public comment on this issue.

In § 483.156(c)(2), we propose that the State may exclude registry entries for

individuals whose registrations have been expired for 24 months or for individuals who have ceased to function as nurse aides for compensation for a period of 24 consecutive months when the individual ceases to be qualified to function as a nurse aide, unless the individual's registry entry includes documented findings of abuse, neglect, or misappropriation of property as specified in paragraph (c)(1)(ix) of this section. We recognize the need to keep the registry to a manageable size by deleting the entries for individuals who no longer qualify as nurse aides. However, we also believe that entries should be retained for individuals who have been found by the State survey and certification agency to have abused or neglected residents or to have misappropriated property since these individuals may otherwise let their registrations lapse and register at a later time to clear their records. we would require that adverse findings by the State survey agency be retained on the registry for at least 5 years. We recognize that there is a question about whether we should permit findings by the State survey and certification agency to be deleted at some point, and we request public comment on the maximum period we should require for retention of these records.

We propose in § 483.156(d) to address disclosure of the information contained in the registry. Sections 1819(e)(2)(B) and 1919(e)(2)(B) of the Act require that "[T]he State shall make available to the public information in the registry." This requirement was added to the law by section 411(l)(2)(H) of the Medicare Catastrophic Coverage Act (Pub. L. 100–360), effective as if included in the enactment of Pub. L. 100–203. However, there was no explanatory Conference Committee language to explain if the intent of Congress was to require that all information in the registry be disclosed or if the nature of the information to be disclosed to the public can be limited.

We propose in § 483.156(d)(l) to require that the State disclose within 10 working days to any requester whether the name of an individual specified by the requester is included on the registry and, if so, the date of the individual's competency evaluation and the name of the entity that performed the competency evaluation. The State could, at its option, disclose any other information on the registry to any requester. However, the State would not be required by these regulations to disclose any other information to any requester. We propose the time limit of 10 days because we think it is reasonable. We propose this requirement because we believe that the public has a right to know if an individual who represents himself or herself as a registered nurse aide has, in fact, been registered by the State as completing a State approved nurse aide training and competency evaluation program or a State approved competency evaluation program. However, much of the other information contained on the registry (date of birth, home address, maiden name or any other names used, etc.) does not seem to be appropriate for public disclosure. We request public comment on this requirement and on what other information contained in the registry should be required to be disclosed to any requester by the registry.

On the other hand, we would require that the State disclose all information on the registry within 10 working days to certain enumerated health care providers, to the State's long term care ombudsman, and to an official agency determined by the State as having a need to know. We believe these entities, which have the greatest need to know all of the information on the registry, should have it available to them.

We also would require that the State provide the nurse aide with a copy of all information contained in the registry on him or her within 30 days of the date the individual's name is placed on the registry. The State must also provide the nurse aide with a copy of all information on him or her contained in the registry within 30 days of the change or addition of any information to the registry. The nurse aide must be permitted at least 30 days within which to correct any misstatements or inaccuracies contained in the information maintained on them by the registry. We are proposing these requirements because we believe that since the livelihood of a nurse aide now depends, in part, on the registry entry to be maintained by the State, the nurse aide must be provided with a copy of the information initially and whenever it is changed, and must be provided a reasonable period of time to correct any errors in it. We recognize that this imposes a burden upon the States, but because the registry information is now a key factor in whether an individual can be hired or can continue to function as a nurse aide, it is important that the safeguards be in place to assure that the information in the registry is correct.

Section 1903(a)(2)(B) of the Act establishes that nurse aide training and competency evaluation are State administrative costs. New § 483.158 would implement this section of the statute. It also would clarify that FFP is only available for nurse aides who are employed by a facility or who have a commitment to be employed by a facility. We are proposing this requirement because we do not believe that there is any indication that Medicaid should pay for competency evaluation programs and training and competency evaluation programs for persons unassociated with a nursing facility.

III. Revisions to the Regulations

We propose to make the following revisions to the regulations in title 42:

1. In part 431, we would add new § 431.120, which specifies State Medicaid agency responsibilities with respect to statutory requirements in sections 4201(a) and 4211(a) of OBRA '87.

2. In part 433, § 433.15, we would specify the FFP rates for administration associated with nurse aide training and competency evaluation programs and competency evaluation programs specified in OBRA '89.

3. In part 483, subpart B, we would revise § 483.75(g) to reflect statutory implementation dates and other ways nurse aide competency can be established, as required by OBRA '89.

4. In part 483, we would redesignate existing subpart D as subpart I, and add a new subpart D containing §§ 483.150 through 483.158, which specify State requirements with respect to nurse aide training and competency evaluation and establishing a nurse aide registry.

IV. Response to Comments

Because of the large number of items of correspondence we normally receive on a proposed rule, we are not able to acknowledge or respond to them individually. However, in preparing the final rule, we will consider all comments that we receive by the date and time specified in the "DATES" section of this preamble, and we will respond to the comments in the preamble of that rule.

V. Regulatory Impact Statement

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

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

enterprises to compete with foreign-based enterprises in domestic or export markets.

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

In addition, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis for any final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital which is located outside a metropolitan statistical area and has fewer than 50 beds.

These proposed changes primarily would conform the regulation to the legislative provisions of sections 4201(a) (for Medicare) and 4211(a) (for Medicaid) of OBRA '87 and section 6901(b)(5) of OBRA '89. The provision requiring States to use an exam to qualify nurses aides for competency could be considered discretionary and may cause some States to incur additional costs.

We expect that a State survey agency or a State approved entity would encounter some incremental costs associated with the development and issuance of an exam. These costs may fall upon either the State or outside entities, depending on each State's decision. However, we believe that these initial costs are likely to produce long-term benefits that cannot be estimated. For example, we expect improvement in the quality of health care in SNFs and NFs as a result of better qualified nurses aides.

Although we believe that this discretionary provision would result in incremental costs, we believe that the costs would be insignificant when compared to the resulting increased quality of care. In that this discussion of costs is not conclusive, we encourage comments and any applicable data concerning this discretionary provision if there is a perception that it may result in significant increased costs.

For these reasons, we have determined that the threshold criteria of E.O. 12291 would not be met, and a regulatory impact analysis is not required. Further, we have determined, and the Secretary certifies, that these proposed regulations would not have a significant economic impact on a substantial number of small entities and would not have a significant impact on the operations of a substantial number of small rural hospitals.

VI. Information Collection Requirements

Ordinarily, we would be required to estimate the public reporting burden for information collection requirements for these regulations in accordance with Chapter 35 of Title 44, United States Code. However, sections 4204(b) and 4214(d) of OBRA '87 provide for a waiver of Paperwork Reduction Act requirements for these regulations.

List of Subjects

42 CFR Part 431

Grant programs—health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 433

Administrative practice and procedure, Child support, Claims, Grant programs—health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 483

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

Chapter IV of title 42 would be amended as set forth below:

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

A. Part 431 is amended as follows:

1. The authority citation for part 431 continues to read as follows:

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

2. A new § 431.120 is added to subpart C to read as follows:

§ 431.120 State requirements with respect to nursing facilities.

(a) *State plan requirements.* A State plan must—

(1) Provide that the requirements of subpart D of part 483 of this chapter are met; and

(2) Specify the procedures and rules that the State follows in carrying out the specified requirements, including review and approval of State-operated programs.

(b) *Basis and scope of requirements.* The requirements set forth in part 483 of this chapter pertain to the following aspects of nursing facility services and are required by the indicated sections of the Act.

(1) Nurse aide training and competency programs, and evaluation of nurse aide competency (1919(e)(1) of the Act).

(2) Nurse aide registry (1919(e)(2) of the Act).

PART 433—STATE FISCAL ADMINISTRATION

B. Part 433 is amended as follows:

1. The authority citation for part 433 is revised to read as follows:

Authority: Secs. 1102, 1137, 1902(a)(4), 1902(a)(25), 1902(a)(45), 1903(a)(3), 1903(d)(2), 1903(d)(5), 1903(o), 1903(p), 1903(r), 1912 and 1919(e) of the Social Security Act; 42 U.S.C. 1302, 1320b–7, 1396a(a)(4), 1396a(a)(25), 1396a(a)(45), 1396b(a)(3),1396b(d)(2), 1396b(d)(5), 1396b(o), 1396b(p), 1396b(r) and 1396k, unless otherwise noted.

2. Section 433.15 is amended by adding a new paragraph (b)(8) to read as follows:

§ 433.15 Rates of FFP for administration.

* * * * *

(b) * * *

(8) Nurse aide training and competency evaluation programs and competency evaluation programs described in 1919(e)(1) of the Act: for calendar quarters beginning on or after 7/1/88 and before 7/1/90: the lesser of 90% or the Federal medical assistance percentage plus 25 percentage points; for calendar quarters beginning after 7/1/90: 50%. (Section 1903(a)(2)(B) of the Act).

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

C. Part 483 is amended as follows:

1. The heading of part 483 is revised to read as set forth above.

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

Authority: Secs. 1102, 1819(a)–(f),1905(c) and (d), and 1919(a)–(f) of the Social Security Act (42 U.S.C. 1302, 1395i(3)(a)–(f), 1396d(c) and (d), and 1396r(a)–(f)).

2. The table of contents for part 483 is amended by redesignating existing subpart D, Conditions of Participation for Intermediate Care Facilities for the Mentally Retarded, as subpart I, and adding a new subpart D containing §§ 483.150 through 483.156 to read as follows:

Sec.
* * * * *

Subpart D—Requirements That Must Be Met by States and State Agencies: Nurse Aide Training and Competency Evaluation

Sec.
Sec. 483.150 Deemed meeting of requirements, waiver of requirements.
Sec. 483.151 State review and approval of nurse aide training and competency evaluation programs.
Sec. 483.152 Requirements for approval of a nurse aide training and competency evaluation program.
Sec. 483.154 Nurse aide competency evaluation.
Sec. 483.156 Registry of nurse aides.
Sec. 483.158 FFP for nurse aide training and competency evaluation.
* * * * *

Subpart B—Requirements for Long Term Care Facilities

3. In subpart B, the undesignated text of § 483.75 is reprinted and paragraph (g) is revised as follows:

§ 483.75 Level A requirement: Administration.

A facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.
* * * * *

(g) *Level B requirement: Required training of nurse aides*—(1) *General rule.* Effective October 1, 1990, a facility must not use any individual working in the facility as a nurse aide for more than 4 months, on a full-time, temporary, per diem, or other basis, unless:

(i) That individual is competent to provide nursing and nursing related services; and

(ii) That individual has completed a training and competency evaluation program, or a competency evaluation program approved by the State as meeting the requirements of §§ 483.151–483.154 of this part; or

(iii) That individual has been deemed competent as provided in § 83.150 (a) and (b).

(2) *Competency evaluation programs for current employees.* Effective January 1, 1990, a facility must provide, for individuals used as nurse aides, a competency evaluation program approved by the State, and preparation necessary for the individual to complete the program by October 1, 1990.

(3) *Competency.* Effective October 1, 1990, a facility must permit an individual to serve as a nurse aide or provide services of a type for which the individual has not demonstrated competence only when—

(i) The individual is in a training and competency evaluation program or a competency evaluation program approved by the State; and

(ii) The facility has asked and not yet evaluated a reply from the State registry for information concerning the individual.

(4) *Required retraining.* Effective October 1, 1990, when an individual has not performed paid nursing or nursing-related services for a continuous period of 24 consecutive months since the most recent completion of a training and competency evaluation program, the facility must require the individual to complete a new training and competency evaluation program.

(5) *Regular in-service education.* Effective October 1,1990, the facility must provide regular performance review and regular in-service education to ensure that individuals used as nurse aides are competent to perform services as nurse aides. In-service education must include training for individuals providing nursing and nursing-related services to residents with cognitive impairments.

(6) *Definition of nurse aide.* For purposes of this section, the term "nurse aide," means any individual providing nursing or nursing-related services to residents in a facility. This definition does not include an individual who volunteers to provide such services without pay.

3a. Subpart D of part 483 is redesignated as subpart I and a new subpart D (§§ 483.150 through 483.156) is added to read as follows:

Subpart D—Requirements That Must Be Met by States and State Agencies: Nurse Aide Training and Competency Evaluation

§ 483.150 Deemed meeting of requirements, waiver of requirements.

(a) A nurse aide is deemed to satisfy the requirement of completing a training and competency evaluation approved by the State if he or she successfully completed a training and competency evaluation program before July 1, 1989 if—

(1) The aide would have satisfied this requirement if—

(i) At least 60 hours were substituted for 75 hours in sections 1819(f)(2) and 1919(f)(2) of the Act; and

(ii) The individual had made up at least the difference in the number of hours in the program he or she completed and 75 hours in supervised practical nurse aide training or in regular in-service nurse aide education; or

(2) The individual was found to be competent (whether or not by the State) after the completion of nurse aide training of at least 100 hours duration.

(b) A State may waive the requirement for an individual to complete a competency evaluation program approved by the State for any individual who can demonstrate to the satisfaction of the State that he or she has served as a nurse aide at one or more facilities of the same employer in the State for at least 24 consecutive months before December 19, 1989.

§ 483.151 State review and approval of nurse aide training and competency evaluation programs.

(a) *State review and administration.* (1) The State must—

(i) Offer a nurse aide training and competency evaluation program that meets the requirements of § 483.152 and/or a competency evaluation program that meets the requirements of § 483.154; and/or

(ii) Specify any nurse aide training and competency evaluation programs not offered by the State that the State approves as meeting the requirements of § 483.152 and/or competency evaluation programs not offered by the State that the State approves as meeting the requirements of § 483.154.

(2) The State may not delegate or subcontract the approval of these programs to an entity outside of the State government.

(3) If the State does not choose to offer one or both of the programs specified in paragraph (a)(1)(i) of this section, the State survey agency or another State government entity must review and approve or disapprove nurse aide training and competency evaluation programs and nurse aide competency evaluation programs when requested to do so by any Medicare participating skilled nursing facility or Medicaid participating nursing facility.

(4) The State survey agency must, in the course of all surveys, determine whether the nurse aide training and competency evaluation requirements of § 483.75(g) are met.

(b) *Requirements for approval of programs.* (1) Before the State approves a nurse aide training and competency evaluation program or a nurse aide competency evaluation program, the State must, on the basis of at least one onsite visit to the entity providing the training or performing the competency evaluation—

(i) Determine whether the nurse aide training and competency evaluation

program meets the course requirements of §§ 483.152; and

(ii) Determine whether the nurse aide competency evaluation program meets the requirements of § 483.154.

(2) The State may not approve a nurse aide training and competency evaluation program or competency evaluation program conducted by a skilled nursing facility or a nursing facility that has been found out of compliance with any of the requirements for participation in part 483 subpart B within any of the 24 consecutive months prior to the State's review of the facility based program.

(c) *Time for acting on a request for approval.* The State must, within 90 days of the date of a request under paragraph (a)(3) of this section or receipt of additional information from the requester—

(1) Advise the requester of the action taken by the State on the request; or

(2) Request additional information from the requesting entity.

(d) *Duration of approval.* The State may not grant approval for a period longer than 2 years.

(e) *Withdrawal of approval.* (1) The State must withdraw approval of a facility-based nurse aide training and competency evaluation program when it makes a determination that the facility is out of compliance with a requirement for participation, as specified in part 483, subpart B, as a skilled nursing facility or as a nursing facility.

(2) The State may withdraw approval of a nurse aide training and competency evaluation program or nurse aide competency evaluation program if the State determines that any of the applicable requirements of §§ 483.152 or 483.154 are not met by a nurse aide training and competency evaluation program or a nurse aide competency evaluation program.

(3) The State must withdraw approval of a nurse aide training and competency evaluation program or a nurse aide competency evaluation program if the entity providing the program refuses to permit unannounced visits by the State to review the program.

§ 483.152 Requirements for approval of a nurse aide training and competency evaluation program.

(a) For a nurse aide training and competency evaluation program to be approved by the State, it must, at a minimum—

(1) Consist of no less than 75 hours of training;

(2) Include at least the subjects specified in paragraph (b) of this section; and

(3) Include at least 16 hours of supervised practical training. "Supervised practical training" means training in a laboratory or other setting in which the trainee demonstrates knowledge while performing tasks on an individual under the direct supervision of a registered nurse or a licensed practical nurse.

(4) Meet the following requirements for instructors who train nurse aides:

(i) The training of nurse aides must be performed by or under the general supervision of a registered nurse who possesses a minimum of 2 years of nursing experience, at least 1 year of which must be in the provision of long term care facility services;

(ii) In a nursing facility-based program, the training of nurse aides may be performed by or under the general supervision of the director of nursing for the facility; and

(iii) Other personnel from the health professions may supplement the instructor, including, but not limited to, registered nurses, licensed practical/vocational nurses, pharmacists, dieticians, social workers, sanitarians, fire safety experts, nursing home administrators, gerontologists, psychologists, physical and occupational therapists, activities specialists, speech/language/hearing therapists, and resident rights experts; and

(5) Contain competency evaluation procedures specified in § 483.154.

(b) The curriculum of the nurse aide training program must include—

(1) At least a total of 16 hours of training in the following areas prior to any direct contact with a resident:

(i) Communication and interpersonal skills;

(ii) Infection control;

(iii) Safety/emergency procedures;

(iv) Promoting residents' independence; and

(v) Respecting residents' rights.

(2) Basic nursing skills:

(i) Taking and recording vital signs;

(ii) Measuring and recording height and weight;

(iii) Caring for the residents' environment;

(iv) Recognizing abnormal signs and symptoms of common diseases and conditions; and

(v) Caring for residents when death is imminent.

(3) Personal care skills, including, but not limited to—

(i) Bathing;

(ii) Grooming, including mouth care;

(iii) Dressing;

(iv) Toileting;

(v) Assisting with eating and hydration;

(vi) Proper feeding techniques;

(vii) Skin care; and

(viii) Transfers, positioning, and turning.

(4) Mental health and social service needs:

(i) Modifying aide's behavior in response to residents' behavior;

(ii) Identifying developmental tasks associated with the aging process;

(iii) How and when to manage behavior by reinforcing appropriate behavior and reducing or eliminating inappropriate behavior;

(iv) Allowing the resident to make personal choices, providing and reinforcing other behavior consistent with the resident's dignity; and

(v) Using the resident's family as a source of emotional support.

(5) Care of cognitively impaired residents:

(i) Techniques for addressing the unique needs and behaviors of individual with dementia (Alzheimer's and others);

(ii) Communicating with cognitively impaired residents;

(iii) Understanding the behavior of cognitively impaired residents;

(iv) Appropriate responses to the behavior of cognitively impaired residents; and

(v) Methods of reducing the effects of cognitive impairments.

(6) Basic restorative services:

(i) Training the resident in self care according to the resident's abilities;

(ii) Use of assistive devices in transferring, ambulation, eating, and dressing;

(iii) Maintenance of range of motion;

(iv) Proper turning and positioning in bed and chair;

(v) Bowel and bladder training; and

(vi) Care and use of prosthetic and orthotic devices.

(7) Residents' Rights.

(i) Providing privacy and maintenance of confidentiality;

(ii) Promoting the residents' right to make personal choices to accommodate their needs;

(iii) Giving assistance in resolving grievances and disputes;

(iv) Providing needed assistance in getting to and participating in resident and family groups and other activities;

(v) Maintaining care and security of residents' personal possessions;

(vi) Providing care which maintains the resident free from abuse, mistreatment, and neglect and the need to report any instances of such treatment to appropriate facility staff;

(vii) Maintaining the resident's environment and care to avoid the need for restraints.

(c) Prohibition of charges. No nurse aide may be charged for any portion of a nurse aide training and competency evaluation program, including any fees for textbooks or other required course materials.

§ 483.154 Nurse aide competency evaluation.

(a) *Notification to Individual.* The State must advise in advance any individual who takes the competency evaluation that a record of the successful completion of the evaluation will be included in the State's nurse aide registry.

(b) *Content of the competency evaluation program*—(1) *Examination and alternative to examination.* The competency evaluation must—

(i) Allow an aide, at his or her option, to establish competency through methods other than passing a written examination;

(ii) Address each course requirement specified in § 483.152(b);

(iii) Be developed from a pool of test questions, only a portion of which is used in any one examination; and

(iv) Use a system that prevents disclosure of both the pool of questions and the individual competency evaluations.

(2) *Demonstration of skills.* The competency evaluation must include an acceptable demonstration of the tasks the individual will be expected to perform as part of his or her function as a nurse aide.

(c) *Administration of the competency evaluation.* (1) The competency examination must be administered and evaluated only by—

(i) The State directly; or

(ii) A State approved entity which is neither a skilled nursing facility that participates in Medicare nor a nursing facility that participates in Medicaid.

(2) No charges for the competency evaluation may be imposed on any nurse aide.

(3) The skills demonstration part of the evaluation must be—

(i) Performed in a facility or laboratory setting comparable to the setting in which the individual will function as a nurse aide; and

(ii) Administered and evaluated by a registered nurse with at least one year's experience in providing care for the elderly or the chronically ill of any age.

(d) *Nursing facility proctoring of the competency evaluation.* (1) The competency evaluation may be conducted at the nursing facility at which the aide is (or will be) employed unless the facility is out of compliance with any of the requirements for participation within any of the 24 consecutive months prior to the competency evaluation.

(2) The State may permit the examination to be proctored by facility personnel if the State finds that the procedure adopted by the facility assures that the competency evaluation program—

(i) Is secure from tampering;

(ii) Is standardized and scored by a testing, educational, or other organization approved by the State; and

(iii) Requires no scoring by facility personnel.

(3) The State may not permit facility personnel to proctor the skills demonstration portion of the evaluation.

(4) The State must retract the right to proctor nurse aide competency evaluations from facilities in which the State finds any evidence of impropriety, including evidence of tampering by facility staff.

(e) *Successful completion of the competency evaluation program.* (1) The State must establish a standard for satisfactory completion of the competency evaluation. To complete the competency evaluation successfully, the individual must, at a minimum, successfully demonstrate all of the personal care skills specified in § 483.152(b)(3) and any others that he or she would be permitted to perform in the facility.

(2) A record of successful completion of the competency evaluation must be included in the nurse aide registry provided in § 483.156 within 30 days of the date the individual is found to be competent.

(f) *Unsuccessful completion of the competency evaluation program.* (1) If the individual fails to complete the evaluation satisfactorily, the individual must be advised—

(i) Of the areas in which he or she was inadequate; and

(ii) That he or she has at least three opportunities to take the evaluation.

(2) The State may impose a maximum upon the number of times an individual may attempt to complete the competency evaluation successfully, but the maximum may be no less than three.

§ 483.156 Registry of nurse aides.

(a) *Establishment of registry.* The State must establish and maintain a registry of nurse aides that meets the requirement of this section. The registry—

(1) Must include as a minimum the information contained in paragraph (c) of this section;

(2) Must be accessible to the public and health providers on a fixed schedule set by the State at least 6 hours per day between the hours of 7 a.m. and 6 p.m., local time, Monday through Friday, except for State and Federal holidays, and notify facilities in advance of changes in the hours of operation;

(3) May include home health aides who have successfully completed a home health aide competency evaluation program approved by the State;

(4) Must include a process for timely responses to written and telephone inquiries that request information from the registry; and

(5) Must provide that any response to an inquiry that includes a finding of abuse, neglect, or misappropriation of property also include any statement disputing the finding made by the nurse aide, as provided under paragraph (c)(1)(ix) of this section.

(b) *Registry operation.* (1) The State may contract the daily operation and maintenance of the registry to a non-State entity. However, the State must maintain accountability for overall operation of the registry and compliance with these regulations.

(2) Only the State survey and certification agency may place on the registry findings of abuse, neglect, or misappropriation of property.

(3) The State must require renewal and updating of a nurse aide's registration at least once every 2 years on a schedule set by the State.

(4) The State may charge registration fees from individuals listed in the registry.

(c) *Registry Content.* (1) The registry must contain at least the following information on each individual who has successfully completed a nurse aide training and competency evaluation program which meets the requirements of § 483.152 or a competency evaluation which meets the requirements of § 483.154 and has been found by the State to be competent to function as a nurse aide or who may function as a nurse aide because of meeting criteria in § 483.150:

(i) The individual's full name, including a maiden name and any other surnames used;

(ii) The individual's last known home address;

(iii) The registration number assigned by the State to the individual when he or she successfully completes the competency evaluation program. The registration number must include a modifier which indicates the type of registration;

(iv) The individual's date of birth;

(v) The individual's last known employer and the date of hiring and termination by that employer;

(vi) For an individual who qualifies under § 483.150, an explanation of how the individual met the criteria of that section;

(vii) The date that the individual passed the competency evaluation and the date of the expiration of the individual's current registration;

(viii) The name and address of the State approved entity which administered the competency evaluation and any control or identification number if the State chooses to assign such a number; and

(ix) The following information on any finding by the State survey agency of abuse, neglect, or misappropriation of property by the individual must be included in the registry within 30 days of the finding and must remain in the registry for at least 5 years:

(A) Documentation of the State's investigation, including the nature of the allegation and the evidence that led the State to conclude that the allegation was valid;

(B) The date of the hearing, if the individual chose to have one, and its outcome; and

(C) A statement by the individual disputing the allegation, if he or she chooses to make one; and

(2) The registry may exclude entries for individuals whose registrations have been expired for 24 consecutive months or for individuals who have ceased to function as nurse aides for compensation for a period of 24 consecutive months when the individual ceases to be qualified to function as a nurse aide unless the individual's registry entry includes documented findings of abuse, neglect, or misappropriation of patient property.

(d) *Disclosure of information.* (1) The State must disclose to any requester within 10 working days a minimum of whether an individual specified by the requester is included on the registry and, if so, the date of the individual's competency evaluation and the name of the entity that performed the competency evaluation. The State may disclose other information it deems appropriate.

(2) The State must disclose all information contained in the registry within 10 working days to any Medicare or Medicaid participating skilled nursing facility, nursing facility, home health agency, hospital, ombudsman, or any other representative of an official agency with a need to know, upon receipt of a written request for such information, which must include the reason for the request.

(3) The State must provide the nurse aide with a copy of all information contained in the registry on him or her within 30 days of the date the individual is placed on the registry. The State must also provide the nurse aide with a copy of all information contained in the registry on him or her within 30 days of any changes or additions to this information. The nurse aide must be permitted at least 30 days within which to correct any misstatements or inaccuracies contained in the information maintained by the registry on that individual.

§ 483.158 FFP for nurse aid training and competency evaluation.

(a) State expenditures for nurse aide training and competency evaluation programs and competency evaluation programs are administrative costs. They are matched as indicated in § 433.15(b)(8) of this chapter.

(b) FFP is only available for State expenditures associated with training and evaluating of persons employed by a facility or who have a commitment to be employed by a facility.

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

Dated: February 27, 1990.

Gail R. Wilensky,

Administrator, Health Care Financing Administration.

Approved: March 16, 1990.

Louis W. Sullivan,

Secretary.

[FR Doc. 90-6614 Filed 3-20-90; 11:36 am]

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42 CFR Parts 405, 431, and 483

[BPD-661-P]

RIN 0938-AD81

Medicare and Medicaid Programs; Preadmission Screening and Annual Resident Review

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

ACTION: Proposed rule.

SUMMARY: This rule proposes State requirements for preadmission screening and annual review of individuals with mental illness or mental retardation who are applicants to or residents of nursing facilities that are certified for Medicaid. It also proposes an appeals system for persons who may be transferred or discharged from facilities or who wish to dispute a determination made in the preadmission screening and annual review process. These provisions would implement several provisions of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87), Pub. L. 100-203.

DATES: To assure consideration, comments must be submitted to the appropriate address, as provided below, and should be received no later than 5:00 p.m. on May 22, 1990.

ADDRESSES: Mail comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD-661-P, P.O. Box 26676, Baltimore, Maryland 21207.

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

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

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

Due to staffing and resource limitations, we cannot accept facsimile (FAX) copies of comments.

In commenting, please refer to file code BPD-661-P. Comments received timely 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 Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (phone: 202-245-7890).

FOR FURTHER INFORMATION, CONTACT: Julie H. Walton, (301) 966-4622.

SUPPLEMENTARY INFORMATION:

I. Background

General

On February 2, 1989, we published in the **Federal Register** (54 FR 5316) final regulations with a comment period which specified new and revised requirements that long-term care facilities (skilled nursing facilities (SNFs) under Medicare, and SNFs, intermediate care facilities (ICFs), and, effective October 1, 1990, nursing facilities (NFs) under Medicaid)) must meet in order to receive Federal funds for the care of residents who are Medicare beneficiaries or Medicaid recipients. We issued the regulations following a notice of proposed rulemaking (52 FR 38582, October 16, 1987) to refocus the requirements for participation in both programs to actual facility performance in meeting residents' needs in a safe and healthful environment. The previous set of requirements had focused on the capacity of the facility to provide

appropriate care. In addition, we needed to simplify Federal enforcement procedures by using a single set of requirements that apply to all activities common to SNFs, ICFs, and NEs.

Many of the requirements in the February 2 regulations reflected detailed, self-implementing provisions of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) (P.L. 100–203), which was enacted after we issued our proposed rule. Commenters were aware of the pending legislation and many commenters supported the OBRA '87 changes. An effective date of August 1, 1989 was specified for the February 2 regulations, except for those OBRA '87 provisions that relied on a statutory effective date of October 1, 1990. On July 14, 1989 (54 FR 29717), and December 29, 1989 (54 FR 53611) we published rules that delayed the effective date from August 1, 1989 to January 1, 1990 and October 1, 1990, respectively. The delay to October 1, 1990 is required by section 6901(a) of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89), Pub. L. 101–239.

Scope of Proposed Rule

This rule proposes the way we would implement the OBRA '87 provisions that affect health and safety requirements for residents of long term care facilities and that require a notice and comment procedure prior to implementation. This proposal contains the following components:

- Requirements imposed on States in accordance with sections 1819(e) and 1919(e) of the Social Security Act (the Act) (sections 4201(a) and 4211(a) of OBRA '87), which include—

—Preadmission screening and annual review (PASARR) of the need for admitting or retaining individuals with mental illness (MI) or mental retardation (MR) in NFs that are certified for Medicaid; and

—Appeals systems for persons who may be transferred or discharged from facilities or who wish to dispute a determination made in the preadmission screening and annual review process.

II. Proposed Requirements of OBRA '87

Legislative Changes

Prior to the enactment of OBRA '87, there was no Federal requirement that all individuals with mental illness or mental retardation who applied for admission to a Medicaid NF, without respect to the method of payment for their care, be screened prior to admission to determine if they required the level of care provided by the NF and, if so, whether they needed active treatment for their mental illness or mental retardation. Similarly, there was no explicit Federal requirement for annual review of all individuals with mental illness or mental retardation who reside in NFs, regardless of their method of payment.

Current Medicaid regulations, however, provide for physician certification and recertification of the need for care, inspections of care and independent professional review by teams which report recommendations to the State Medicaid agency, and the facility's own internal utilization review. All three of these Medicaid utilization control mechanisms apply only to Medicaid recipients, not all residents without respect to their method of payment. They also apply to all Medicaid recipients, not just those with mental illness or mental retardation. The populations covered by the existing utilization control mechanisms and by the preadmission screening and annual resident review requirements are, thus, different, but overlapping.

The physician certification requirements, located at 42 CFR 456.260, 456.270, 456.271, 456.360, and 456.372, require that a physician certify each Medicaid recipient as needing the level of care provided by the facility prior to admission or prior to payment for SNF/ICF services. This level of care need must be certified by a physician based on an evaluation and must be recertified every 60 days. Similarly, for payment for SNF services under Medicare, physician certification of the need for that level of care is required at 42 CFR 424.20. Recertification of the need for SNF care is required by the 14th day and every 30 days thereafter. The statutory basis for these physician certification and recertification requirements is section 1902(a)(44) of the Act.

The professional review and inspection of care requirements in section 1902(a)(31) of the Act are located in part 456, subpart I. These requirements provide for—

- With respect to each Medicaid recipient, a written plan of care prior to admission or authorization of benefits and independent professional review, including medical evaluation, which periodically reviews the need for SNF or ICF services;
- With respect to each SNF or ICF, periodic on-site inspections of care by professional review teams, including the adequacy of the services available to meet each recipient's current health needs and promote his or her maximum physical and mental well-being; the necessity and desirability of the resident's continued placement in the facility; and the feasibility of meeting the recipient's health care needs through alternative institutional or noninstitutional services; and
- Full reports to the State Medicaid agency by the independent professional review teams of each inspection of care together with any recommendations.

Section 1902(a)(30)(A) of the Act also provides for utilization control within the facility by medical and professional personnel who are not themselves directly responsible for the care of the recipient involved. Facility review committees must review a sample of their patients who are Medicaid recipients.

All three of the existing Medicaid utilization control mechanisms will no longer be required of NFs, effective October 1, 1990, as a result of OBRA '87. Section 4212(e)(1) abolishes the requirements for physician certification and recertification; section 4212(d)(2) removes the requirement for professional review and inspections of care; and section 4211(h)(3) removes the requirement for utilization control by the facility's utilization review committee.

Section 4211(a) of OBRA '87 redesignates existing section 1919 of the Act as section 1922, and adds a new section 1919 to the Act. With respect to new admissions occurring on or after January 1, 1989, new section 1919(b)(3)(F) of the Act prohibits a Medicaid NF from admitting any new resident who has MI or MR (or a related condition), unless the State mental health authority (in the case of a person with MI) or State mental retardation or developmental disability authority (in the case of a person with MR) has determined that the prospective resident, because of his or her physical and mental condition, requires the level of services provided by a nursing facility. In addition, if the appropriate State authority determines that the individual needs a nursing facility level of care, the State authority must further determine whether the individual needs active treatment for the MI or MR. The responsibilities placed on NFs by section 1919(b)(3)(F) of the Act are contained in the February 2 regulations at § 483.20(f). The responsibilities placed on States are contained in section 1919(e)(7) of the Act. These State responsibilities are the subject of this proposed rule.

Section 1919(e)(7)(A) of the Act requires the State to have a preadmission screening program, consistent with the requirements of section 1919(b)(3)(F), in operation by January 1, 1989. Section 1919(e)(7)(B) establishes State requirements for annual resident review. With respect to

all current residents with MI or MR who were admitted prior to January 1, 1989, section 1919(e)(7)(B)(iii) of the Act requires the State mental health authority (in the case of the person with MI) or the State mental retardation or developmental disability authority (in the case of a person with MR) to take the following actions. First the appropriate State entity must have reviewed and determined by April 1, 1990, whether or not the resident, because of his or her physical and mental condition, requires the level of services provided by a nursing facility or requires the level of services of an inpatient psychiatric hospital for individuals under age 21 or of an institution for mental diseases (IMD) providing medical assistance to individuals 65 years or older, in the case of residents with MI, or the level of services of an ICF/MR, in the case of residents with MR. Secondly, regardless of the outcome of the nursing facility level of care determination, the appropriate State entity must determine whether or not the current resident requires active treatment for his or her MI or MR. In the case of current residents with MI, the Act further specifies that the determinations made by the State mental health authority must be based on an evaluation performed by a person or entity independent of that authority.

Section 1919(e)(7)(B)(iii) of the Act also requires that as of April 1, 1990, reviews and determinations be repeated on at least an annual basis on all NF residents who have mental illness or mental retardation regardless of whether they were first screened under preadmission screening or under an initial resident review.

Section 1919(e)(7)(C) provides for the disposition of residents who are determined under section 1919(e)(7)(B) not to require NF services. In dealing with residents whose only need is for active treatment, the Act distinguishes between short- and long-term residents. Residents who have continuously resided in a NF for 30 months or more are allowed the choice of staying in the NF with active treatment provided or arranged for by the State, of moving to a more appropriate institutional setting such as an ICF/MR or an institution for mental diseases, or of receiving services in an alternative appropriate non-institutional setting. Shorter-term residents must be relocated in accordance with the transfer and discharge provisions of section 1919(c)(2) of the Act (implemented by § 483.12(a)) and provided active treatment by the State. Residents who need neither NF services nor active treatment, regardless of the length of their stay in the NF, must also be discharged in accordance with section 1919(c)(2) of the Act (implemented by § 483.12(a)). The statutory provisions of 1919(e)(7)(C) are discussed more fully below under the provisions of this rule. (See discussion of § 483.118).

Other relevant statutory provisions include:

- Section 1919(e)(7)(D) of the Act, which provides for denial of payments to a State for NF services furnished to an individual for whom preadmission screening or annual resident review determinations are required but for whom determinations have not been made.
- Section 1919(e)(7)(E) of the Act which permits States to submit alternative disposition plans (ADPs) for residents determined under section 1919(e)(7)(B) of the Act not to need NF services but to need active treatment. If by April 1, 1989, the State has entered into an agreement relating to the disposition of such residents and remains in compliance with this agreement, the State may have an extended time period as identified in the ADP for appropriately placing these individuals in other settings or providing active treatment to them, or both. Without an approved ADP, the State is required under section 1919(e)(7)(C) of the Act to have relocated or provided active treatment, or both, to all such residents by April 1, 1990.
- Section 1919(e)(7)(F) of the Act, which requires each State, as a condition of approval of its Medicaid State plan to have in effect, as of January 1, 1989, an appeals process for individuals adversely affected by determinations under PASARR.
- Section 1919(e)(7)(G) of the Act which provides definitions for mental illness, mental retardation and active treatment. These are discussed more fully under the provisions of this rule. (See discussion of §§ 483.102 and 483.120.
- Sections 1819(b)(3)(E) and 1919(b)(3)(E) of the Act, which require coordination between the State's PASARR process and the NF's resident assessment process as described in sections 1819(b)(3)(A)–(D) and 1919(b)(3)(A)–(D). As of October 1, 1990, the NF's resident assessment process must use an instrument based on the minimum data set and specified by the State Medicaid agency. The purpose of this requirement is to avoid duplicative testing and effort to the maximum extent practicable.
- Section 1919(f)(8) of the Act, which requires the Secretary to develop, by no later than October 1, 1988, minimum criteria for States to use in making the required determinations on new admissions and current residents, and procedures to appeal such determinations for individuals adversely affected. However, section 1919(e)(7)(A) of the Act requires the States to have a preadmission screening and annual resident review program in operation by the effective dates regardless of whether the Federal criteria are available.

Development of Criteria

In order to offer maximum guidance to States and provide as much technical assistance as possible, we began developing draft criteria through an exhaustive consultation process in the Spring and Summer of 1988. In September, 1988, we made available a draft, commonly referred to as the "Third Draft," which reflected the results of our consultation. These criteria were again revised based on further experience, analysis, and advice and were published in the State Medicaid Manual (HCFA Pub. 45–4) in May 1989 (Transmittal No. 42). In order to offer the public further opportunity to comment on these criteria before they are used as the basis for monitoring State performance of the PASARR function, we are issuing this proposed rule. After analyzing the comments we receive, we will issue a final regulation, the specific requirements of which, to the extent they reflect administrative discretion, will then be binding on States for prospective periods. Statutory requirements are currently binding on States in accordance with the statutory effective date language. We will also subsequently revise the program instruction, based on the final rule. In the interim, these criteria are advisory to the States. States are free to devise PASARR programs that meet the requirements of the law

It is worth noting that the Act, as amended by OBRA '87, did not require issuance of final regulations, only criteria. Nevertheless, the Act clearly requires that the States implement the preadmission screening requirements by January 1, 1989 and complete the initial reviews on residents who entered NFs prior to the commencement of preadmission screening by April 1, 1990, even in the absence of Federal criteria. This position was upheld in Federal court in May, 1989, when the judge removed a preliminary injunction in *Idaho Health Care Assoc., et al.* v. *Sullivan*, No. 88–1425 (D. Idaho May 11, 1989) and, soon after, in *Rayford, et al.*

v. *Bowen*, No. 89-0418 (W.D. La. May 25, 1989). As a result of a provision (section 6901(c)) of OBRA '89, we are now required to publish these criteria as a proposed rule within 90 days of enactment. Despite this deadline, States continue to be bound by the statutory requirements to perform PASARR activities.

III. Proposed Revisions to Rules

General Rule

PASARR is an unusual program which clearly requires a cooperative effort among State agencies. The PASARR provisions are one of the few instances in which Congress has granted responsibility for a portion of the administration of a Medicaid program requirement to an agency of State government other than the Medicaid single State agency. The other instance of an administrative separation of powers is the survey and certification function, which is the responsibility of the State health department or other licensing body within the State. Because of the special character of PASARR, it is essential to establish in Medicaid regulations the interrelationship of the separate agencies within the State government.

Since the State Medicaid agency is charged with administration of the State plan, it is accountable to HCFA for assuring that the State mental health and mental retardation authorities, who are charged with making the required determinations, fulfill their statutory responsibilities and comply with these regulations, and that the State's PASARR program operates as it should, in accordance with the statute and these regulations. If the program does not operate properly, the State Medicaid agency bears ultimate responsibility. While not an all-inclusive list, we enumerate below a number of specific responsibilities that fall to the State Medicaid agency as part of its role as the administrator of the State plan of which the PASARR requirements are a part. The State Medicaid agency is responsible for the funding of PASARR activities and, as such, has accounting, auditing and enforcement functions to perform. It must see that no individual with MI or MR is admitted to a NF unless he or she has been screened and found to be appropriate for placement or that no resident with MI or MR remains in a NF unless these rules permit continued residence. It must withhold Medicaid payment for NF services for any individual with MI or MR who may not receive them under these regulations. In identifying individuals who should have been screened or reviewed but were not, the State survey and certification agency cooperates in the operation of the PASARR program. The State Medicaid agency must also ensure that the resident assessments conducted by the NF are coordinated with the State's PASARR evaluations as required by section 1919(b)(3)(E) of the Act. We anticipate that coordination complexities may arise since the State Medicaid agency has the responsibility of specifying the instrument, based on the uniform minimum data set that will be used by NFs in the State but shares responsibility for developing the instruments to be used for PASARR evaluations with the State mental health and mental retardation authorities.

Additionally, the State Medicaid agency must ensure that individuals who must be discharged under section 1919(e)(7)(C) of the Act are discharged; but it may need to work with the State mental health and mental retardation authorities in order to develop the needed alternative placements for individuals who must be relocated and to provide the statutorily required active treatment services for those individuals who are determined to need them. Ensuring adherence to the terms of an approved alternative disposition plan (ADP) is also the responsibility of the State Medicaid agency although it should work cooperatively with the State mental health and mental retardation authorities in carrying out the plan.

Since the provision of active treatment to individuals who are determined by the State mental health and mental retardation authorities to need it is a State plan requirement, the State Medicaid agency has responsibility for ensuring that it is provided and for monitoring its provision. The actual delivery of these services may be performed by the State mental health and mental retardation authorities, but the State Medicaid agency is ultimately responsible for seeing that the State meets this obligation under its State plan.

Because of the complexity of the interagency arrangements that are called for by PASARR, we are adding a new § 431.621. This new section follows immediately after the requirement that the State Medicaid agency have an interagency agreement with the State mental health authority or mental institutions if the State plan includes Medicaid services in institutions for mental diseases for recipients aged 65 or older. Section 431.621 would require that the State Medicaid agency have an interagency agreement with the State mental health and mental retardation authorities specifying the respective roles of each agency in operation of the State's PASARR program. We would further specify the basis and purpose for requiring an interagency agreement as a State plan requirement and stipulate the provisions that are required in such an agreement. Among these are requirements for joint planning, access to records, exchange of information concerning individuals with MI or MR, and other provisions that ensure that the interagency agreement is consistent with all requirements of §§ 483.100–483.136.

We do not believe that we need to amend section 431.10(e), which prohibits delegation of the single State agency's authority to exercise administrative discretion in the administration or supervision of the State plan to other than its own officials because the making of PASARR determinations is not a statutory responsibility of the State Medicaid agency. Absent limitations upon the ability to delegate, an agency can, as a general principle, delegate authority that belongs to it. Authority for making PASARR determinations, however, does not belong to the State Medicaid agency. Therefore, the State Medicaid agency cannot delegate what it does not have. We are continuing to study the Medicaid regulations to determine the need for conforming changes to accommodate PASARR requirements. We specifically solicit comments on this topic.

To comply with the PASARR requirements of OBRA '87 and OBRA '89, we propose to retitle part 483 as "Requirements for States and Long Term Care Facilities" and to establish new §§ 483.100 to 483.138. The new part name appropriately reflects the fact that States as well as long term care facilities must meet our requirements.

In § 483.100 we would identify the basis of these requirements governing the State's responsibility for PASARR. These requirements are based on section 1919(e)(7) of the Act.

In § 483.102 we would specify to whom the PASARR program, which the State must operate, applies. Our interpretation is that the PASARR program must apply to all individuals with MI or MR who apply to reside in a Medicaid-certified NF, regardless of the source of payment for the NF services. This interpretation is based on the fact that, in the absence of language in the statute limiting the scope of PASARR (e.g. "for individuals eligible for services under title XIX" or "for persons receiving benefits under this title"), we must rely on a plain reading of the statutory language which states that

preadmission screening applies to "any new resident," and that annual resident review applies to "each resident of a nursing facility" if the applicant or resident has mental illness or mental retardation. Therefore, in § 483.102(a) we would specify that this subpart applies to the screening or reviewing of all individuals with MI or MR, who apply to or reside in Medicaid-certified NFs, regardless of the source of payment for the NF services.

Because an institution for mental diseases (IMD) can be a NF, and all NFs are subject to the PASARR requirements, we believe NFs that participate in Medicaid as IMDs are subject to PASARR. We note that the definition of a NF set forth in section 1919(a) of the Act appears to be somewhat inconsistent with the definition of an IMD in that it states that a NF is an institution that "is not primarily for the care and treatment of mental diseases." We believe, however, that the best reading of these two definitions is that an NF can be both an NF and an IMD. In such situations, the NF maintains its status as a certified NF, but the IMD classification applies. That is, when NFs provide IMD services for persons over 65 years of age or inpatient psychiatric services for individuals under 21, we consider these facilities in the context of these benefits even though they meet NF requirements. For individuals aged 22 to 64, residence in an IMD precludes them from receiving any Medicaid benefits.

The PASARR requirements do not currently apply to swing beds because the existing swing bed regulations at 42 CFR 482.66(b) list those SNF requirements which swing beds must meet and would need to be revised to include PASARR requirements before they would be applicable. In another regulation we will deal with swing bed requirements.

Definitions

In § 483.102(b), we would include the definition of mental illness as it is specified in section 1919(e)(7)(G)(i) of the Act. We would consider an individual to be mentally ill if he or she has a primary or secondary diagnosis of mental disorder, as defined in the Diagnostic and Statistical Manual of Mental Disorders, third edition, and does not have a primary diagnosis of dementia (including Alzheimer's disease or a related disorder). We would consider an individual to have dementia if he or she has a primary diagnosis of dementia, as described in the Diagnostic and Statistical Manual of Mental Disorders, third edition, and does not have MR. (See later preamble discussion of the Level I process under § 483.128(a).)

We note that the Act excludes dementias from the definition of mental illness but not from the definition of mental retardation. Therefore, an individual with a primary diagnosis of dementia and any diagnosis of mental retardation or a related condition would still have to be subjected to PASARR by virtue of having a diagnosis of mental retardation or a related condition. Section 483.102(b)(2)(ii) indicates that a person cannot be viewed as having dementia, for purposes of the exclusion, if he or she has mental retardation (or a related condition).

Also in § 483.102(b) we would provide that an individual is considered to have mental retardation if he or she has a level of retardation (mild, moderate, severe or profound) described in the American Association on Mental Deficiency's Manual on Classification in Mental Retardation (1983), or a related condition, as described in section 1905(d) of the Act and regulations at § 435.1009. We are supplying this definition because the Act does not define MR. It simply states that a person is mentally retarded if the person is mentally retarded or has a related condition as described in section 1905(d). Section 1905(d), however, only defines an intermediate care facility for the mentally retarded (ICF/MR), not mental retardation. ICFs/MR, under section 1905(d), are institutions whose primary purpose is to provide health and rehabilitative services to individuals with MR or related conditions.

In § 483.104 we would require as a condition for approval of the State plan, that the State must operate a PASARR program that meets the requirements of §§ 483.100–483.136. Failure by a State to operate a PASARR program in accordance with these requirements could lead to compliance actions against the State under section 1904 of the Act. Particularly, the failure to implement the clear statutory mandates such as subjecting all categories of individuals with MI or MR (Medicaid, Medicare, and private pay) to PASARR and requiring NFs to not admit unscreened individuals would be viewed as a failure to meet Medicaid State plan requirements. Compliance proceedings could result in loss of FFP in the State's Medicaid nursing home program until compliance is achieved.

In § 483.106(a) we would specify, in general terms, which individuals are subject to preadmission screening and which are subject to annual resident review. Also, we would specify when these activities must be done, based on the timeframes established by the statute. Section 1919 (e)(7)(A) and (e)(7)(B) create a schedule by which States were required by January 1, 1989 to have commenced preadmission screening of all individuals with MI or MR who seek entry into NFs as new resident admissions. The statute identifies no start-up date for the initial reviews of NF residents with MI or MR who entered facilities prior to the commencement of preadmission screening. However, all residents with MI or MR who were not subject to preadmission screening must be subjected to initial reviews by April 1, 1990. Thus, States were allowed to phase-in the resident review function, but are required to have reviewed their entire population of NF residents with MI or MR within the 15 month period between January 1, 1989 and April 1, 1990. As of April 1, 1990, the State must require at least annual review of all residents with MI or MR, regardless of whether they were initially screened under preadmission screening or the initial resident reviews. In other words, by April 1, 1990, the State's PASARR program must be running on a routine basis with all new admissions with MI or MR being screened prior to entrance and all continuing residents with MI or MR being subjected to periodic reviews.

Because a number of States have asked us to clarify the term "new resident," we would specify in § 483.106(b) that a new resident is an individual being admitted to any NF in which he or she has not recently resided and to which he or she cannot qualify as a readmission. Such an individual is subject to preadmission screening if he or she has MI or MR. Readmissions to the same NF following a temporary absence for hospitalization or therapeutic leave are not new admissions. These individuals with MI or MR are subject to annual resident review, not preadmission screening. Interfacility transfers, with or without an intervening hospital stay, are new admissions because these individuals are "new" to the admitting facility. Like new admissions, inter-facility transfers are subject to preadmission screening.

Section 483.106(b) (1) and (2), taken together, mean that a new resident is any individual who is not a readmission to the same facility from which he or she has been only temporarily absent. In cases of new admissions, the admitting NF is either unfamiliar with the individual because he or she has never resided in that particular NF or the individual is a former resident who has been absent from the NF long enough that the NF would have reason to

question whether information it may have on the individual is still current. When a new NF is involved (i.e., one in which the individual has never resided), the individual is unquestionably a new admission. When an individual has resided in a particular NF at some time in the past, questions arise.

We are not specifying a definition for "recently resided" or for "temporary absence." Rather, we are leaving it to the State to define these terms. (See the later preamble discussion of temporary absences which may count toward continuous residence under § 483.118). For both types of cases (readmissions versus new admissions and calculations of continuous residence), we believe that the State should develop a consistent policy. If a State has a bed-hold policy, it may choose to use this period to define temporary absence and recently resided for the purpose of determining whether an individual is a new admission or a readmission when the same NF is involved. While we are not requiring that a State use its bed-hold period for this purpose, we believe that any different definition the State develops should be at least as liberal as the bed-hold period. States without a bed-hold policy may wish to develop definitions of temporary absence and recently resided in order to differentiate between new admissions and readmissions.

We are aware that section 1919(c)(2)(D) of the Act, as amended by OBRA '87, refers to readmissions that may occur at a time beyond the time period that we are allowing States to specify as a temporary absence for the purposes of differentiating between new admissions and readmissions and of calculating terms of continuous residence under PASARR. Section 1919(c)(2)(D) of the Act and § 483.12(b)(3) in the February 2, 1989 final regulation which implements it require a NF to establish a written policy under which a Medicaid eligible resident who is transferred from the NF for hospitalization or therapeutic leave but whose period of absence from the facility exceeds the State's bed-hold period will be readmitted to the NF upon the first availability of a semi-private room if, at the time of readmission, the resident requires the services provided by the facility. We believe that the question of whether the resident requires the services of the facility needs to be answered by a new preadmission screening. Therefore, even though the statute speaks of a "readmission," readmissions that occur after the time period established by the State as a temporary absence are, in fact, new admissions for the purposes of PASARR.

In order to avoid unnecessary duplicative testing, we would permit, however, in the case of an individual who formerly resided in a NF but failed to meet the State's rules for being considered a readmission, a preadmission screening or annual resident review that has been performed within the past year to be updated so long as there has been no significant change in the resident's health status. We would, nevertheless, caution that updates in the case of interfacility transfers or lapsed readmissions and delays in reevaluations at the time of readmission to the same facility (i.e., up to nearly 1 year while awaiting the next ARR) cannot be justified if the hospital admission or interfacility transfer were necessitated by a significant change in the resident's health status which has a bearing on his or her active treatment needs.

For example, if an individual with MI or MR residing in a NF breaks a hip and is sent to the hospital for surgery, he or she could likely be readmitted to the NF for convalescence without the need for reevaluation of the need for NF care or for active treatment. On the other hand, if an individual with MI experiences an acute episode of MI and is transferred to a psychiatric unit in a general hospital or a psychiatric hospital, a change has occurred in his or her mental condition which would raise questions about a change in treatment needs once he or she is ready to return to the NF.

We call attention to the NF requirement at § 483.20 that a change in the resident's health status should precipitate a new facility assessment. Annual resident reviews are similarly required to be done at least annually, but may be required more frequently if a change occurs in the resident's condition. If the facility's new resident assessment indicates that a more immediate annual resident review is warranted, the facility should alert the State mental health authority. Judgment is, therefore, required in determining when updates or delays are appropriate and when a more thorough annual resident review is required.

Section 483.106(c) would specify the purpose of the PASARR program which is to result in the determinations that are described in §§ 483.112 and 483.114. Because there are slight but significant differences between preadmission screening and annual review determinations, it is almost impossible to make accurate general statements applicable to both sets of determinations. Therefore, we are describing each type of determination in a separate section.

In § 483.106 (d) and (e), we would specify who has responsibility for PASARR evaluations and determinations and would deal with the issue of delegation of responsibility about which we have received many questions. The Act provides that PASARR determinations are the responsibility of the State mental health and mental retardation authorities, each for its respective population. On the other hand, with respect to evaluations, the Act treats the two authorities very differently. It requires that the State mental retardation authority have responsibility for the evaluations upon which its determinations are based but removes the State mental health authority from responsibility for the evaluation of individuals with MI. These evaluations must be performed "by a person or entity independent of the State mental health authority."

In part, because we encouraged the 35 States that had preadmission screening programs in place prior to the enactment of OBRA '87 to build PASARR into their systems rather than jettison existing programs, a number of questions have arisen concerning whether the State mental health and mental retardation authorities may delegate their responsibilities to another agent. In many cases, this has meant delegation to the State Medicaid agency, which usually operated the preexisting preadmission screening program. Our interpretation has been that, absent specific statutory limitations, a grant of authority may generally be delegated or contracted so long as the empowered body retains control over the actions of its agent and ultimate responsibility for the performance of its statutory obligations. We therefore would require that if the State mental health and mental retardation authorities choose to delegate or subcontract their responsibilities, they must, according to the Act, retain ultimate authority over and responsibility for the performance of their statutory obligations. "Delegation" cannot be construed to mean an abdication by an agency of a binding statutory duty or usurpation of it by another agency. Moreover, the State mental health authority cannot delegate, in the sense described above, evaluations of individuals with MI. The responsibility for these evaluations is not theirs to delegate. Another agent must do them. Since the State Medicaid agency is charged with ensuring operation of the State PASARR program, it must see that an independent evaluation agent is used.

In § 483.108, we would specify the relationship of PASARR to other Medicaid processes. Specifically, in § 483.108(a) we would clarify that PASARR determinations made by the State mental health and mental retardation authorities cannot be countermanded by the State Medicaid agency either in the claims process or through other utilization review/control processes. In § 483.108(b) we would require, however, that the State mental health and mental retardation authorities use criteria that are consistent with those contained in applicable regulations or adopted by the State Medicaid agency under the approved State plan.

In § 483.108(c), we would require coordination of PASARR activities with the resident assessment activities required of facilities. To the maximum extent practicable, in order to avoid duplicative testing and effort, the PASARR must be coordinated with the routine resident assessments required by § 483.20(b). In the State Medicaid Manual, Transmittal No. 42, we suggested that data gathered in performing a preadmission screening on an individual with MI or MR could be used in performing the first resident assessment once he or she is admitted to the NF. Similarly, the facility's routine assessments, which must be performed at least annually but may be required more frequently if a change occurs in the resident's condition, should trigger an annual resident review on individuals who are identified as having MI or MR. Data collected as part of the facility's routine assessments may be used by the State in performing the annual resident review.

In § 483.110, we would provide for out-of-State arrangements relating to PASARR. We would specify that for an individual eligible for Medicaid, the State in which the individual is a legal resident must pay for the PASARR and make the required determinations, in accordance with § 431.52(b)(1), which specifies requirements for furnishing Medicaid services to State residents who are absent from the State. For non-Medicaid individuals, the State in which the facility is located pays for the review unless the States have mutually agreed to other arrangements. We propose that a State may include arrangements for PASARR in its provider agreement with an out-of-State facility or in its reciprocal interstate agreement. We do not, however, propose to require either type of agreement.

Preadmission Screening (PAS)

We would require in a new § 483.112, Preadmission Screening of Applicants for Admission to Nursing Facilities, that for each NF applicant with mental illness or mental retardation, the State mental health or mental retardation authority (as appropriate) must determine, in accordance with § 483.130, whether, because of the applicant's physical and mental condition, he or she requires the level of services provided by a NF. Also, if the individual with mental illness or mental retardation is determined to require an NF level of care, the State mental health or mental retardation authority (as appropriate) must also determine, in accordance with §§ 483.134–483.136 (as appropriate), whether the individual requires active treatment for the mental illness or mental retardation, as defined in § 483.120. As noted in the general requirements for PASARR in § 483.106, all determinations by the State mental health authority are to be based on evaluations performed by a person or entity independent of the State mental health authority.

To this preadmission screening requirement, we would also add a timeliness standard in § 483.112(c), which would require that the State mental health or mental retardation authorities make preadmission screening determinations in writing within 7 working days of referral by the NF, hospital discharge planner or whomever is responsible under the State's system for identifying individuals with MI or MR and for referring them to the State mental health or mental retardation authority for preadmission screening. (See the preamble discussion of § 483.118(a) concerning the Level I identification process.) Telephone calls may be used to announce determinations within the 7 working days to permit speedier admissions or the making of other arrangements if NF admission is denied so that applicants to NFs do not have to await the arrival of paperwork.

We specifically solicit comments on this timeliness standard. We are aware that circumstances vary around the country. We also recognize that States may have acquired experience in conducting these reviews which bears on the issue of a timeliness standard. We have proposed this period because we do not want individuals seeking admission to have to wait an unduly long time to receive results of the PAS; however, we recognize that experience may dictate use of an alternative standard of timeliness. We, therefore, welcome comments as to the reasonableness of this requirement.

Annual Resident Review (ARR)

We would require in a new 483.114, Annual Resident Review of NF Residents, that the State's program comply with the requirements of section 1919(e)(7)(B) of the Act. For residents with MI, we would require the State mental health authority to determine, based on the resident's physical and mental condition, whether the resident requires the level of services provided by a NF, an inpatient psychiatric hospital for individuals under age 21, as described in section 1905(h) of the Act, or an institution for mental diseases providing medical assistance to individuals age 65 or older. Regardless of the outcome of the first determination, the State mental health authority would also need to determine whether the individual needs active treatment for MI. As noted in the general requirements for PASARR in §§ 483.106(d), all determinations by the State mental health authority are to be based on evaluations performed by a person or entity independent of the State mental health authority.

For persons with MR, we would require the State mental retardation authority to determine whether the resident, because of his or her physical or mental condition, requires the level of services provided by a NF or by an intermediate care facility for the mentally retarded (ICF/MR). Additionally, regardless of the outcome of the first determination, the State mental retardation authority would need to determine whether the resident needs active treatment.

In § 483.114(c), we would prescribe the frequency of resident reviews. As of April 1, 1990, a review and determination must be conducted for each resident of a Medicaid NF who has MI or MR at least annually. This requirement for at least annual review applies to all individuals with MI or MR regardless of whether they were originally reviewed under preadmission screening, the initial review provisions, or are subsequently detected through the facility's routine resident assessments. In the State Medicaid Manual, Transmittal No. 42, we suggested that the facility's routine resident assessment process may be used as a means of performing the Level I identification function for continuing residents (Level I is discussed in connection with § 483.128(a), following). More frequent than annual resident assessments by the NF that are precipitated by a change in the resident's physical or mental condition

should trigger more frequent than annual resident reviews by the State. The State, however, is ultimately responsible for ensuring that all residents with MI or MR receive timely reviews.

Additionally, in § 483.114(d) we would repeat the statutory requirement that the first set of reviews of residents with MI or MR who entered Medicaid NFs prior to January 1, 1989 be completed on or before April 1, 1990.

Results of PAS and ARR

We would require in a new § 483.116, Residents and applicants determined to require NF level of services, that, if the State mental health or mental retardation authority determines that a resident or applicant for admission to a NF requires a NF level of services, the NF may admit or retain the individual. If the State mental health or mental retardation authority determines that a resident or applicant for admission requires both an NF level of services and active treatment for the MI or MR, we would permit the NF to admit or retain the individual and we require the State to provide or arrange for the provision of the active treatment needed by the individual while he or she resides in the NF.

The requirement that the State provide or arrange for the provision of active treatment for all individuals who are identified to need active treatment under the PASARR process, whether or not they remain in nursing facilities, is clearly the intent of the Congress. The committee language describing these provisions of the bill makes it clear that the Congress intended this process to result in either appropriate placement outside a nursing facility or provision to the resident in the nursing facility of needed active treatment services. Thus, while a State may have some latitude in refining its procedures relating to admissions to and continued stays in NFs, it must do so with the understanding that it bears the obligation of assuring proper treatment of individuals needing active treatment who are approved for NF admission.

In a new § 483.118, residents and applicants determined not to require NF level of services, we would require in paragraph (a) that if the results of a State's screening for a new admission indicate that a NF level of services is not needed, then the NF must not admit that individual. This means that even if the individual is a private pay or Medicare patient who otherwise has the means to pay for the NF care and chooses to purchase this service, he or she cannot be admitted. If the individual is Medicaid eligible, the NF similarly may not admit him or her. Moreover, from a payment perspective, NF care is not considered a covered Medicaid service for that individual. As noted earlier in section 483.102, these PASARR requirements apply to all individuals without respect to the method of payment for their care. The result of this fact is that all individuals are subject to these determinations, whether or not they are eligible for Medicaid, and cannot be admitted to a Medicaid certified facility if they have not been determined to need NF services. As provided for in § 483.20(f) in the February 2 rule, the NF cannot admit any individual with MI or MR who has not been determined to be appropriate for NF placement without violating its requirements for participation as a Medicaid-certified facility. Also, when it has determined that an individual with MI or MR does not need NF services, the State mental health or mental retardation authority is not required to complete the remainder of the screening.

In § 483.118(b), we would deal with residents who require neither NF services nor active treatment for MI or MR. Section 1919(e)(7)(C)(iii) of the Act requires that any nursing facility resident who has been determined not to require the level of services provided in a NF and not to require active treatment for mental illness or mental retardation must be discharged from the NF. In accordance with the Act, the State must—

- Arrange for the safe and orderly discharge of the resident from the facility; and
- Prepare and orient the resident for discharge.

(See our later discussion concerning Federal financial participation (FFP) in § 483.122. Also see § 483.12(a) in the February 2, 1989 rule for transfer and discharge rights of residents. These provisions implement section 1919(c)(2) of the Act).

Because, as noted above, these PASARR requirements apply to all individuals without respect to the method of payment for their care, the State must arrange for the discharge of all residents who are determined to need neither NF nor active treatment services, even if these residents are not Medicaid eligible.

For residents of NFs who are determined not to require NF services but to require active treatment, we would follow section 1919(e)(7) of the Act, which differentiates between individuals who have resided in a NF for 30 months or longer and those who have resided in a NF for fewer than 30 months. Section 1919(e)(7)(C)(i) of the Act provides that in the case of an individual who has resided in a NF for at least 30 months before the date of the review determination that he or she does not require the level of services provided in a NF, but requires active treatment for MI or MR, the State must in consultation with the resident's family or legal representative and caregivers, do the following:

- Inform the resident of the institutional and noninstitutional alternatives covered under the State plan for the resident;
- Offer the resident the choice of remaining in the facility or of receiving covered services in an alternative appropriate institutional or noninstitutional setting;
- Clarify the effect on eligibility for services under the State plan if the resident chooses to leave the facility, including its effect on readmission to the facility; and
- Regardless of the resident's choice of placement, provide for, or arrange for the provision of active treatment for the mental illness or mental retardation.

While the options that must be presented to long-term residents consist exclusively of Medicaid covered services, all long-term residents with MI or MR who need only active treatment, regardless of the method of payment for their care, must be offered these choices. If non-Medicaid eligible individuals in this group elect to stay, their continued stay is funded by whatever means it was paid for prior to the determination (i.e., the right to stay does not carry with it the right to Medicaid coverage). This statutory provision would be implemented in § 483.118(c)(1).

The Act contains other provisions that apply to short-term residents of NFs who do not require NF services but do require active treatment for mental illness or mental retardation. Section 1919(e)(7)(C)(ii) provides that in the case of an individual who has not continuously resided in a NF for at least 30 months before the date of the determination, and has been determined not to require the level of services provided by a NF, but to require active treatment, the State must, in consultation with the resident's family or legal representative and caregivers—

- Arrange for the safe and orderly discharge of the resident from the facility;
- Prepare and orient the resident for discharge; and
- Provide for, or arrange for the provision of active treatment for mental illness or mental retardation.

We note that the requirement that the State must arrange for the discharge of short-term residents with MI or MR who

do not require NF services applies, as explained earlier, to all residents without regard to the method of payment for their care. We would implement this provision in § 483.118(c)(2).

A delay in application of certain aspects of § 483.118(c) (1) and (2) is allowed if the State has in effect an approved alternative disposition plan (ADP) and is complying with the terms of this agreement. Alternative disposition plans are permitted by section 1919(e)(7)(E) of the Act. Section 483.118(c) allows a State and the nursing facility to be considered in compliance with the PASARR requirements if, before April 1, 1989, the State and the Secretary have entered into an agreement relating to the disposition of residents who do not need NF services but do need active treatment and the State is in compliance with the agreement. Section 1919(e)(7)(E) further states that an ADP agreement may provide for the disposition of these residents after April 1, 1990, the date by which all initial reviews of residents who entered the NF prior to the start of preadmission screening must be completed.

A State with an approved ADP gains extra time for only two functions:

- Relocating residents to alternative settings residents; and
- Providing active treatment.

An ADP does not give a State extra time to complete the initial reviews that are required under section 1919(e)(7)(B) of the Act.

Congress recognized that the problem of inappropriate placements in the past could not be solved overnight, but it did require that the State start taking steps to solve it. By April 1, 1990, States should know precisely who is in their ADP population:

- Individuals in need of relocation (i.e., long-term residents, identified in § 483.118(c)(1), who choose not to remain in the NF but to go to another more appropriate institutional or non-institutional setting and short-term residents, identified in § 483.118(c)(2), who do not have the choice of staying in the NF and must be relocated to a more appropriate setting); and
- Individuals in need of active treatment (i.e., all residents who are identified as not needing NF but needing active treatment, wherever they are, whether in the NF, another institutional setting, or in the community).

Alternative placements can take various forms: for instance, beds in an IMD, a psychiatric hospital, an ICF/MR, a group home, or another type of supervised living setting. Similarly, the means of delivering active treatment services may take various forms. Some individuals in the ADP population will have to receive active treatment in the NF. Others may be able to leave the NF to receive these services. Still others who will be moved to community settings will have to receive active treatment there. The extra time allowed by an ADP is for working out the logistics involved in creating placement slots and developing delivery systems for active treatment services. Logistical problems may include requesting and obtaining legislative appropriations, securing certifications of need, submitting waivers to HCFA, locating existing or building new housing units, or hiring and training staff.

In response to Congress' offer, 46 States submitted ADPs timely and had them approved by HCFA by April 1, 1989. States without approved ADPs are responsible under the statute for not only having reviewed all continuing NF residents, but also for having relocated all who need or choose to move and for having commenced, by April 1, 1990, the provision of active treatment services to those determined to need them.

Because questions have been raised concerning the meaning of "continuously residing in a NF" we would clarify in § 483.118(c)(4) that for the purposes of establishing length of stay in a NF, the 30 months or longer of continuous residence in a NF is calculated back from the date of the annual resident review determination which finds that the individual is not in need of NF level of services. Moreover, we would specify, consistent with the legislative history (H.R. Rep. No. 391, 100th Cong., 1st Sess. 461 (1987)) that the continuous residence may include temporary absences for hospitalization or therapeutic leave and may include consecutive residences in more than one NF.

We are not specifying a definition of "temporary absences" for hospitalization or therapeutic leave because we wish to preserve States flexibility. Many States have bed-hold policies while others do not. States may wish to use their bed-hold time frame in defining a temporary absence but we do not require them to do so. In fairness to residents, however, we believe that a State's definition of a temporary absence should be at least as liberal as its bed-hold period. Also, we believe that, in order to abide by Congressional intent, States without bed-hold policies should establish rules allowing for some amount of interruption of a NF stay for hospitalization or therapeutic leave when calculating whether a resident qualifies as a long-term resident.

Active Treatment

As indicated earlier, for individuals who are determined by preadmission screening to need NF services, the State program must make a determination of the individual's need for active treatment of the MI or MR. For current NF residents, the State must determine if active treatment is needed independent of the need for NF services. Section 1919(e)(7)(G)(iii) of the Act does not define the term, active treatment, indicating only that it does not include, in the case of a resident of a NF, services within the scope of services that the facility must provide or arrange for its residents under 1919(b)(4). (These required NF services are nursing and related services and specialized rehabilitative services, medically-related social services, pharmaceutical services, dietary services, an activities program, and dental services.) Active treatment is, thus, not a NF service and its provision is not the NF's responsibility. Responsibility for provision of active treatment, as discussed below, lies with the State. The two terms are, as a result of the statutory language, mutually exclusive. However, as a practical matter, individual needs cannot be assessed piecemeal, nor can treatment of individual needs be separated, service-by-service, into NF care and active treatment. The only reasonable way to implement this provision is to view the active treatment services an individual requires as services that wrap around any NF services the individual needs and, combined with it, create the therapeutic environment needed by the resident.

Section 1919(e)(7)(G)(iii) of the Act states that the term "active treatment" has the meaning given it by the Secretary in regulations. While Congress did not specify whether it meant existing or future regulations, the definitions contained in existing regulations are relatively narrow, as explained below. Moreover, the Act clearly envisions that not all individuals with MI or MR will need active treatment. Hence, the question, "Does the individual need active treatment?" If the question could only be answered in the affirmative, there would be no point to asking the question. If Congress believed that all individuals with MI or MR needed active treatment, it would presumably have simply required that active treatment be provided to all individuals with MI or MR. Because Congress chose, instead, to ask the question, we believe it intended a definition of active treatment that is

more restrictive than an all-inclusive category of mental health services which anyone with any mental disorder listed in the Diagnostic and Statistical Manual of Mental Disorders, 3rd edition, Revised (DSM–III–R), however mild, might need.

For the normal NF population (i.e., those individuals with MR or MI who do not need active treatment and other individuals who do not have MR or MI but do have some mental health needs), Congress made provisions for mental health services. In describing the scope of services and activities under the NF's plan of care, section 1919(b)(2) of the Act requires that the plan of care describe a resident's psychosocial needs and requires that the NF provide services and activities to attain or maintain the highest practical physical, mental, and psychosocial well-being of each resident in accordance with the plan of care. Among all the services that a NF must provide, section 1919(b)(4) of the Act particularly singles out nursing and related services, specialized rehabilitative services, medically-related social services and an on-going program of activities to reemphasize that all of these services must be designed to attain or maintain the highest practical physical, mental, and psychosocial well-being of each resident.

We note that commenters to the February 2, 1989 rule believed it was essential that we differentiate between active treatment for mental illness and the regular mental health and psychosocial services a resident requires and is entitled to receive as NF services. We agree and plan to incorporate commenters' suggestions that we add psychiatric rehabilitation to the list of specialized rehabilitative services that the facility must provide to residents who need them, thus making these services NF services under Medicaid. We expect to discuss, in a final regulation that responds to comments on the February 2, 1989 rule, the types of activities we believe are commonly understood to be included among the mental health and psychiatric rehabilitative services that are within the scope of a NF. We also plan to clarify in that rule that specialized psychiatric rehabilitation is not active treatment. We view specialized psychiatric rehabilitation as providing intermittent or maintenance services to individuals with mental illness who have been determined under a State's PASARR process to need NF care and not need active treatment. Residents who are determined under PASARR to need both NF services and active treatment will likely need to receive such NF services as medically related social services, an activities program, and psychiatric rehabilitation as part of their plans of care. These services will be inadequate to meet their total needs. The State will have to provide or arrange for the provision of additional services to raise the level of intensity of services from the NF level to a level analogous to that which the resident would receive in a higher level of care such as a psychiatric hospital or an ICF/MR.

In revisions to the February 2 rule, we also intend to amend the resident assessment sections of that rule to require mental status evaluations so that baseline data that are needed to develop the plan of care will be developed. In addition, in keeping with our focus on outcomes of care, we expect to require in the quality of care sections of that rule that identified mental health needs be met.

Between the long term care facility requirements of the other regulation and the State requirements proposed here, we believe we are developing a stance that is faithful to the statute which both clearly indicates at sections 1819 and 1919(b) (2) and (4) that residents' mental health needs must be served by NFs and at section 1919(e)(7)(G)(iii) that active treatment services are outside the scope of nursing facility mental health services.

In this rule we would define active treatment in § 483.120 by providing separate definitions for active treatment for MI and for MR. In the State Medicaid Manual, Transmittal No. 42, we suggested a combined definition of active treatment for both groups; however, we have decided to return to separate definitions for several reasons. First, the needs of the two groups are relatively different, thus, making a combined definition difficult to construct. Secondly, the character of the two conditions is different. MR is a stable condition whereas MI is frequently transitory or intermittent, requiring frequent rediagnosis or reevaluation as part of the treatment. Individuals with MI do not form a fixed population the way persons with MR do.

Chiefly, however, our decision to return to separate definitions is motivated by the desire to use in this context the same definition of active treatment published as a final rule on June 3, 1988 (53 FR 20448) in connection with the conditions of participation for intermediate care facilities for the mentally retarded (ICFs/MR). 42 CFR 435.1009 defines "active treatment in intermediate care facilities for the mentally retarded" as, "treatment that meets the requirements, specified in the standard concerning active treatment for intermediate care facilities for persons with mental retardation under section 483.440(a) of this subchapter."

By contrast, a comprehensive definition of active treatment for mental illness does not currently exist in the Medicaid regulations although the rudiments of such a definition do exist at 42 CFR 441.154 and following sections for inpatient psychiatric services for individuals under age 21 (See 441.150–441.156). Active treatment for mental illness is somewhat more thoroughly defined and described for inpatient services in psychiatric hospitals under Medicare, not in regulations, but in the Medicare hospital and Part A manuals (sections 212.1–212.2 and 3102.1 respectively).

Drawing upon these two sources for a comprehensive definition, we would define active treatment for persons with MI in § 483.120(a)(1) to mean the continuous and aggressive implementation of an individualized plan of care that is developed under and supervised by a physician in conjunction with an interdisciplinary team of qualified mental health professionals; that prescribes specific therapies and activities for the treatment of persons experiencing an acute episode of severe mental illness, which necessitates supervision by trained MI personnel; and that is directed toward diagnosing and reducing the resident's psychotic symptoms that necessitated institutionalization, improving his or her level of independent functioning, and achieving a functioning level that permits reduction in the level of need for mental health services to below the active treatment level of services at the earliest possible time. Although we are not specifying requirements at this point, we would expect that the interdisciplinary team of qualified mental health professionals administering the active treatment program for a person with MI would have a composition and qualifications similar to those required at § 441.156 for the team providing inpatient psychiatric services to individuals under age 21 (with the deletion to the reference in § 441.156(b) to competence in child psychiatry and addition of a reference to general psychiatry).

For persons with MR, we are defining active treatment by cross-referring to the active treatment requirements used for the ICF/MR program at § 483.440(a)(1).

We would clarify in § 483.120(b)(1) that active treatment for persons with MI does not include intermittent or periodic psychiatric services for residents who do not require 24-hour supervision by qualified mental health personnel. For persons with MR, we have already clarified at § 483.440(a)(2) that active treatment does not include services to maintain generally independent clients who are able to function with little supervision or in the absence of a continuous active treatment program. In § 483.120(b)(2), we cross-refer to this portion of the ICF/MR regulations.

In § 483.120(c) we would specify who must receive active treatment and who must provide it. The State must assure that active treatment is furnished in accordance with these regulations to all NF residents with MI or MR whose needs are such that 24-hour supervision, treatment and training by qualified mental health or mental retardation personnel is necessary, as identified by the screening provided in §§ 438.130, or 483.134 and 483.136.

In § 483.120(d), we would require that the NF must provide mental health services including specialized psychiatric rehabilitation (which are of a lesser intensity than active treatment) to all residents who need such services. Because the Act, at section 1919(e)(7)(G), excludes active treatment from NF services, the NF cannot be held responsible for providing active treatment to individuals who are determined to need it and who are admitted or allowed to stay in the NF.

We believe that active treatment services can be delivered in the NF setting only with difficulty because the overall level of services is not so intense. If the State's PASARR program determines that an individual with mental retardation or mental illness may enter or continue to reside in the NF, even though he or she needs active treatment, and the individual does so, then the State must provide or arrange for the provision of services to raise the level of intensity of services from the NF level of mental health and psychiatric rehabilitation services to the active treatment level. Given the definition of active treatment we are proposing for MI, however, we expect that few individuals with MI who are found appropriate for NF placement will be found also to need active treatment. We expect that a much larger group of applicants and residents with MI will need mental health services of a lesser intensity than active treatment connotes. Because of the coordination required between PASARR evaluations and resident assessments in § 483.108(d), PASARR findings that indicate a need for mental health services which are less intensive than active treatment must be reflected in the resident assessment performed by the facility and must be incorporated into the individual's plan of care.

We base the use of the narrow definition of active treatment for mental illness presented in § 483.120 upon the following factors:

- Statutory basis. The Act clearly envisions that some individuals with MI will not require active treatment. The Act further indicates that we are to look to existing regulatory definitions in establishing a new one by regulation.
- Existing regulatory and programmatic instructional basis. This narrow definition of active treatment is consistent with and grows out of the active treatment provisions applicable to the inpatient psychiatric services for individuals under age 21 and to psychiatric hospitals under Medicare. A similarly narrow definition of active treatment was also proposed in the State Medicaid Manual, Transmittal No. 42.
- Established practice. Active treatment for MI, like active treatment for MR, is a "term of art" among professionals practicing in the field. For MI, the term is generally accepted as being limited to individuals who are experiencing acute episodes of severe mental illness that requires 24-hour supervision by trained mental health personnel. As noted earlier, MI, unlike MR, is frequently a transitory or intermittent diagnosis. Even when MI is a current diagnosis, it can often be managed successfully through maintenance drugs and periodic therapy. Only during acute episodes, does the individual with MI require the intensity of intervention that active treatment commonly connotes. While the services provided may be the same in both instances, mental health professionals point out, the critical difference between active treatment and "regular" mental health services lies in the level of intensity.
- Advice of consultants. Psychiatrists and other individuals in the mental health advocacy and provider groups who supplied us with advice and comment in the course of developing the current operating instructions universally and strongly urged that we retain the narrow definition of active treatment employed in the Medicaid and Medicare programs for inpatient psychiatric facilities. This same constituency voiced identical views on the relevant sections of the February 2, 1989 rule. We therefore anticipate widespread support of this definition from these groups.

We note, however, that since existing provisions in regulations concerning active treatment for MI under the psychiatric services for individuals under age 21 are not as detailed as those for the ICF/MR program and, in the case of the Medicare program, the definition is not spelled out in regulations, but rather in program instructions alone, we have had to develop extensive changes to the regulations. For this reason, we specifically solicit comments on the definition of active treatment for MI we are proposing.

Availability of FFP for NF Services

In § 483.122(a) (1) and (2), we would provide, except as otherwise may be provided in an alternative disposition plan adopted under section 1919(e)(7)(E) of the Act, that FFP is available for NF services provided to Medicaid eligible individuals subject to the requirements of this part only if they have been determined to need NF care under § 483.116(a), or if, as a long term resident, they have been determined not to need NF services but to currently need active treatment under § 483.118(c)(1) and they elect to stay in the NF.

In negative terms, § 483.122(a)(1) means that FFP is not available for NF services furnished to a Medicaid eligible individual with MI or MR who was admitted on or after January 1, 1989 if the State mental health or mental retardation authority failed to conduct a preadmission screening on the individual. Also, on or after April 1, 1990, we would provide that FFP for NF services will not be available for any Medicaid eligible resident with MI or MR who was not subjected to annual resident review as required under these regulations. We base the denial of payment for non-performance of a required preadmission screening or annual resident review on section 1919(e)(7)(D) of the Act.

In addition, with the exception of the long-term resident group to which Congress afforded the choice of staying in a facility (§ 483.122(a)(2)), we would provide that FFP is not available if the State mental health or mental retardation authority has determined that NF services are not needed. The denial of payment for services that are not required is based in section 1919(b)(3)(F) of the Act, which prohibits a State from admitting an individual with MI or MR to a NF who does not require NF services, and the fact that Congress created an exception for long-

term residents in section 1919(e)(7)(C)(i) of the Act. Section 1919(e)(7)(C)(i) provides that a State is not to be denied FFP for NF services for a Medicaid eligible individual who has resided in a NF for at least 30 months before the date of the annual resident review determination who is found to not need NF services, but to need active treatment and who chooses to remain in the NF. If, under these regulations, a short term resident should not be in the NF, we cannot pay for his or her being there.

In positive terms, § 483.122(a)(1) means that for Medicaid eligible individuals with MI or MR who have been screened before entering a NF and have been determined to require NF level of services, FFP is available for NF services, regardless of whether active treatment for the MI or MR is also needed. Section 483.122(a) also means that, for current Medicaid eligible residents who are determined to need NF services, FFP is available regardless of the length of stay in the NF and regardless of a need for active treatment.

We considered, but rejected the idea of specifying in § 483.122(a) that, if a preadmission screening or a timely resident review is not conducted, FFP could be provided for days of care that occur after the date upon which the required determinations are made. This idea would have prevented the State's failure to perform a preadmission screening or a timely resident review on an individual or resident who has MI or MR from resulting in denial of payment for that individual for the NF stay. Under such a provision, payments could begin or recommence once the required resident review was performed. We rejected this idea because we believe that the entire PASARR process would be seriously undermined if payment could be permitted as soon as a review was performed, for instance, within two or three days of admission when preadmission screening never occurred or timely resident review was not conducted. We are therefore taking the position that section 1919(e)(7)(D) of the Act requires denial of FFP for the stay. The statute does not create intermediate sanctions which could be used in case of error on the part of the State.

We would also specify in § 483.122(b) that FFP for NF services cannot remain available if the individual with MI or MR has not been subjected to timely (at least annual) reviews to reevaluate NF and active treatment service needs. While reviews must be performed at least annually, a change in the resident's physical or mental condition may precipitate a more frequent review. (See the previous discussion of the need for more frequent reviews under preamble discussion of §§ 483.106(b) and 483.114(c)). The statutory basis for proposing that the availability of FFP for PASARR-affected residents be subject to reevaluation and reconfirmation of NF and active treatment needs through annual resident reviews is found in section 1919(e)(7)(C)(iii) of the Act. Should an individual subsequently be found to need neither NF nor active treatment services, the individual would have to be discharged as provided for in § 483.118(b). However, an individual who no longer needs active treatment could be reclassified as needing mental health services or specialized psychiatric rehabilitation which are below the level of active treatment, and are NF services. Because he or she needs NF services, the individual would not need to be discharged.

We would also note that for short term residents who must be discharged, FFP would not be available after a reasonable time period for arranging the discharge and orienting the resident. By a reasonable period of time, we generally mean the 30 days notice that the facility must normally provide the resident in the case of a transfer or discharge unless the resident's health improves so as to allow for an earlier discharge or an earlier transfer is necessitated by the resident's urgent medical needs. Given the intensity of need for services that active treatment connotes, a more timely transfer may be necessary; however, many of these individuals needing transfer as a result of the annual resident review determinations have been inappropriately placed in the NF for some time and 30 more days would appear to make little difference. If an appeal is made, FFP would continue until the appeal is completed. If an appeal is completed, withdrawn or terminated before the 30 days have elapsed, the resident would still be entitled to the full 30 days and FFP should continue until discharge. (See preamble discussion of subpart E.) Also, as noted above, FFP may continue if the individual is covered under the provisions of an approved ADP and the State is in compliance with that plan.

In § 483.124, we would specify that FFP is not available for active treatment furnished to NF residents as a NF service, although the Act requires that it be furnished by States. We base this provision on section 1919(e)(7)(G)(iii) of the Act, which expressly excludes nursing facility services from the definition of active treatment and vice-versa. Indeed, Congress made it quite plain when drafting the nursing home reform provisions that it expected the States to provide or arrange for active treatment to NF residents without the benefit of Federal Medicaid funds. Specifically, the House Committee Report provided:

> The Committee recognizes and intends that the Committee amendment would impose an affirmative obligation on States to provide active treatment services with respect to certain individuals without providing commensurate Federal matching funds, except in the context of ICF/MR services (and psychiatric services for individuals under age 21) where such funds are readily available under current law * * *. In the Committee's view, the responsibility for providing, or paying for the provision of, active treatment lies with the States. (H.R. Rep. No. 391, 100th Cong., 1st Sess. 462 (1987).)

In specifying that active treatment services cannot be covered by FFP as NF services, we are not suggesting that active treatment services, per se, can be covered by FFP if the services are provided outside a NF. Active treatment services are neither a mandatory nor an optional service under the Medicaid program. However, individual components of an active treatment program may be covered services under the State plan. In the State Medicaid Manual, Transmittal No. 42, we suggested that States could receive FFP for some components of an active treatment program by using other optional services in their State plans (such as physical, occupational, or speech therapies, rehabilitation services, or clinic services) to build active treatment programs for individuals. What makes treatment "active" is the level of intensity and integration of discrete services into a comprehensive package which is directed toward meeting the individual's needs. The individual components on their own do not equal active treatment; but by employing various building blocks for which reimbursement is available, the State may receive some Federal help in meeting the active treatment needs of individuals. The State may also use targeted case management, if it is an optional service under its State plan, to coordinate the delivery of active treatment services, both to individuals in NFs and to individuals in other settings.

We wish to stress, however, that delivery of active treatment, as we have defined it, in a NF setting is extremely difficult. We would, therefore, require that the State provide assurances of how it will deliver active treatment

services to NF residents who need them. To reinforce this point, we would propose at § 483.126 a definition of appropriate placement. Specifically, we would provide that placement of an individual with MI or MR in a NF may be considered appropriate only when the individual's needs are such that he or she meets the minimum standards for admission and the individual's needs for treatment do not exceed the level of services that can be delivered in the NF to which the individual is admitted either through NF services alone or, when necessary, through NF services supplemented by active treatment services provided by or arranged for by the State.

We conceive of a NF level of care as a stratum in a vertical continuum of care. The NF layer has both top and bottom limits. The lower limit is established by section 1919(a)(1) of the Act. That is, a NF provides health and related services above the level of room and board. The upper limit consists of the practical limitations on the intensity of services a NF, given the staffing and funding it has available, can be reasonably expected to provide within the range of services specified by the statute in section 1919(b)(4). Such a conception of a NF level of care is provided for in the statute at least with respect to current residents. The statute requires that the State mental health and mental retardation authorities determine whether the resident requires a NF level of care or the level of care provided by a different specialized provider (i.e., a psychiatric hospital, an IMD, or an ICF/MR). We believe this same concept of a level of care also applies to new admissions being subjected to preadmission screening because Congress seems unlikely to have enacted these PASARR provisions in order to have a less stringent understanding of a NF level of care for new entrants into the system that it had for the current residents.

PASARR Criteria

Section 1919(f)(8)(A) of the Act, as added by section 4211 of OBRA '87, requires that we develop minimum criteria for the State to use in making determinations under the PASARR requirements.

In new §§ 483.128 and 483.130, we establish general criteria that States must use in establishing a PASARR program. Section 483.128 deals with requirements for the evaluation phase of the PASARR while § 483.130 deals chiefly with requirements for the determination phase although it also details the evaluative bases for making categorical, as opposed to individualized, determinations. In our instruction, and again in this preamble, we note that we are outlining criteria, not process. We propose that each State may develop its own process within these guidelines.

The first criterion, presented in § 483.128(a), is that the State must have a system for identifying individuals who are suspected of having MI or MR as defined in § 483.102. The identification phase of PASARR we described as Level I in the State Medicaid Manual, Transmittal No. 42. Level II, as presented in the same instruction, is the evaluation and determination phase of PASARR which answers two questions: First, does this individual, already identified as having MI or MR, need NF services, and secondly, does he or she need active treatment. Only the Level II functions are described in the statute. The statute is silent on the issue of who should determine who has MI or MR, or how it should be done yet clearly this function must be performed because individuals who do not have MI or MR are not subject to PASARR. Because the Act prohibits a NF from admitting any individual with MI or MR who has not been screened by the State authorities and determined appropriate for placement, the facility obviously has a considerable interest in saying who has MI or MR and therefore must be screened. As a matter of logic, we indicated in early memoranda to the State Medicaid agencies that NFs should perform the level I identification screens.

In the first months of PASARR implementation by the States, it was alleged that, because a large proportion of NF admissions come directly from hospitals, a hospital back-up problem was occurring in certain areas or States. To alleviate any such occurrences, hospitals asked to be allowed to make Level I referrals to the State authorities as part of their discharge planning process rather than waiting for the prospective admitting NF to make the referral.

We suggested in the State Medicaid Manual, Transmittal No. 42, and restate in this proposed rule that the State has considerable flexibility in designing its Level I process. If the State chooses, it may use facilities or hospital discharge planners to perform the Level I screening and make referrals to the State mental health and mental retardation authorities. If the State allows hospitals to participate, they can begin the discharge planning process immediately upon admission by alerting the State mental health or mental retardation authority of the need for screening for all individuals with MI or MR who would be likely to need convalescent care after the hospital stay. Alternatively, the State may delegate or contract the Level I activity to another entity, or it may retain it for itself. States appear to have selected a variety of organizational methods for performing the Level I identifications. We are not dictating process, only requiring that the State have a mechanism for identifying who has MI or MR and providing for timely screenings and determinations.

The State's Level I mechanism is responsible for identifying all individuals who have MI or MR, as defined in § 483.102. The statute does not provide any basis for limiting PASARR to only those individuals who have a "known diagnosis" of MI or MR. In the State Medicaid Manual, Transmittal 42, we suggested that facilities and States could protect themselves from the imposition of possible sanctions for failure to identify some individuals who have MI or MR by screening all individuals applying to or residing in the NF in some fashion to determine if they have MI or MR regardless of the "known diagnosis." For current residents, the facility's routine resident assessment process can serve simultaneously as the Level I for annual resident reviews. For new admissions, however, the Level I process may be somewhat more difficult because of a lack of comprehensive and consistent data.

For this reason, we further suggested in the instruction that the Level I evaluator should use discretion in reviewing client data and look behind diagnostic labels when determining whether an individual has a primary or secondary diagnosis of MI and does not have a primary diagnosis of dementia. When no diagnosis of MI is indicated, the Level I evaluator should look for any presenting evidence of MI. (See the instruction for a number of clues that might indicate that MI is the "real" primary or secondary diagnosis). We also cautioned against the possibility of a misdiagnosis resulting from a confusion of MI and dementia. Because a diagnosis of dementia would exclude an individual from further screening, we suggested that a diagnosis of dementia should be supported by positive evidence from a thorough mental status examination which focuses especially on cognitive functioning and which is performed in the context of a complete neurological or neuro-psychiatric examination. We also indicated that a neurological examination on its own may corroborate a diagnosis of

dementia, but such examinations are not determinative. Because we recognize that not everyone will agree with us that the diagnostic screening requirements for determining whether an individual has a primary diagnosis of dementia need be as stringent as these to achieve their purpose, we specifically solicit comments on this issue.

Since a Level I mechanism is required as a necessary component for the State's PASARR program to work, funding issues arise. In State Medicaid Manual transmittal No. 63, issued in July 1989, we clarified PASARR funding issues with respect to Level I and Level II as follows:

• The responsibility for identifying individuals (through Level I screening) who appear to have MI or MR lies with the NF since it is prohibited from admitting any new resident who has MI or MR unless the State mental health or mental retardation authority has determined that the individual requires a NF level of care. (Also, the State cannot make payment for services for any current resident for whom a PASARR determination is required but none has been made.) Depending upon the method of entry of new admissions into a NF, the expense of identifying those individuals who are subject to PAS can possibly be incurred by either the NF or a State employee or contractor. Since a large portion of new admissions to NFs come directly from hospitals, a State may choose to contract with hospitals to have their discharge planners do the Level I screening and referral to the State authorities for PAS. Referrals to the State of current residents for ARR is normally the responsibility of the NF (as an outcome of the routine resident assessments required under section 1919(b)(3) of the Act) unless the State chooses to do the Level I identifications for ARR itself in conjunction with performing Level II evaluations.

If the State performs the identification screening, it is a PASARR activity and will be reimbursed at the 75 percent FFP rate as an administrative cost. If the identification screen is done by the NF it may be made part of the NF rate, and thereby be reimbursed as a Medicaid service at the applicable Federal medical assistance percentage. If the State contracts with third parties such as hospital discharge planners for the identification of individuals who appear to have MI or MR, the reimbursement rate is 75 percent. However, the State may not contract with a NF for the Level I screenings and receive 75 percent FFP since the NF itself has the responsibility to identify and deny admission to those individuals who may have MI or MR.

State expenditures incurred to evaluate and make the required determinations regarding the level of services and active treatment needs for individuals identified as possibly having MI or MR during either the PAS or ARR are reimbursed at the 75 percent rate. This rate also applies to the independent physical and mental evaluation by a person or entity other than the State mental health authority which is required for individuals with MI.

At this time we do not believe it is necessary to establish a time frame for Level I reviews because these decisions appear to be being made speedily. We specifically solicit comments, however, on the issue of whether a time frame is needed and, if so, of what duration.

Because Level I PASARR determinations are appealable (See the preamble discussion of subpart E), we would further specify that the State's Level I mechanism include issuance of written notice to the individual or resident of a decision to refer him or her to the State mental health or mental retardation authority for a Level II PASARR screening because he or she is suspected of having MI or MR.

As another criterion (§ 483.128(b)), we would require that evaluations performed under PASARR must be adapted to the cultural background, language, ethnic origin and means of communication used by the individual being evaluated.

We would require at § 483.128(c) that the State's PASARR program use at least the evaluative criteria of § 483.130 (if one or both determinations can easily be made categorically as described in § 483.130) or of §§ 483.132 and 483.134 or 483.136 (or, in the case of individuals with both MI and MR, §§ 483.132, 483.134 and 483.136 if a more extensive individualized evaluation is required). (See the preamble discussion of categorical determinations under § 483.130).

We would require at § 483.128(d) that in the case of individualized evaluations, information that is necessary for determining whether it is appropriate for the individual with MI or MR to be placed in a NF or in another appropriate setting should be gathered throughout all applicable portions of the PASARR evaluation (§§ 463.132 and 483.134 and/or 483.136). The two determinations relating to the need for NF level of care and active treatment are interrelated and must be based upon a comprehensive analysis of all client data. (See definition of appropriate placement under § 483.126).

In § 483.128(e) we would allow evaluators to use relevant evaluative data, obtained prior to initiation of preadmission screening or annual resident review, if the data are considered valid and accurate and reflect the current functional status of the individual. In cases where categorical determinations can readily be made, existing data must, out of necessity, be used. In more complex cases where individualized determinations must be made, the State's PASARR program will likely need to gather additional information necessary to supplement and verify the currency and accuracy of existing data and to assess proper placement and treatment.

We would require in § 483.128(f) that for both categorical and individualized determinations, findings of the evaluation must correspond to the person's current functional status as documented in medical and social history records.

We would require in § 483.128(g) that for individualized PASARR determinations, findings must be issued in the form of a written evaluative report which meets the following requirements. It must identify the name and professional title of the person(s) who performed the evaluation(s) and the date on which each portion of the evaluation was administered. It must provide a summary of the evaluated individual's medical and social history, including his or her positive traits or developmental strengths and weaknesses or developmental needs. If NF services are recommended, the report must identify the specific services which are required to meet the evaluated individual's needs. If active treatment is not recommended, the report must identify among the NF services that are needed any specific mental retardation or mental health services that are of a lesser intensity than active treatment and are required to meet the evaluated individual's needs. If active treatment services are recommended, the report must identify the specific mental retardation or mental health services required to meet the evaluated individual's needs. Finally, the report must include the bases for the report's conclusions.

We would require in § 483.128(h) that, for categorical PASARR determinations, findings be issued in the form of an abbreviated written evaluative report which meets the following requirements. It must identify the name and professional title of the person applying the categorical determination and the date on which the application was

made. It must explain the categorical determination(s) that has (have) been made and describe the nature of any further screening which is required (if only one of the two required determinations can be made categorically). The report must identify, to the extent possible, based on the available data, NF services, including any mental health or specialized psychiatric rehabilitative services, that may be needed (see the preamble discussion of categorical determinations under § 483.130). We note that under § 438.130(g) a determination that active treatment is needed cannot be made categorically without being followed by a more extensive individualized evaluation to determine the exact nature of the services needed and that, under § 438.130(h) all individuals with MR must receive the more extensive individualized evaluation to determine whether active treatment is needed. Finally, the report must include the bases for the report's conclusions.

For both categorical and individualized determinations, we would require in § 438.128(i) that findings of the evaluation be interpreted and explained to the individual and, to his or her legal representative, when applicable. The individual and his or her representative must also receive a copy of the written evaluation report.

We would require in § 483.128(j), in the case of applicants for NF services, that the evaluation report be submitted within 5 working days by the evaluator to the appropriate State authority so that the appropriate State authority may make the necessary determinations with the 7 working days of referral, as required in § 483.112(c). Since we have specifically solicited comments on the 7 day time frame for completing Level II preadmission screenings, we, of course, would similarly welcome comments on this 5 day requirement.

Lastly, in § 483.128(k) we would permit the evaluation to be terminated if the evaluator finds at any time during the evaluation that the individual being evaluated does not have MI or MR or has a primary diagnosis of dementia (including Alzheimer's Disease or a related disorder) and does not have a diagnosis of MR or a related condition.

In § 483.130 we would specify general requirements for PASARR programs with respect to determinations. Specifically, we would require that all determinations made under the State's PASARR program meet the determinative criteria described below.

First, in § 483.130(a) we require that determinations made by the State mental health or mental retardation authority as to whether NF level of services and active treatment are needed must be based on an evaluation of data on the individual, either as specified in (b) of this paragraph or in §§ 483.132 (PASARR/NF), 483.134 (PASARR/MI) 483.136 (PASARR/MR) (or, in the case of an individual having both MR and MI, §§ 483.132, 483.134 and 483.136).

In § 483.130(b) we would permit the determinations in paragraph (a) of this section to take the form of advance group determinations by category that take into account that certain diagnoses or levels of severity of illness clearly indicate that admission to or residence in a NF or the provision of active treatment is or is not normally needed or the determinations may take the form of individualized determinations based on more extensive individualized evaluations as required in § 483.132, 483.134, or 483.136. In the case of an individual having both MR and MI, 483.132, 483.134 and 483.136 would both be required.

In § 483.130(c), we would permit advance group categorical determinations developed by the State mental health or mental retardation authorities to be applied by the NF or other evaluator following Level I review only if existing data on the individual appear to be current and accurate and are sufficient to allow the evaluator to determine readily that the individual fits into the category established by the State authorities. At a minimum, existing data should include all the data requirements listed in § 483.132(c). Sources of existing data on the individual which could form the basis for applying a categorical determination by the State authorities would be hospital records, physician's evaluations, election of hospice status, records or community mental health centers or community mental retardation or developmental disability providers.

In § 483.130(d), we present examples of categories for which the State mental health or mental retardation authority may make an advance group determination that NF services are needed. These include, but are not limited to, convalescent care from an acute physical illness for which hospitalization was required; terminal illness as defined for hospice purposes in § 418.3; and severe physical illness such as coma, ventilator dependence, functioning at a brain stem level, or diagnoses such as obstructive pulmonary disease, Parkinson's disease, Huntington's disease, amyotrophic lateral sclerosis, and congestive heart failure which result in a level of physical impairment so severe that the individual could not be expected to benefit from active treatment.

We would also permit a category which provides for provisional admissions pending further assessment in cases of delirium when an accurate diagnosis cannot be made until the delirium clears. Another category would provide for very brief and finite stays of up to a fixed number of days to provide respite to in-home caregivers to whom the individual with MI or MR is expected to return following the brief NF stay or in order to permit alternative arrangements for longer term care in emergency situations requiring protective services.

In § 483.130(d) (1)–(5), we are proposing five types of categorical determinations for which NF care is normally needed. However, we do not wish to imply that this list is all-inclusive. States may wish to establish other reasonable categories for expedited determinations so long as the intent of the process is not to create a means of avoiding the PASARR requirements.

For this same reason, we would further specify that the State may establish time limits for categorical determinations that NF services are needed and, in the case of paragraph (d) (4) and (5), must specify a time limit which is appropriate for provisional admissions pending further assessment and for respite care. If an individual, originally admitted under paragraphs (d) (4) or (5), is later found to need a longer stay than the State's limit allows, the individual would have to be subjected to a more thorough individualized PASARR evaluation before continuation of the stay could be permitted and payment could be made for days of NF care beyond the State's time limit. We believe this requirement is necessary in order to prevent provisional and respite admissions from being used as a loophole for avoiding performance of more thorough PASARR screenings. Once the individual has been admitted to the NF, a "preadmission" screening obviously cannot be performed, but resident reviews are required "at least annually." Under this requirement, an immediate resident review would have to be performed if a resident's stay exceeded the State limit for the categorical admission. We would anticipate, however, updating of the resident's preadmission screening results (as in the case of inter-facility transfers at § 483.106(b)) if portions of the original preadmission screening determination were based on the more thorough individualized evaluation.

We would specify in § 483.130(e), that the State mental health authority must require the more extensive individualized evaluations for at least each resident or applicant with a diagnosis in any of the following categories to see whether active treatment services for MI are needed: schizophrenia, paranoia, major affective disorders, schizoaffective disorders, and atypical psychosis.

In § 483.130(f), we would permit the State mental health authority to devise lists of minor mental disorders (with the exception of MR) which alone normally do not warrant active treatment and should not serve as barriers to admission to or continued residence in a NF. In general, we would anticipate that nearly all categorical determinations with respect to the need for active treatment should only be in the negative—that the individual does not need active treatment because of the presence of data indicating that the individual has only some minor mental disorder.

We would propose in § 483.130(g) that the State mental health and mental retardation authorities must not make categorical determinations that active treatment is needed without requiring that such a determination be followed by a more extensive individualized evaluation under § 483.134 or 483.136 to determine the exact nature of the active treatment services which are needed.

In § 483.130(h) we would propose that the State mental retardation authority must not make categorical determinations that active treatment is not needed for individuals with MR. A determination that an individual with MR does not need active treatment must be based on a more extensive individualized evaluation under § 483.136.

We would also propose, however, in § 483.130(i) that the State mental health or mental retardation authority may make categorical determinations that certain mental conditions or levels of severity of MI would normally require active treatment services of such an intensity that an acceptable active treatment program could not be delivered by the State in most, if not all, NFs and that another, more appropriate placement must be utilized in all optional placement situations. We would provide for an exception to this type of categorical determination for the long-term resident group identified in § 483.118(c)(1) to whom the Act grants a right to stay in the NF, if they so choose. In all other cases, under § 483.130(g), the State must not admit the individual to a NF even if the individual meets other criteria for a categorical determination with respect to physical needs. The eventual placement decision would have to be made after a more extensive individualized evaluation of the active treatment needs. This might mean, for instance, that even though the severely psychotic individual is ventilator dependent, suffers from congestive heart failure, or is terminally ill, he or she should receive the physical care he or she needs in a psychiatric hospital rather than in a NF.

In § 483.130(j), we would permit the State mental health or mental retardation authority to make a categorical determination that certain individuals of advanced years may, for payment and placement purposes, be allowed to decline active treatment in a NF under certain limited circumstances. First, the individuals must have already been determined either categorically or individually to need NF care and, based on an individualized evaluation, to need active treatment. We do not believe that a positive determination that an individual needs active treatment can be made categorically. A more extensive evaluation to determine the exact nature of the services needed must be performed before active treatment services can be declined. In addition, for payment and placement purposes, we would specify that in order to permit an individual to decline active treatment on the basis of advanced years, the individual must not be a danger to him or herself or others; the categorical determination to let the individual forego active treatment must be left open as to a specific age; and the decision must be made on an individual basis by the client or his or her legal representative. As they age, individuals with MR or MI vary considerably in their abilty to benefit from active treatment. Any advanced years category which the State might adopt must take this fact into account.

In permitting such an advanced years category, we in no way intend to limit a resident's right to refuse treatment. As provided for in the February 2, 1989 rule in § 483.10(b)(4), a resident always has a general right to decline any medical treatment he or she chooses to decline. Our discussion here of an advanced years category is aimed at preventing a blanket application by a State of an advanced years categorical determination to all individuals with MI or MR in a NF who are of a certain age specified by the State. We are concerned that States could easily abuse such a category in an effort to relieve themselves of the responsibility of providing active treatment to individuals in the group who need it. Many of these individuals, we believe, would not, except for the urging of the State, decline these services. We do believe, however, that an advanced years category may be useful in making placement and payment decisions. (For the origins of this categorical determination, see a pre-existing section of the State Medicaid Manual, section 4395, on inappropriate placement of mentally retarded persons in SNFs and ICFs, which was most recently revised in August 1986).

In § 483.130(k) we would require that the State make determinations for all mental disorders described in the Diagnostic and Statistical Manual of Mental Disorders, 3rd edition, Revised, except for dementias, and require determinations, either categorically or individually.

In § 483.130(l), we would specify that if a determination concerning NF needs takes the form of a categorical determination, the State may not waive the active treatment determination. The individual must also receive either a categorical determination that active treatment is not needed, or be subjected to a more extensive individualized evaluation as specified in §§ 483.134 or 483.136.

In § 483.130(m), we would require that all determinations of whether an individual requires the services provided by a NF, regardless of how they are arrived at, must be recorded in the individual's record. If the individual resides in or is admitted to the NF, the NF's records on the resident must state that the individual was subjected to PASARR and must provide substantive information concerning the date and nature of the determinations. This information is needed in the NF resident's record for compliance as well as administrative purposes. That is, the NF must be able to demonstrate the PASARR status of all residents with MI or MR. The NF's resident records must also permit identification of residents who either are or are not subject to annual residents reviews. For example, if an individual was subjected to PASARR, or a partial PASARR, and was determined not to have MR or MI, this information should be noted in the resident's record so that he or she will not be subjected to subsequent annual reviews (unless evidence subsequently emerges to question the determination that the individual does not have MR or MI). An indication of a previous PASARR in the resident's records will also serve as a reminder that PASARR data must be taken into account in performing the NF's routine assessments on the resident.

In § 483.130(n) we would require that the evaluated individual and his or her legal representative, when applicable, be advised in writing of the determinations that have been made and, with the notice of determinations, be advised of his or her appeal rights under Subpart E of this part.

In § 483.130(o), we would specify that the notice of determinations made by the State mental health or mental retardation authority must indicate clearly whether a NF level of services and active treatment are needed. Also, the notice of determination must indicate the placement options that are available to the individual consistent with these determinations.

In § 483.130(p) we would identify the placement options and the required State actions that are consistent with the Act and these regulations. For applicants to a NF, there are two placement options, described in § 483.130(p) (1) and (2). Applicants either can or cannot be admitted to the NF. Those who can be admitted to the NF are applicants with MI or MR who require the level of services provided by the NF, regardless of whether active treatment is also needed, if the placement is appropriate (see § 483.126). If active treatment is also needed, the State is responsible for providing or arranging for the provision of the active treatment services. The NF, however, is not required to admit the individual even if the State mental health or mental health authority determines that the individual can be admitted. Those who cannot be admitted to the NF are applicants with MI or MR who do not require the level of services provided by a NF, regardless of whether active treatment is also needed. Because they do not require a NF level of services, they are inappropriate for NF placement and cannot be admitted.

For current residents, the placement options are more complex. In § 483.130(p)(3), we would specify who can be considered appropriate for continued placement in a NF. Any resident with MI or MR who requires the level of services provided by a NF, regardless of the length of his or her stay or the need for active treatment, can continue to reside in the NF, if the placement is appropriate (See § 483.126).

In § 483.130(p)(4), we would specify who may choose to remain in the NF even though the placement would otherwise be inappropriate. Any resident with MI or MR who does not require the level of services provided by the NF but does require active treatment and who has continuously resided in a NF for at least 30 consecutive months before the date of determination may choose to continue to reside in the facility or to receive covered services in an alternative appropriate institutional or noninstitutional setting. Wherever the resident chooses to reside, the State must meet his or her active treatment needs. The determination notice must provide information concerning how, when, and by whom the various placement options available to the resident will be fully explained to the resident.

In § 483.130(p)(5) we would specify who cannot be considered appropriate for continued placement in a NF and must be discharged (short-term residents). Any resident with MI or MR who does not require the level of services provided by a NF but does require active treatment and who has resided in a NF for less than 30 consecutive months must be discharged in accordance with § 483.12(a) to an appropriate setting in which the State must provide active treatment services. The determination notice must provide information of how, when, and by whom the resident will be advised of discharge arrangements and of his or her appeal rights under both PASARR and discharge provisions. Provisions of an approved ADP under which the individual is covered may also be explained.

In § 483.130(p)(6), we specify who cannot be considered appropriate for continued placement in a NF and must be discharged (short- or long-term residents). Any resident with MI or MR who requires neither the level of services provided by a NF nor active treatment must be discharged in accordance with § 483.12(a), regardless of the length of his or her stay. The determination notice must provide information about how, when, and by whom the resident will be advised of discharge arrangements and of his or her appeal rights under both PASARR and discharge provisions.

We would require in § 483.130(q), that if a determination is made to admit or allow to remain in a NF an individual who requires active treatment, the determination must be supported by assurances that the active treatment services which are needed can, or in the case of a long term resident who chooses to remain in the NF, will be provided or arranged for by the State while the individual resides in the NF.

In § 483.130(r) we would require the State PASARR system to maintain records of evaluations and determinations, regardless of whether they are performed categorically or individually, in order to support its determinations and actions and to protect the appeal rights of individuals subjected to PASARR. We believe that documentation to support findings is important to justifying determinations made by the State mental health and mental retardation authorities, should individuals feel they are adversely affected by any aspect of the PASARR process (See the later discussion of appeals in this preamble). Since individuals may appeal a decision that they have or do not have MI or MR, that they do or do not need NF services, or that they do or do not need active treatment, accurate records of all parts of Level I and Level II decisions must be maintained.

In addition to providing support for its determinations and protecting individuals' appeal rights, maintenance of records indicating dates of determinations and notification is needed to establish schedules for subsequent annual resident reviews. To this same end, we would impose as a final requirement in § 483.130(s) that the State PASARR system must establish and maintain a tracking system for all individuals with MI or MR in NFs to ensure that future reviews are performed in accordance with the requirements of this subpart. Tracking is also needed for operating the appeals system.

We base these criteria on the advice of our consultants and other individuals who have provided us with advice and comment in the course of developing the current operating instructions and this proposed regulation. As indicated earlier, this consultive process has been in progress since early 1988.

In § 483.132 we would provide specific criteria for evaluating the need for NF services and NF level of care. In the State Medicaid Manual we referred to this portion of the PASARR evaluation process as PASARR/NF. These criteria must be used in performing individualized evaluations. The minimum data requirements of subsection (c) should also serve as a guide in judging the adequacy and completeness of existing data before applying categorical determinations with respect to the need for NF care which the State has developed. Categorical determinations cannot be made without sufficient evaluative data. (See § 483.130(c)).

In § 483.132(a) we would require that for each individual or resident with MI or MR the evaluator must assess whether the individual's total needs are such that they can only be met on an institutional basis and whether the NF is the appropriate institutional setting for meeting those needs (See § 483.126). We are aware that considerable difference

of opinion can exist over whether institutionalization is necessary or whether community care is a viable option. We note that the entire determination of whether NF care is needed is subject to appeal. Therefore, judgments concerning institutional versus community placement, which are a part of the larger determination, are also appealable.

We would further specify in § 483.132(b) that prioritization of needs is essential to determining appropriate placement. Therefore, the evaluator must prioritize the physical and mental needs of the individual being evaluated and the severity of each condition.

In § 483.132(c) we would require that, at a minimum, the data used in evaluating an individual's need for NF care include the following: an evaluation of physical status (for example, diagnoses, date of onset, medical history, and prognosis); an evaluation of mental status (for example, diagnoses, date of onset, medical history, likelihood that the individual may be a danger to him or herself or others); and a functional assessment (activities of daily living). Criteria for determining whether individuals with mental illness require active treatment (PASARR/MI).

In § 483.134, we identify the minimum data needs and process requirements for a State to determine whether or not the individual with mental illness needs an active treatment program for mental illness.

In § 483.134(b), we would require that the data collected include—

- A comprehensive history and physical examination of the individual. If the history and physical examination are not performed by a physician, then a physician must review and concur with the conclusions. The following areas must be included (if not previously addressed):

—Complete medical history;
—Review of all body systems;
—Specific evaluation of the individual's neurological system in the areas of motor functioning, sensory functioning, gait, deep tendon reflexes, cranial nerves, and abnormal reflexes; and
—In case of abnormal findings which are the basis for a NF placement, additional evaluations conducted by appropriate specialists.

- A comprehensive drug history including, but not limited to, current or immediate past use of medications that could mask symptoms or mimic mental illness.
- A psychosocial evaluation of the individual, including current living arrangements, medical, and support systems. If the psychosocial evaluation is not conducted by a licensed social worker, then a licensed social worker must review and concur with the conclusions.
- A comprehensive psychiatric evaluation including a complete psychiatric history, evaluation of intellectual functioning, memory functioning, and orientation, description of current attitudes and overt behaviors, affect, suicidal or homicidal ideation, paranoia, and degree of reality testing (presence and content of delusions) and hallucinations. If the psychiatric evaluation is not performed by a physician, then a board-eligible or board-certified psychiatrist must review and concur with the conclusions.
- A functional assessment of the individual's ability to engage in activities of daily living and the level of support that would be needed to assist the individual to perform these activities while living in the community. The assessment must determine whether this level of support can be provided to the individual in an alternative community setting or whether the level of support needed is such that NF placement is required.
- The functional assessment must address the following areas: Self-monitoring of health status; self-administering and scheduling of medical treatment, including medication compliance; self-monitoring of nutritional status; handling money; dressing appropriately; and grooming.

Based on the data compiled, we would require a board-eligible or board-certified psychiatrist to validate the diagnosis of mental illness and determine whether and to what extent a program of psychiatric active treatment is needed.

Criteria for Determining Whether an Individual With Mental Retardation Requires Active Treatment (PASARR/MR)

In § 483.136(a), we specify the purpose of § 483.136, which is to identify the minimum data needs and process requirements for a State to determine whether or not the individual with mental retardation or a related condition needs a continuous active treatment program, as defined in § 435.1009, "Active treatment in Intermediate Care Facilities for the Mentally Retarded" and § 483.440.

In § 483.136(b), we would require that minimum data collected must include the individual's comprehensive history and physical examination results to identify the following information or, in the absence of data, specific information that permits a reviewer to assess:

- The individual's medical problems;
- The level of impact these problems have on the individual's independent functioning;
- All current medications used by the individual and the current response of the individual to any prescribed medications in the following drug groups:

—Hypnotics,
—Antipsychotics (neuroleptics),
—Mood stabilizers and antidepressants,
—Antianxiety-sedative agents, and
—Anti-Parkinsonian agents.

- Self-monitoring of health status;
- Self-administering and scheduling of medical treatments;
- Self-monitoring of nutritional status;
- Self-help development such as toileting, dressing, grooming, and eating;
- Sensorimotor development, such as ambulation, positioning, transfer skills, gross motor dexterity, visual motor perception, fine motor dexterity, eye-hand coordination, and extent to which prosthetic, orthotic, corrective or mechanical supportive devices can improve the individual's functional capacity;
- Speech and language (communication) development such as expressive language (verbal and nonverbal), receptive language (verbal or nonverbal), extent to which non-oral commuication systems can improve the individual's function capacity, auditory functioning, and extent to which amplification devices (e.g. hearing aid) or a program of amplification can improve the individual's functional capacity;
- Social development, such as interpersonal skills, recreation-leisure skills, and relationships with others;
- Academic/educational development, including functional learning skills;
- Independent living development such as meal preparation, budgeting and personal finances, survival skills, mobility skills (orientation to the neighborhood, town, city), laundry, housekeeping, shopping, bedmaking, care of clothing, and orientation skills (for individuals with visual impairments);
- Vocational development, including present vocational skills;
- Affective development such as interest and skills involved with expressing emotions, making judgments, and making independent decisions; and
- The presence of identifiable maladaptive or inappropriate behaviors of the individual based on systematic observation including, but not limited to, the frequency and intensity of identified maladaptive or inappropriate behaviors.

We would require that States ensure that a psychologist who meets the qualifications of a Qualified Mental Retardation Professional, as defined in 42 CFR 483.430(a), identify the individual's intellectual functioning measurement and validate that the individual has mental retardation or is a person with a related condition. The State mental retardation authority must review the data collected from this section and determine whether the person's status compares with each of the following characteristics commonly associated with a need for active treatment:

- Inability to—
- Take care of most personal care needs;
- Understand simple commands;
- Communicate basic needs and wants;
- Be employed at a productive wage level without systematic long term supervision or support;
- Learn new skills without aggressive and consistent training;
- Apply skills learned in a training situation to other environments or settings without aggressive and consistent training;
- Demonstrate behavior appropriate to the time, situation or place without direct supervision; and
- Make decisions requiring informed consent without extreme difficulty;
- Demonstration of severe maladaptive behavior(s) that place the individual's or others health or safety in jeopardy; and
- Presence of other skill deficits or specialized training needs that necessitate the availability of trained MR personnel, 24 hours per day, to teach the person functional skills.

Credentialing Issues

We recognize that some readers will disagree with the judgments we have made concerning the qualifications that persons taking part in PASARR evaluations and determinations should have in order to perform these functions. We are also aware that Congress has recently been expanding the role of certain mental health providers under the Medicare program where States have authorized them to practice autonomously. In this proposed rule we have retained the credentialing requirements essentially as they were stated in the May 1989 State Medicaid Manual issuance which we developed through extensive consultation with a wide variety of groups. The sole change we have made thus far is to permit board-eligible as well as board-certified psychiatrists to pass judgment on whether active treatment is needed.

We considered making further and more substantial revisions to these requirements in this proposed rule, but decided that to do so now would be to listen only to select views rather than to the full range of public opinion which could be expected to respond during the public comment period. We believe that if active treatment is analogous to the care one would receive in a psychiatric hospital where the care is required to be supervised by a physician or a psychiatrist, a physician or psychiatrist ought to at least concur in positive determinations that active treatment is needed.

By deciding to not revise the credentialing recommendations of the program instruction in this proposed rule, we do not wish to imply that we are wedded to the particular position espoused here. We believe that full consideration needs to be given to all sides through the process of public comment. We therefore specifically solicit comments on these manpower and credentialing issues. In particular, we wish to receive comments on whether other professionals, for example, psychologists or clinical social workers, may have the skills needed to make these determinations.

Instructional Materials

Since the publication of our May 1989 State Medicaid Manual issuance containing implementation instructions, some additional information has come to light. First, we have learned that in discussing the statutory definition of MI our comments on Axis I and II diagnoses in DSM–III–R was somewhat inaccurate. In making categorical determinations as to the need for active treatment, States should not automatically assume that all Axis II diagnosis are minor. Regardless of under which axis a diagnosis appears, the current severity of impairment caused by the disorder is more important to making a valid determination concerning appropriate placement and the need for active treatment than the diagnosis itself. Categorical determinations by States should, therefore, be behaviorally-based rather than diagnosis-based.

Second, we have received additional questions concerning the clinical basis for discrimination between a diagnosis of dementia and that of another category of mental illness. We are taking the position that in order to serve as a means of excluding an individual from further screening, a diagnosis of dementia should be supported by positive evidence from a thorough mental status examination which focuses especially on cognitive functioning and which is performed in the context of a complete neuro-psychiatric examination. A full neurological examination is generally not required. We have also received anecdotal information that at least one State may be routinely requiring CAT scans or MRI examinations to verify a diagnosis of dementia. Employing these measures routinely would appear to be inappropriate as well as wasteful when the diagnosis has been reasonably established on the basis of a prior examination and a patient's medical history. Our principal concern is that if an individual is exempted from further screening under PASARR based on this exclusion, the reason for the non-referral should be well documented.

Third, some individuals have raised the question of whether dementia as a secondary diagnosis still fits the definition of a mental illness since it is a mental disorder described in DMS–III–R and it is not primary. We have been advised that in most cases dementia would be classified as the primary diagnosis if a person also had another mental illness. However, in the case of someone with dementia seeking admission to a nursing facility for a physical problem, the order might be reversed. If the dementia were the secondary diagnosis, further screening would be required.

Fourth, we have become aware that the terms primary and secondary need definition. We are taking the view that a primary diagnosis is the principal diagnosis or that condition which is chiefly responsible for the proposed admission or continued residence in a NF. The secondary diagnosis would be the second most important reason for admission or continued residence. Since we have been advised that these PASARR requirements apply to individuals with mental illness or mental retardation without regard to "known diagnosis," the mere order in which diagnoses are listed on a chart cannot alone establish which diagnosis is primary and which is secondary or tertiary, etc. The mere listing of diagnoses would encourage avoidance of PASARR screening. The purpose of the Level I identification screen is to determine what the individual's real needs are since the NF will have to deal with them if the individual is admitted or allowed to stay in the NF.

In order to offer the public further opportunity to comment on this new information, we are publishing these comments on the instructional materials with this proposed rule. Readers who wish to comment may wish to consult the program manual instruction for more detailed discussions of the issues

involved. Copies of the State Medicaid Manual Transmittal No. 42 HCFA Pub. 45–4 can be obtained by calling the contact person listed at the beginning of this preamble.

Section 1919(c)(2)(B) of the Act requires that before a NF discharges or transfers a resident, the NF must notify the resident or the legal representative at least 30 days in advance of the resident's discharge or transfer. The law provides that under certain circumstances, the notice period may be less than 30 days. We would provide in § 483.138 that if a NF mails a 30 day notice of its intent to discharge or transfer a resident, under existing provisions in § 483.12(a), the agency may not terminate or reduce services until the 30 day notice period has expired. FFP would be available for NF services provided to Medicaid recipients during the notice period. We believe it would be inequitable to require that the agency maintain services to a resident who has received a 30 day notice and not have the period covered by FFP. FFP may also continue beyond the 30 day notice period if the decision to transfer or discharge is under appeal and the appeals process has not yet reached a conclusion.

Appeals of Discharges, Transfers, and PASARR Determinations

Section 1819(c)(2) and 1919(c)(2) of the Act set forth the transfer and discharge rights of residents of skilled nursing facilities participating in Medicare and nursing facilities participating in Medicaid. The requirements for ensuring the transfer and discharge rights of residents in nursing facilities (section 1919(c)(2)) are likewise applicable to residents required to be transferred or discharged as a result of the annual resident review process in accordance with section 1919(e)(7)(C)(ii)(I) and section 1919(e)(7)(C)(iii)(I) of the Act. These requirements are addressed at 42 CFR 483.12 as part of the rules governing long term care facilities published at 54 FR 5316, 5362 (Feb. 2, 1989). (The effective date of those regulations was delayed to October 1, 1990 by a notice published in the Federal Register December 29, 1989 at 54 FR 53611.) While 42 CFR 483.12 sets forth the requirements for notification of the right to appeal, the appeals process to be used is proposed in this regulation. These proposed regulations also implement the appeals rights of individuals adversely affected by the PASARR determinations as required by section 1919(e)(7)(F) of the Act.

In particular, these regulations would implement the requirements of sections 1819(c)(2)(B)(iii)(I), 1819(e)(3), and 1819(f)(3) of the Act with respect to appeals of discharges and transfers made by skilled nursing facilities participating in Medicare, sections 1919(c)(2)(B)(iii), 1919(e)(3), and 1919(f)(3) of the Act with respect to appeals of involuntary transfers and discharges made by nursing facilities which participate in Medicaid, and section 1919(e)(7)(F) of the Act with respect to appeals of adverse determinations made by the State in its preadmission screening and annual resident review of NF residents with mental illness or mental retardation. These sections of the Act require that the State establish and maintain an appeals process that is available to individuals proposed to be transferred or discharged from skilled nursing facilities and nursing facilities or adversely affected by a PASARR determination.

In developing these proposed rules we examined sections 1819(e)(3), 1819(f)(3), 1919(e)(3) and 1919(f)(3) of the Act, which require that the State must provide for a fair mechanism for hearing appeals on transfers and discharges and section 1919(e)(7)(F) of the Act, which provides that the State must have in effect an appeals process for individuals adversely affected by PASARR determinations. We also examined the legislative history of section 1919(e)(7)(F) which states that:

> [t]he [C]committee on the Budget] expects that these appeals procedures will offer mentally ill and mentally retarded individuals at least the due process protection of a Medicaid fair hearing under current law, including notice of the right to appeal, right to representation by counsel, and right to a fair and impartial decision-making process. (H.R. Rep. No. 391, 100th Cong., 1st Sess. 463 (1987)).

Therefore, to the extent possible, we propose an appeals process that uses the Medicaid fair hearing process specified in 42 CFR part 431, subpart E. While we believe the majority of the fair hearing processes can be applied to appeals regarding SNF and NF transfers, discharges, and adverse PASARR determinations, there are certain elements of the fair hearing regulations that cannot be made applicable because of unique statutory requirements governing these appeals.

The fair hearing regulations require, with some exceptions, that a notice must be mailed 10 days, or in some cases 5 days, before the date the adverse action will be taken. Sections 1819(e)(2)(B)(i) and 1919(c)(2)(B)(ii) of the Act require that, subject to certain exceptions, 30 days notice must be given for transfers and discharges. If, as a result of one of these exceptions, the facility provides less than 10 days notice, we would provide in § 431.213(h) that the State may mail a notice of the action not later than the date of the action since 10 days notice would be impossible in such situations. Likewise, an exception from the 10 day notice requirement has also been made for notices involving preadmission screening determinations.

The fair hearing regulations specify the contents of the notice to be given by the State to an individual. Sections 1819(c)(2) and 1919(c)(2) state the requirements for transfer and discharge notices to be given by the facilities. These requirements are set forth in regulations at 42 CFR 483.12 and will be required in addition to those required of the State by the fair hearing regulations.

The fair hearing regulations provide for the maintenance and the reinstatement of services, and for FFP for expenditures for such services, until after the hearing is conducted, if certain conditions are met. This same process would apply to hearings for the transfer and discharge of Medicaid recipients under the proposed regulation. The fair hearing provisions and these proposed regulations provide only for continued funding for Medicaid recipients, not for Medicare recipients. Funding of Medicare services is available only to the extent it is otherwise available under Title XVIII of the Act.

In this regulation, we propose to make changes in the fair hearings regulations at 42 CFR part 431, subpart E in order to add the appeals required by these regulations as well as to make conforming changes to accommodate the differences in the appeals process that are discussed above.

In § 483.200, we restate the statutory basis for the provisions in subpart E, which are sections 1819(e)(3), 1819(f)(3), 1919(e)(3), and 1919(f)(3) of the Act.

In § 483.202 we propose to include definitions of resident, individual, transfer and discharge for purposes of this subpart and subparts B and C. We propose to define a "resident" as being a resident of a SNF or NF or any legal representative of the resident. Similarly, we propose to define "individual" with respect to PASARR determinations, as being an individual or any legal representative of the individual. We propose these definitions so that the resident or individual may be represented by anyone of his or her choosing (including legal counsel, a long term care ombudsman, family or friend) so long as the representative is appointed through some legal process designated under State law.

We propose to define "transfer" as meaning movement of a resident from

an entity that participates in Medicare as a skilled nursing facility, a Medicare certified distinct part, an entity that participates in Medicaid as a nursing facility, or a Medicaid certified distinct part to another institutional setting and the legal responsibility for the care of the resident changes from the transferring facility to the receiving facility. Similarly, we propose to define "discharge" as meaning movement from an entity that participates in Medicare as a skilled nursing facility, a Medicare certified distinct part, an entity that participates in Medicaid as a nursing facility or a Medicaid certified distinct part to a noninstitutional setting and the discharging facility ceases to be legally responsible for the care of the resident.

States and consumer advocates have asked whether we define "transfer" and "discharge" for purposes of this requirement as including relocation within the facility. As specified in § 483.206, appeals of discharges and transfers would apply only to discharges from the facility and to transfers to another facility; they do not apply to the relocation of a resident within a facility. We believe that both the Act and the relevant legislative history support our interpretation. Specifically, sections 1819(c)(2)(A) and 1919(c)(2)(A) both refer to "transfer and discharge * * * from the facility." Moreover, the report of the Budget Committee report also refers to transfer and discharge from the facility (H.R. Rep. No. 391, 100th Cong., lst Sess. 932 (1987)).

However, note that, for this purpose, we consider a "facility" to be the certified entity so that:

- When a resident is moved from a certified bed into a noncertified bed, he or she is transferred to another facility and would have appeal rights;
- When he or she is moved from one bed in the certified entity to another bed in the same certified entity, he or she is relocated, not transferred and would have no appeal rights;
- When he or she is moved from a bed in a certified entity to a bed in an entity which is certified as a different provider, he or she is transferred and would have appeal rights.

Although these regulations do not propose to require States to establish appeals processes for relocations of residents in facilities, we are aware that some States and localities already have appeals procedures for relocation within a facility. Since facilities must comply with relevant State and local laws and regulations, such requirements would continue in effect and States would not need to conform them to these regulations. Similarly, some States and localities have more stringent requirements for the timeliness of appeals of transfers, discharges and relocations than we propose. Where the current requirements are more stringent than the proposed Federal requirements, no changes would be necessary to conform them to these requirements once final.

Because we have received questions from some States concerning the scope of PASARR appeals, we wish to clarify that both of the formal PASARR determinations made by the State mental health and mental retardation authorities are appealable (i.e., that NF care is (or is not) needed and that active treatment is (or is not) needed). We base our view that PASARR appeals are not to be limited solely to denials of admissions to a NF on the legislative history which states:

> To protect individuals against erroneous State determinations the Committee amendment would require States, by January 1, 1989, to have in place a fair process to allow individuals adversely affected by a State determination in the context of either a preadmission screening or an annual review to appeal that determination. Individuals could be adversely affected not only by a determination that he or she does not need nursing facility services, but also by determinations that he or she does not need active treatment. (H.R Rep. No. 391, 100th Cong., 1st Sess. 462–463 (1987)).

Both categorical and individualized determinations made by the State mental health and mental retardation authorities with respect to the need for NF care and active treatment, as described in section 483.130, are appealable The determination that NF level of care is or is not needed contains within it a judgment concerning institutional versus community placement. As such, this judgment is also appealable.

In addition, we believe that the State's PASARR system could err at other points than solely through the two formal PASARR determinations. Such erroneous actions could adversely affect individuals and are, therefore, appealable. For instance, an individual could object to being classified as having or not having mental illness or mental retardation. Such a determination is made during the Level I phase of PASARR and in the final verification at the end of PASARR. We believe that an individual cannot appeal the requirement that he or she is subject to PASARR because he or she has mental illness or mental retardation, but the Level I determination, performed by the NF or other Level I agent of the State, that the individual has mental illness or mental retardation (and is therefore subject to PASARR) is appealable. (See § 483.128(a) which requires that the State have a system for making Level I determinations).

Determinations of who has mental illness or mental retardation are likely to be subject to question for a number of reasons. First, the statutory definition of mental illness is very broad, including minor mental disorders. Secondly, because the definition of mental illness rests on a ranking of the individual's medical problems, an individual could dispute the determination that a mental disorder is the primary or secondary diagnosis. In addition, there is the possibility of misdiagnosis between dementia, which would exclude an individual from PASARR, and mental illness, which would necessitate screening. Also, individuals with certain forms of mental retardation, such as Down's Syndrome, often develop dementia as they reach the middle years. Since NFs may have a vested interest in referring all suspected cases of mental illness or mental retardation for screening, individuals need a mechanism to appeal a positive Level I determination.

Such individuals could claim they are adversely affected when a PASARR referral may result in delayed admission or a denial of NF care. In the case of NF applicants, having to await completion of preadmission screening may result in at least a temporary denial of appropriate care, added hospital bills, or other hardships. However, under the 7 day timeframe we have proposed for preadmission screenings (see § 483.112(c)), a screening would take less time than an appeal. Therefore, in including Level I determinations within the scope of appeals, we do not believe we would be inviting a large number of frivolous appeals.

Similarly, we believe a negative finding of mental illness or mental retardation is appealable. For example, a determination could be made during the course of a PASARR evaluation that the individual does not have mental illness or mental retardation. Also, an individual could contest a determination that he or she is not subject to PASARR because he or she does not have mental illness or mental retardation. Because section 1919(e)(7)(C) of the Act provides benefits to certain individuals, principally the right of long-term residents to choose to remain in the NF if it is found that he or she does not need NF services but does need active treatment, an individual must have a right to request a PASARR if one has been denied or to question the cessation of PASARR on the grounds that the

individual does not have mental illness or mental retardation.

We considered how negative Level I determinations could result in a request for a hearing without having to require issuance of a notice to all individuals who are excluded from PASARR by virtue of not having MI or MR. Requiring individual negative notices would create an overwhelming paperwork burden. That is, every applicant to a Medicaid-certified nursing facility who is found not to have MI or MR would have to be issued a notice to this effect. In addition, all continuing residents without MI or MR would have to be issued a notice on an annual basis. Since we envision that the nursing facility's annual resident assessment process may serve as the Level I mechanism for identifying continuing residents who have MI or MR and must be referred to the State mental health and mental retardation authorities for annual resident review, the responsibility of issuing notices to residents who do not have MI or MR would likely fall to the NF. We are unwilling to impose such a burden. However, without a notice, it is unclear how applicants and residents can know of the action which was taken concerning them and of their right to appeal that action. We specifically solicit comments on how we might devise a method of notification which works without being unnecessarily burdensome.

Because we believe that all PASARR determinations (both Level I or Level II) are appealable, we would specify in § 483.204 that the State must provide a system for an individual who has been provided any PASARR determination (Level I or Level II) by the State under subpart C of part 483 to appeal that determination. Since the State is reguired to have a Level I mechanism for indentifying individuals or residents with MI or MR (§ 483.128(a)), we consider Level I decisions made by whatever agent(s) the State designates to perform this function to be State actions.

The proposed regulation requires that payment be maintained for services provided under the Medicaid program at least during the 30 day period required for notification of a transfer or discharge under 42 CFR 483.12(a)(4). Thus, even if the State completed the appeals process before the 30 day period concluded, a decision adverse to the patient would not take effect until after the 30 day period. Authorization for payment for services provided under the Medicare program is not provided by these regulations. Thus payment for such services during the course of the appeal and including the 30 day notification period is available only so far as it is otherwise available under the Medicare program.

The appeals process proposed in these regulations will be used in lieu of other appeals processes available to individuals under Titles XVIII and XIX of the Act with regard to the issues included in the appeal. In this regulation, we propose to make changes in the fair hearing regulations at 42 CFR part 431, subpart E in order to add the appeals required by this regulation and make conforming changes in the regulations governing reconsiderations and appeals under the Medicare program at 42 CFR 405.705.

We recognize that the appeals procedures we propose raise several difficult questions. We are particularly concerned about the application of the process to preadmission screening appeals, and to appeals of the various types of transfers and discharges which are exempt from the 30 day notice requirement. In both these instances, a faster appeals process than provided for here may be appropriate. We are also concerned about the application of these appeals procedures to private pay individuals and to individuals for whom Medicare coverage would not be available for the entire appeals period. We would welcome comments and suggestions regarding any aspects of the process and particularly regarding how we might modify the process to permit expedited consideration of certain types of appeals, as mentioned above.

IV. Revisions to the Regulations

We propose to make the following revisions to the regulations in title 42:

1. In part 431 subpart E, we would revise §§ 431.200, 431.201, 431.206, 431.210, 431.213, 431.220, 431.241, 431.242, 431.246 to reflect appeals provisions, which conform to OBRA '87 requirements.

2. To part 431, we would add new § 431.621, which specifies State Medicaid agency responsibilities with respect to statutory requirements in section 4211(a) of OBRA '87.

3. In part 483, we would add a new subpart C containing §§ 483.100 to 483.138, which specify requirements that must be met by States concerning preadmission screening and annual resident review of mentally ill and mentally retarded individuals.

4. Also in part 483, we would add a new subpart E containing § 483.200, which provides State requirements for appeals of discharges, transfers and PASARR determinations.

5. We would also make conforming changes to the Medicare fair hearings regulations in § 405.705.

V. Response to Comments

Because of the large number of items of correspondence we normally receive on a proposed rule, we are not able to acknowledge or respond to them individually. However, in preparing the final rule, we will consider all comments that we receive by the date and time specified in the "DATES" section of this preamble, and we will respond to the comments in the preamble of that rule.

VI. Regulatory Impact Statement

Regulatory Impact Statement

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

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

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

In addition, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis for any final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital which is located outside a metropolitan statistical area and has fewer than 50 beds.

These proposed changes primarily would conform the regulations to the legislative provisions of sections 4201(a) (for Medicare) and 4211(a) (for

Medicaid) of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87), Public Law 100–203. Certain provisions of this regulation involve discretionary determinations; however, we believe that no significant costs would be associated with them. We have identified the following discretionary provisions that may or may not have the potential for small increases in costs to States and NFs:

• The requirement that State's provide active treatment to residents with dual needs NF and active treatment).

Although we believe that this discretionary provision would result in incremental costs, we believe that the costs would be insignificant because of the limited number of individuals falling into this category. Also, we expect that some FFP will be available to offset costs.

• Requirement that Level I screening be conducted to determine who has MI or MR.

For the reasons mentioned above we are also predicting insignificant costs as a result of this provision.

We believe that these provisions would result in incremental costs, we believe that the costs would be insignificant when compared to the resulting increased quality of care. In that this discussion of costs is not conclusive, we encourage comments and any applicable data concerning these discretionary provisions if there is a perception that they may result in significant increased costs.

For these reasons, we have determined that the threshold criteria of E.O. 12291 would not be met, and a regulatory impact analysis is not required. Further, we have determined, and the Secretary certifies, that these proposed regulations would not have a significant economic impact on a substantial number of small entities and would not have a significant impact on the operations of a substantial number of small rural hospitals.

VII. Information Collection Requirements

Section 4214(d) of OBRA '87 provides a waiver of Office of Management and Budget review for the purpose of implementing the nursing home reform amendments.

List of Subjects

42 CFR Part 431

Grant programs-health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 483

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

Chapter IV of title 42 would be amended as set forth below:

Subchapter B—Medicare Programs

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

A. Part 405 is amended as follows:

Subpart G—Reconsiderations and Appeals Under the Hospital Insurance Program

1. The authority citation for part 405 subpart G is revised to read as follows:

Authority: Secs. 1102, 1154, 1155, 1819(c)(2), 1869(b), 1871, 1872 and 1879 of the Social Security Act (42 U.S.C. 1302, 1320c, 1395 (i)–3(c), 1395ff(b), 1395hh, 1395ii and 1395pp).

2. Section 405.705 is amended by revising paragraphs (c) and (d), and adding paragraphs (e) and (f) and the introductory text is republished to read as follows:

§ 405.705 Actions which are not initial determinations.

An initial determination under part A of Medicare does not include determinations relating to:

* * * * *

(c) Whether an individual is qualified for use of the expedited appeals process as provided in § 405.718;

(d) An action regarding compromise of a claim arising under the Medicare program, or termination or suspension of collection action on such a claim under the Federal Claims Collection Act of 1966 (31 U.S.C. 951–953). See 20 CFR 404.515 for overpayment claims against an individual, § 405.374 for overpayment claims against a provider, physician or other supplier, and § 408.110 for claims concerning unpaid Medicare premiums;

(e) The transfer or discharge of residents of skilled nursing facilities in accordance with § 483.12 of this chapter; or

(f) The preadmission screening and annual resident review processes required by part 483 subparts C and E of this chapter.

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

B. Part 431 is amended as follows:

1. The authority citation for part 431 continues to read as follows:

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

2. The table of contents for part 431 is amended by adding new § 431.621 to subpart M to read as follows:

Subpart M—Relations With Other Agencies

Sec.

* * * * *

§ 431.621 State requirements with respect to nursing facilities.

* * * * *

Subpart E—Fair Hearings for Applicants and Recipients

3. In subpart E, § 431.200 is revised to read as follows:

§ 431.200 Basis and purpose.

This subpart implements section 1902(a)(3) of the Act, which requires that a State plan provide an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly. This subpart also prescribes procedures for an opportunity for hearing if the Medicaid agency takes action to suspend, terminate, or reduce services. This subpart also implements sections 1819(f)(3), 1919(f)(3), and 1919(e)(7)(F) of the Act by providing an appeals process for individuals proposed to be transferred or discharged from skilled nursing facilities and nursing facilities and those adversely affected by the preadmission screening and annual resident review requirements of section 1919(e)(7) of the Act.

4. Section 431.201 is amended by revising the definitions of "action" and "date of action" to read as follows:

§ 431.201 Definitions.

* * * * *

Action means a termination, suspension, or reduction of Medicaid eligibility or covered services. It also means determinations by skilled nursing facilities and nursing facilities to transfer or discharge patients and determinations made by a State with regard to the preadmission screening and annual resident review requirements of section 1919(e)(7) of the Act.

Date of action means the intended date on which a termination, suspension, reduction, transfer or discharge becomes effective. It also means the date of the determination made by a State with regard to the preadmission screening and annual resident review requirements of section 1919(e)(7) of the Act.

* * * * *

5. Section 431.206(c) is revised to read as follows:

§ 431.206 Informing applicants and recipients.

* * * * *

(c) The agency must provide the information required in paragraph (b) of this section—

(1) At the time that the individual applies for Medicaid;

(2) At the time of any action affecting his claim;

(3) At the time a skilled nursing facility or a nursing facility notifies a resident in accordance with § 483.12 of this chapter that he or she is to be transferred or discharged; and

(4) At the time an individual receives an adverse determination by the State with regard to the preadmission screening and annual resident review requirements of section 1919(e)(7) of the Act.

6. Section 431.210 is amended by revising the undesignated introductory paragraph and paragraph (a) to read as follows:

§ 431.210 Content of notice.

A notice required under § 431.206 (c)(2), (c)(3), or (c)(4) of this subpart must contain—

(a) A statement of what action the State, skilled nursing facility, or nursing facility intends to take;

* * * * *

7. Section 431.213 is amended by revising paragraphs (e) and (f) and adding a new paragraphs (g) and (h) to read as follows:

§ 431.213 Exceptions from advance notice.

The agency may mail a notice not later than the date of action if—

* * * * *

(e) The agency establishes the fact that the recipient has been accepted for Medicaid services by another local jurisdiction, State, territory, or commonwealth;

(f) A change in the level of medical care is prescribed by the recipient's physician;

(g) The notice involves an adverse determination made with regard to the preadmission screening requirements of section 1919(e)(7) of the Act; or

(h) The date of action will occur in less than 10 days, in accordance with § 483.12(a)(4)(ii), which provides exceptions to the 30 days notice requirements of § 483.12(a)(4)(i).

8. Section 431.220(a) is amended by revising paragraph to read as follows:

§ 431.220 When a hearing is required.

(a) The agency must grant an opportunity for a hearing to:

(1) Any applicant who requests it because his claim for services is denied or is not acted upon with reasonable promptness;

(2) Any recipient who requests it because he believes the agency has taken an action erroneously;

(3) Any resident who requests it because he or she believes a skilled nursing facility or nursing facility has erroneously determined that he or she must be transferred or discharged; and

(4) Any individual who requests it because he or she believes the State has made an erroneous determination with regard to the preadmission and annual resident review requirements of section 1919(e)(7) of the Act.

* * * * *

9. Section 431.241 is revised to read as follows:

§ 431.241 Matters to be considered at the hearing.

The hearing must cover—

(a) Agency action or failure to act with reasonable promptness on a claim for services, including both initial and subsequent decisions regarding eligibility;

(b) Agency decisions regarding changes in the type or amount of services;

(c) A decision by a skilled nursing facility or nursing facility to transfer or discharge a patient; and

(d) A State determination with regard to the preadmission screening and annual resident review requirements of section 1919(e)(7) of the Act.

10. Section 431.242 is amended by revising paragraph (a)(2) to read as follows:

§ 431.242 Procedural rights of the applicant or recipient.

* * * * *

(a) * * *

(2) All documents and records to be used by State or local agency or the skilled nursing facility or nursing facility at the hearing;

* * * * *

Subpart M—Relations With Other Agencies

11. Section 431.246 is revised to read as follows:

§ 431.246 Corrective action.

The agency must promptly make corrective payments, retroactive to the date an incorrect action was taken, and, if appropriate, provide for admission or readmission of an individual to a facility if—

(a) The hearing decision is favorable to the applicant or recipient; or

(b) The agency decides in the applicant's or recipient's favor before the hearing.

12. In subpart M, a new § 431.621 is added, to read as follows:

§ 431.621 State requirements with respect to nursing facilities.

(a) *Basis and purpose.* This section implements sections 3919(b)(3)(F) and 1919(e)(7) of the Act by specifying the terms of the agreement the State must have with the State mental health and mental retardation authorities concerning the operation of the State's preadmission screening and annual resident review (PASARR) program.

(b) *State plan requirement.* The State plan must provide that the Medicaid agency has in effect a written agreement with the State mental health and mental retardation authorities that meets the requirements specified in paragraph (c) of this section.

(c) *Provisions required in an agreement.* The agreement must specify the respective responsibilities of the agency and the State mental health and mental retardation authorities, including arrangements for—

(1) Joint planning between the parties to the agreement;

(2) Access by the agency to the State mental health and mental retardation authorities' records when necessary to carry out the agency's responsibilities;

(3) Recording, reporting, and exchanging medical and social information about individuals subject to PASARR;

(4) Ensuring that preadmission screenings and annual resident reviews are performed timely in accordance with §§ 483.112(c) and 483.114(c) of this part;

(5) Ensuring that, if the State mental health and mental retardation authorities delegate their respective responsibilities, these delegations comply with § 483.106(e) of this part;

(6) Ensuring that PASARR determinations made by the State mental health and mental retardation authorities are not countermanded by the State Medicaid agency but that the State mental health and mental retardation authorities do not use criteria which are inconsistent with those adopted by the State Medicaid agency under its approved State plan;

(7) Designating the independent person or entity who performs the PASARR evaluations for individuals with MI; and

(8) Ensuring that all requirements of §§ 483.100–483.136 are met.

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

C. Part 483 is amended as follows:

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

Authority: Secs. 1102, 1819 (a)–(f), 1905 (c) and (d), and 1919 (a)–(f) of the Social Security Act (42 U.S.C. 1302, 1395i(3)(a)–(f), 1396d (c) and (d), and 1396r (a)–(f)).

2. The table of contents for part 483 is amended by adding a new subpart C containing §§ 483.100 through 483.138, and new subpart E containing § 483.200 to read as follows:

Sec.

* * * * *

Subpart C—Preadmission Screening and Annual Review of Mentally Ill and Mentally Retarded Individuals

* * * * *

Subpart E—Appeals of Discharges, Transfers, and Preadmission Screening and Annual Resident Review (PASARR) Determinations

3. A new subpart C is added containing §§ 483.100 through 483.138 to read as follows:

§ 483.100 Basis.

The requirements of §§ 483.100 through 483.138 governing the State's responsibility for preadmission screening and annual resident review (PASARR) of individuals with mental illness and mental retardation are based on section 1919(e)(7) of the Act.

§ 483.102 Applicability.

(a) This subpart applies to the screening or reviewing of all individuals and residents with mental illness or mental retardation who apply to or reside in Medicaid certified NFs regardless of the source of payment for the NF services, and regardless of the individual's or resident's known diagnoses.

(b) As used in this subpart—

(1) An individual is considered to have a mental illness (MI) if he or she—

(i) Has a primary or secondary diagnosis of mental disorder, as defined in the Diagnostic and Statistical Manual of Mental Disorders, 3rd edition, Revised; and

(ii) Does not have a primary diagnosis of dementia, including Alzheimer's disease or a related disorder.

(2) An individual is considered to have dementia if he or she—

(i) Has a primary diagnosis of dementia, as described in the Diagnostic and Statistical Manual of Mental Disorders, 3rd edition, Revised; and

(ii) Does not have mental retardation.

(3) An individual is considered to have mental retardation (MR) if he or she has—

(i) A level of retardation (mild, moderate, severe or profound) described in the "American Association on Mental Deficiency's Manual on Classification in Mental Retardation" (1983); or

(ii) A related condition, as defined by § 435.1009 of this chapter.

§ 483.104 State plan requirement.

As a condition of approval of the State plan, the State must operate a preadmission screening and annual resident review program that meets the requirements of §§ 483.100 through 438.138.

§ 483.106 Basic rule.

(a) The State PASARR program must require—

(1) Preadmission screening of all individuals with mental illness or mental retardation who apply as new admissions to Medicaid NFs on or after January 1, 1989;

(2) Initial review, by April 1, 1990, of all current residents with mental retardation or mental illness who entered Medicaid NFs prior to January 1, 1989; and

(3) At least annual review, as of April 1, 1990, of all residents with mental illness of mental retardation, regardless of whether they were first screened under the preadmission screening or annual resident review requirements.

(b) *New admissions, readmissions, and interfacility transfers.* An individual being—

(1) Admitted to any NF in which he or she has not recently resided and to which he or she cannot qualify as a readmission is a new admission. New admissions are subject to preadmission screening.

(2) Readmitted, following a temporary absence for hospitalization or for therapeutic leave, to a NF in which he or she has resided is not a new admission. Readmissions are subject to annual resident review rather than preadmission screening.

(3) Transferred from one NF to another NF, with or without an intervening hospital stay, is a new admission and is subject to preadmission screening.

(c) *Purpose.* The preadmission screening and annual resident review process must result in determinations, based on a physical and mental evaluation of each individual with mental illness or mental retardation, that are described in §§ 483.112 and 483.114.

(d) *Responsibility for evaluations and determinations.* The PASARR determinations of whether an individual requires the level of services provided by a NF and whether active treatment is needed—

(1) For individuals with mental illness, must be made by the State mental health authority and be based on an independent physical and mental evaluation performed by a person or entity other than the State mental health authority; and

(2) For individuals with mental retardation, must be made by the State mental retardation or developmental disabilities authority.

(e) *Delegation of responsibility.* (1) The State mental health and mental retardation authorities may delegate the evaluation and determination functions for which they are responsible (see below) to another entity only if—

(i) The State mental health and mental retardation authorities retain ultimate control and responsibility for the performance of their statutory obligations; and

(ii) The two determinations as to the need for NF services and for active treatment are made, based on a consistent analysis of the data.

(2) The State mental retardation authority has responsibility for both the evaluation and determination functions for individuals with MR whereas the State mental health authority has responsibility only for the determination function.

(3) The evaluation of individuals with MI cannot be delegated by the State mental health authority because it does

not have responsibility for this function. The evaluation function must be performed by a person or entity other than the State mental health authority.

§ 483.108 Relationship of PASARR to other medicaid processes.

(a) PASARR determinations made by the State mental health or mental retardation authorities cannot be countermanded by the State Medicaid agency, either in the claims process or through other utilization control/review processes or by the State survey and certification agency.

(b) In making their determinations, however, the State mental health and mental retardation authorities must not use criteria relating to the need for NF care or active treatment that are inconsistent with this regulation and any supplementary criteria adopted by the State Medicaid agency under its approved State plan.

(c) To the maximum extent practicable, in order to avoid duplicative testing and effort, the PASARR must be coordinated with the routine resident assessments required by § 483.20(b).

§ 483.110 Out-of-State arrangements.

(a) For an individual eligible for Medicaid, the State in which the individual is a legal resident must pay for the PASARR and make the required determinations, in accordance with § 431.52(b)(1).

(b) For individuals not eligible for Medicaid, the State in which the facility is located pays for the PASARR unless the States have mutually agreed to other arrangements.

(c) A State may include arrangements for PASARR in its provider agreements with out-of-State facilities or reciprocal interstate agreements.

§ 483.112 Preadmission screening of applicants for admission to NFs.

(a) For each NF applicant with MI or MR, the State mental health or mental retardation authority (as appropriate) must determine, in accordance with § 483.130, whether, because of the resident's physical and mental condition, the individual requires the level of services provided by a NF.

(b) If the individual with mental illness or mental retardation is determined to require an NF level of care, the State mental health or mental retardation authority (as appropriate) must also determine, in accordance with § 483.130, whether the individual requires active treatment for the mental illness or mental retardation, as defined in § 483.120.

(c) *Timeliness.* A preadmission screening determination must be made in writing within 7 working days of referral of the individual with MI or MR by whatever agent performs the Level I identification, under § 483.128(a) of this part, to the State mental health or mental retardation authority for screening. (See § 483.128(a) for discussion of Level I).

§ 483.114 Annual review of NF residents.

(a) *Individuals with mental illness.* For each resident of a NF who has mental illness, the State mental health authority must determine in accordance with § 483.130 whether, because of the resident's physical and mental condition, the resident requires—

(1) The level of services provided by—

(i) A NF;

(ii) An inpatient psychiatric hospital for individuals under age 21, as described in section 1905(h) of the Act; or

(iii) An institution for mental diseases providing medical assistance to individuals age 65 or older; and

(2) Active treatment for mental illness, as defined in § 483.120.

(b) *Individuals with mental retardation.* For each resident of a NF who has mental retardation, the State mental retardation or developmental disability authority must determine in accordance with § 483.130 whether, because of his or her physical or mental condition, the resident requires—

(1) The level of services provided by a NF or an intermediate care facility for the mentally retarded; and

(2) Active treatment for mental retardation as defined in § 483.120.

(c) *Frequency of review.* A review and determination must be conducted for each resident of a Medicaid NF who has mental illness or mental retardation not less often than annually.

(d) The first set of annual reviews on residents who entered the NF prior to January 1, 1989 must be completed by April 1, 1990.

§ 483.116 Residents and applicants determined to require NF level of services.

(a) If the State mental health or mental retardation authority determines that a resident or applicant for admission to a NF requires an NF level of services, the NF may admit or retain the individual.

(b) If the State mental health or mental retardation authority determines that a resident or applicant for admission requires both an NF level of services and active treatment for the mental illness or mental retardation—

(1) The NF may admit or retain the individual; and

(2) The State must provide or arrange for the provision of the active treatment needed by the individual while he or she resides in the NF.

§ 483.118 Residents and applicants determined not to require NF level of services.

(a) *Applicants who do not require NF services.* If the State mental health or mental retardation authority determines that an applicant for admission to a NF does not require NF services, the applicant cannot be admitted, NF services are not a covered Medicaid service for that individual, and further screening is not required.

(b) *Residents who require neither NF services nor active treatment for MI or MR.* If the State mental health or mental retardation authority determines that a resident requires neither the level of services provided by a NF nor active treatment for MI or MR, regardless of the length of stay in the facility, the State must—

(1) Arrange for the safe and orderly discharge of the resident from the facility in accordance with § 483.12(a); and

(2) Prepare and orient the resident for discharge.

(c) *Residents who do not require NF services but require active treatment for MI or MR*—(1) *Long term residents.* Except as otherwise may be provided in an alternative disposition plan adopted under section 1919(e)(7)(E) of the Act, for any resident who has continuously resided in a NF for a least 30 months before the date of the determination, and who requires only active treatment as defined in § 483.120, the State must, in consultation with the resident's family or legal representative and caregivers—

(i) Provide for, or arrange for the provision of active treatment for the mental illness or mental retardation;

(ii) Offer the resident the choice of remaining in the facility or of receiving services in an alternative setting;

(iii) Inform the resident of the institutional and noninstitutional alternatives covered under the State Medicaid plan for the resident; and

(iv) Clarify the effect on eligibility for Medicaid services under the State plan if the resident chooses to leave the facility, including its effect on readmission to the facility.

(2) *Short term residents.* Except as otherwise may be provided in an alternative disposition plan adopted under section 1919(e)(7)(E) of the Act, for any resident who requires only active treatment, as defined in § 483.120, and who has not continuously resided in a NF for at least 30 months before the date of the determination, the State

must, in consultation with the resident's family or legal representative and caregivers—

(i) Arrange for the safe and orderly discharge of the resident from the facility in accordance with § 483.12(a);

(ii) Prepare and orient the resident for discharge; and

(iii) Provide for, or arrange for the provision of, active treatment for the mental illness or mental retardation.

(3) For the purposes of establishing length of stay in a NF, the 30 months of continuous residence in a NF or longer—

(i) Is calculated back from the date of the annual resident review determination which finds that the individual is not in need of NF level of services;

(ii) May include temporary absences for hospitalization or therapeutic leave; and

(iii) May consist of consecutive residences in more than one NF.

§ 483.120 Active treatment.

(a) *Definition.* (1) For mental illness, active treatment means the continuous and aggressive implementation of an individualized plan of care that—

(i) Is developed under and supervised by a physician in conjunction with an interdisciplinary team of qualified mental health professionals;

(ii) Prescribes specific therapies and activities for the treatment of persons experiencing an acute episode of severe mental illness, which necessitates supervision by trained mental health personnel; and

(iii) Is directed toward diagnosing and reducing the resident's psychotic symptoms that necessitated institutionalization, improving his or her level of independent functioning, and achieving a functioning level that permits reduction in the intensity of mental health services to below the active treatment level of services at the earliest possible time.

(2) For mental retardation; active treatment means treatment which meets the requirements of § 483.440(a)(1).

(b) *What active treatment does not include.* (1) For mental illness, active treatment does not include intermittent or periodic psychiatric services for residents who do not require 24-hour supervision by qualified mental health personnel.

(2) For mental retardation, active treatment does not include the services described in § 483.440(a)(2).

(c) *Who must receive active treatment.* The State must provide or arrange for the provision of active treatment, in accordance with this subpart, to all NF residents with MI or MR whose needs are such that 24-hour supervision, treatment and training by qualified mental health or mental retardation personnel is necessary, as identified by the screening provided in §§ 483.130 or 483.134 and 483.136.

(d) The NF must provide mental health or mental retardation services which are of a lesser intensity than active treatment to all residents who need such services.

§ 483.122 Availability of FFP for NF services.

(a) Except as otherwise may be provided in an alternative disposition plan adopted under section 1919(e)(7)(E) of the Act, FFP is available for NF services provided to a Medicaid eligible individual subject to the requirements of this part only if the individual has been determined—

(1) To need NF care under § 483.116(a) or

(2) Not to need NF services but to need active treatment, meets the requirements of § 483.118(c)(1), and elects to stay in the NF.

(b) FFP for NF services cannot remain available if the Medicaid eligible individual with MI or MR has not been subjected to timely (at least annual) reviews, in accordance with this subpart, to reevaluate NF and active treatment service needs.

§ 483.124 Availability of FFP for active treatment

FFP is not available for active treatment furnished to NF residents as NF services.

§ 483.126 Appropriate Placement

Placement of an individual with MI or MR in a NF may be considered appropriate only when the individual's needs are such that he or she meets the minimum standards for admission and the individual's needs for treatment do not exceed the level of services which can be delivered in the NF to which the individual is admitted either through NF services alone or, where necessary, through NF services supplemented by active treatment services provided by or arranged for by the State.

§ 483.128 PASARR Evaluation criteria.

(a) The State's PASARR program must identify all individuals who are suspected of having MI or MR as defined in § 483.102. This identification function is termed Level I. Level II is the function of evaluating and determining whether NF services and active treatment are needed. The State's performance of the Level I identification function must provide for the issuance of written notice to the individual or resident that he or she is suspected of having MI or MR and is being referred to the State mental health or mental retardation authority for Level II screening.

(b) Evaluations performed under PASARR must be adapted to the cultural background, language, ethnic origin and means of communication used by the individual being evaluated.

(c) The State's PASARR program must use at least the evaluative criteria of § 483.130 (if one or both determinations can easily be made categorically as described in § 483.130) or of §§ 483.132 and 483.134 or 483.136 (or, in the case of individuals with both MS and MR, §§ 483.132, 483.134 and 483.136 if a more extensive individualized evaluation is required).

(d) In the case of individualized evaluations, information that is necessary for determining whether it is appropriate for the individual with MI or MR to be placed in a NF or in another appropriate setting should be gathered throughout all applicable portions of the PASARR evaluation (§§ 483.132 and 483.134 and/or 483.136). The two determinations relating to the need for NF level of care and active treatment are interrelated and must be based upon a comprehensive analysis of all data concerning the individual.

(e) Evaluators may use relevant evaluative data, obtained prior to initiation of preadmission screening or annual resident review, if the data are considered valid and accurate and reflect the current functional status of the individual. However, in the case of individualized evaluations, to supplement and verify the currency and accuracy of existing data, the State's PASARR program may need to gather additional information necessary to assess proper placement and treatment.

(f) For both categorical and individualized determinations, findings of the evaluation must correspond to the person's current functional status as documented in medical and social history records.

(g) For individualized PASARR determinations, findings must be issued in the form of a written evaluative report which—

(1) Identifies the name and professional title of the person(s) who performed the evaluation(s) and the date on which each portion of the evaluation was administered;

(2) Provides a summary of the medical and social history, including the positive traits or developmental strengths and weaknesses or developmental needs of the evaluated individual;

(3) If NF services are recommended, identifies the specific services which are required to meet the evaluated individual's needs, including services

required in paragraph (g)(4) of this section;

(4) If active treatment is not recommended, identifies any specific mental retardation or mental health services which are of a lesser intensity than active treatment and are required to meet the evaluated individual's needs;

(5) If active treatment is recommended, identifies the specific mental retardation or mental health services required to meet the evaluated individual's needs; and

(6) Includes the basis for the report's conclusions.

(h) For categorical PASARR determinations, findings must be issued in the form of an abbreviated written evaluative report which—

(1) Identifies the name and professional title of the person applying the categorical determination and the data on which the application was made;

(2) Explains the categorical determination(s) that has (have) been made and, if only one of the two required determinations can be made categorically, describes the nature of any further screening which is required;

(3) Identifies, to the extent possible, based on the available data, NF services, including any mental health or specialized psychiatric rehabilitative services, that may be needed; and

(4) Includes the basis for the report's conclusions.

(i) For both categorical and individualized determinations, findings of the evaluation must be interpreted and explained to the individual or, where applicable, to a legal representative designated under State law and the individual or his or her legal representative must receive a copy of the written evaluative report.

(j) In the case of applicants for NF services, the evaluation report must be submitted within 5 working days by the evaluator to the appropriate State authority so that the appropriate State authority may make the necessary determinations within the timeframe of 7 working days required in § 483.112(c).

(k) The evaluation may be terminated if the evaluator finds at any time during the evaluation that the individual being evaluated—

(1) Does not have MI or MR; or

(2) Has a primary diagnosis of dementia (including Alzheimer's Disease or a related disorder) and does not have a diagnosis of MR or a related condition.

§ 483.130 PASARR determination criteria.

(a) Determinations made by the State mental health or mental retardation authority as to whether NF level of services and active treatment are needed must be based on an evaluation of data concerning the individual, either as specified in paragraph (b) of this section, or in §§ 483.132 and 483.134 or 483.136 (or, in the case of an individual having both MR and MI, §§ 483.134 and 483.136).

(b) Determinations may be—

(1) Advance group determinations, in accordance with this section, by category that take into account that certain diagnoses or levels of severity of illness clearly indicate that admission to or residence in a NF or the provision of active treatment is or is not normally needed; or

(2) Individualized determinations based on more extensive individualized evaluations as required in §§ 483.132, 483.134, or 483.136 (or, in the case of an individual having both MR and MI, §§ 483.134 and 483.136).

(c) Advance group determinations by category developed by the State mental health or mental retardation authorities may be applied by the NF or other evaluator following Level I review only if existing data on the individual appear to be current and accurate and are sufficient to allow the evaluator readily to determine that the individual fits into the category established by the State authorities (See § 483.132(c)). Sources of existing data on the individual that could form the basis for applying a categorical determination by the State authorities would be hospital records, physician's evaluations, election of hospice status, records of community mental health centers or community mental retardation or developmental disability providers.

(d) Examples of categories for which the State mental health or mental retardation authority may make an advance group determination that NF services are needed are—

(1) Convalescent care from an acute physical illness for which hospitalization was required;

(2) Terminal illness as defined for hospice purposes in § 418.3 of this chapter;

(3) Severe physical illnesses such as coma, ventilator dependence, functioning at a brain stem level, or diagnoses such as chronic obstructive pulmonary disease, Parkinson's disease, Huntington's disease, amyotrophic lateral sclerosis, and congestive heart failure which result in a level of impairment so severe that the individual could not be expected to benefit from active treatment;

(4) Provisional admissions pending further assessment in cases of delirium where an accurate diagnosis cannot be made until the delirium clears;

(5) Very brief and finite stays of up to a fixed number of days to provide respite to in-home caregivers to whom the individual with MI or MR is expected to return following the brief NF stay or in order to permit alternative arrangements for longer term care in emergency situations requiring protective services; and

(6) The State may specify time limits for categorical determinations that NF services are needed and in the case of paragraphs (d) (4) and (5) of this section, must specify a time limit which is appropriate for provisional admissions pending further assessment and for respite care. If an individual is later determined to need a longer stay than the State's limit allows, the individual must be subjected to a new PASARR before continuation of the stay may be permitted and payment made for days of NF care beyond the State's time limit.

(e) The State mental health authority must require the more extensive individualized evaluations for at least each resident or applicant with a diagnosis in any of the following categories to see whether active treatment services for MI are needed:

(1) Schizophrenia;

(2) Paranoia;

(3) Major affective disorders;

(4) Schizoaffective disorders; and

(5) Atypical psychosis.

(f) The State mental health authority may devise lists of minor mental disorders (with the exception of MR) which alone normally do not warrant active treatment and should not serve as barriers to admission to or continued residence in a NF.

(g) The State mental health and mental retardation authorities must not make categorical determinations that active treatment is needed without requiring that such a determination be followed by a more extensive individualized evaluation under § 483.134 or § 483.136 to determine the exact nature of the active treatment services that are needed.

(h) The State mental retardation authority must not make categorical determinations that active treatment is not needed for individuals with MR. A determination that an individual with MR does not need active treatment must be based on a more extensive individualized evaluation under § 483.136.

(i) Except for long term residents identified in § 483.118(c)(l), the State mental health or mental retardation authority may make categorical determinations that individuals with certain mental conditions or levels of severity of MI would normally require

active treatment services of such an intensity that an acceptable active treatment program could not be delivered by the State in most, if not all, NFs and that another, more appropriate placement must be utilized.

(j) The State mental health or mental retardation authority may make a categorical determination that certain individuals of advanced years be allowed to decline active treatment in a NF when—

(1) The individuals have already been determined by categorical determination or by a determination based on more extensive individualized evaluation to need NF level of services and also a more extensive individualized evaluation to need active treatment;

(2) The individuals are not a danger to themselves or others;

(3) The decision to let the resident forego active treatment is left open as to a specific age; and

(4) The decision is made on an individual basis by the individual or his or her legal representative.

(k) *Need for determinations in all cases.* Except for dementias, all mental disorders described in the Diagnostic and Statistical Manual of Mental Disorders, 3rd edition, Revised, require determinations, either categorically or individually.

(l) If a State mental health or mental retardation authority determines NF needs by category, it may not waive the active treatment determination. The appropriate State authority must also determine by category that active treatment is not needed, or subject the individual to a more extensive individualized evaluation as specified in § 483.134 or § 483.136.

(m) All determinations made by the State mental health and mental retardation authority, regardless of how they are arrived at, must be recorded in the individual's record.

(n) The evaluated individual and his or her legal representative, where applicable, must be notified in writing of—

(1) Any determinations that have been made under this subpart; and

(2) The rights of the individual to appeal the determinations under subpart E of this part.

(o) Each notice of the determination made by the State mental health or mental retardation authority must include—

(1) Whether a NF level of services is needed;

(2) Whether active treatment is needed; and

(3) The placement options that are available to the individual consistent with these determinations.

(p) Except as otherwise may be provided in an alternative disposition plan adopted under section 1919(e)(7)(E) of the Act, the placement options and the required State actions are as follows:

(1) *Can be admitted to a NF.* Any applicant for admission to a NF who has MI or MR and who requires the level of services provided by a NF, regardless of whether active treatment is also needed, may be admitted to a NF, if the placement is appropriate, as determined in § 483.126. If active treatment is also needed, the State is responsible for providing or arranging for the provision of the active treatment services.

(2) *Cannot be admitted to a NF.* Any applicant for admission to a NF who has MI or MR and who does not require the level of services provided by a NF, regardless of whether active treatment is also needed, is inappropriate for NF placement and must not be admitted.

(3) *Can be considered appropriate for continued placement in a NF.* Any NF resident with MI or MR who requires the level of services provided by a NF, regardless of the length of his or her stay or the need for active treatment, can continue to reside in the NF, if the placement is appropriate, as determined in § 483.126.

(4) *May Choose to Remain in the NF even though the placement would otherwise be inappropriate.* Any NF resident with MI or MR who does not require the level of services provided by the NF but does require active treatment and who has continuously resided in a NF for at least 30 consecutive months before the date of determination may choose to continue to reside in the facility or to receive covered services in an alternative appropriate institutional or noninstitutional setting. Wherever the resident chooses to reside, the State must meet his or her active treatment needs. The determination notice must provide information concerning how, when, and by whom the various placement options available to the resident will be fully explained to the resident.

(5) *Cannot be considered appropriate for continued placement in a NF and must be discharged (Short-term residents).* Any NF resident with MI or MR who does not require the level of services provided by a NF but does require active treatment and who has resided in a NF for less than 30 consecutive months must be discharged in accordance with § 483.12(a) to an appropriate setting where the State must provide active treatment services. The determination notice must provide information of how, when, and by whom the resident will be advised of discharge arrangements and of his/her appeal rights under both PASARR and discharge provisions.

(6) *Cannot be considered appropriate for continued placement in a NF and must be discharged (short or long-term residents).* Any NF resident with MI or MR who does not require the level of services provided by a NF and does not require active treatment regardless of his or her length of stay, must be discharged in accordance with § 483.12(a). The determination notice must provide information of how, when, and by whom the resident will be advised of discharge arrangements and of his or her appeal rights under both PASARR and discharge provisions.

(q) If a determination is made to admit or allow to remain in a NF any individual who requires active treatment, the determination must be supported by assurances that the active treatment services that are needed can and will be provided or arranged for by the State while the individual resides in the NF.

(r) The State PASARR system must maintain records of evaluations and determinations, regardless of whether they are performed categorically or individually, in order to support its determinations and actions and to protect the appeal rights of individuals subjected to PASARR; and

(s) The State PASARR system must establish and maintain a tracking system for all individuals with MI or MR in NFs to ensure that appeals and future reviews are performed in accordance with this subpart and subpart E.

§ 483.132 Evaluating the need for NF services and NF level of care (PASARR/NF).

(a) For each applicant for admission to a NF and each NF resident who has MI or MR, the evaluator must assess whether—

(1) The applicant's or resident's total needs are such that these needs can only be met on an institutional basis; and

(2) The NF is an appropriate institutional setting for meeting those needs in accordance with § 483.126.

(b) In determining appropriate placement, the evaluator must prioritize the physical and mental needs of the individual being evaluated, taking into account the severity of each condition.

(c) At a minimum the data relied on to make a determination must include:

(1) Evaluation of physical status (for example, diagnoses, date of onset, medical history, and prognosis);

(2) Evaluation of mental status (for example, diagnoses, date of onset,

medical history, likelihood that the individual may be a danger to himself/herself or others); and

(3) Functional assessment (activities of daily living).

§ 483.134 Evaluating whether an individual with mental illness requires active treatment (PASARR/MI).

(a) *Purpose.* The purpose of this section is to identify the minimum data needs and process requirements for the State mental health authority, which is responsible for determining whether or not the applicant or resident with MI, as defined in § 483.102(b)(1) of this part, needs an active treatment program for mental illness as defined in § 483.120.

(b) *Data.* Minimum data collected must include—

(1) A comprehensive history and physical examination of the person. If the history and physical examination are not performed by a physician, then a physician must review and concur with the conclusions. The following areas must be included (if not previously addressed):

(i) Complete medical history;

(ii) Review of all body systems;

(iii) Specific evaluation of the person's neurological system in the areas of motor functioning, sensory functioning, gait, deep tendon reflexes, cranial nerves, and abnormal reflexes; and

(iv) In case of abnormal findings which are the basis for a NF placement, additional evaluations conducted by appropriate specialists.

(2) A comprehensive drug history including current or immediate past use of medications that could mask symptoms or mimic mental illness.

(3) A psychosocial evaluation of the person, including current living arrangements and medical and support systems. If the psychosocial evaluation is not conducted by a licensed social worker, then a licensed social worker must review and concur with the conclusions.

(4) A comprehensive psychiatric evaluation including a complete psychiatric history, evaluation of intellectual functioning, memory functioning, and orientation, description of current attitudes and overt behaviors, affect, suicidal or homicidal ideation, paranoia, and degree of reality testing (presence and content of delusions) and hallucinations. If the psychiatric evaluation is not performed by a physician, then a board-eligible or board-certified psychiatrist must review and concur with the conclusions.

(5) A functional assessment of the individual's ability to engage in activities of daily living and the level of support that would be needed to assist the individual to perform these activities while living in the community. The assessment must determine whether this level of support can be provided to the individual in an alternative community setting or whether the level of support needed is such that NF placement is required.

(6) The functional assessment must address the following areas: Self-monitoring of health status, self-administering and scheduling of medical treatment, including medication compliance, or both, self-monitoring of nutritional status, handling money, dressing appropriately, and grooming.

(c) *Data interpretation.* Based on the data compiled, a board-eligible or board-certified psychiatrist must validate the diagnosis of mental illness and determine whether a program of psychiatric active treatment is needed.

§ 483.136 Evaluating whether an individual with mental retardation requires active treatment (PASARR/MR).

(a) *Purpose.* The purpose of this section is to identify the minimum data needs and process requirements for the State mental retardation authority to determine whether or not the applicant or resident with mental retardation, as defined in § 483.102(b)(3) of this part, needs a continuous active treatment program, as defined in §§ 435.1009 and 483.440 of this chapter.

(b) *Data.* Minimum data collected must include the individual's comprehensive history and physical examination results to identify the following information or, in the absence of data, must include information that permits a reviewer specifically to assess:

(1) The individual's medical problems;

(2) The level of impact these problems have on the individual's independent functioning;

(3) All current medications used by the individual and the current response of the individual to any prescribed medications in the following drug groups:

(i) Hypnotics,

(ii) Antipsychotics (neuroleptics),

(iii) Mood stabilizers and antidepressants,

(iv) Antianxiety-sedative agents, and

(v) Anti-Parkinsonian agents.

(4) Self-monitoring of health status;

(5) Self-administering and scheduling of medical treatments;

(6) Self-monitoring of nutritional status;

(7) Self-help development such as toileting, dressing, grooming, and eating;

(8) Sensorimotor development, such as ambulation, positioning, transfer skills, gross motor dexterity, visual motor perception, fine motor dexterity, eye-hand coordination, and extent to which prosthetic, orthotic, corrective or mechanical supportive devices can improve the individual's functional capacity;

(9) Speech and language (communication) development, such as expressive language (verbal and nonverbal), receptive language (verbal and nonverbal), extent to which non-oral communication systems can improve the individual's function capacity, auditory functioning, and extent to which amplification devices (e.g. hearing aid) or a program of amplification can improve the individual's functional capacity;

(10) Social development, such as interpersonal skills, recreation-leisure skills, and relationships with others;

(11) Academic/educational development, including functional learning skills;

(12) Independent living development such as meal preparation, budgeting and personal finances, survival skills, mobility skills (orientation to the neighborhood, town, city), laundry, housekeeping, shopping, bedmaking, care of clothing, and orientation skills (for individuals with visual impairments);

(13) Vocational development, including present vocational skills;

(14) Affective development such as interests, and skills involved with expressing emotions, making judgments, and making independent decisions; and

(15) The presence of identifiable maladaptive or inappropriate behaviors of the individual based on systematic observation (including, but not limited to, the frequency and intensity of identified maladaptive or inappropriate behaviors).

(c) *Data interpretation.* (1) The State must ensure that a licensed psychologist who meets the qualifications of a qualified mental retardation professional, as defined in § 483.430(a) of this part, identifies the individual's intellectual functioning measurement and validates that the individual has MR or is a person with a related condition.

(2) The State mental retardation authority must review the data described in paragraph (b) of this section and determine whether the person's status compares with each of the following characteristics commonly associated with a need for active treatment:

(i) Inability to—

(A) Take care of most personal care needs;

(B) Understand simple commands;

(C) Communicate basic needs and wants;

(D) Be employed at a productive wage level without systematic long term supervision or support;

(E) Learn new skills without aggressive and consistent training;

(F) Apply skills learned in a training situation to other environments or settings without aggressive and consistent training;

(G) Demonstrate behavior appropriate to the time, situation or place without direct supervision; and

(H) Make decisions requiring informed consent without extreme difficulty;

(ii) Demonstration of severe maladaptive behavior(s) that place the person or others in jeopardy to health and safety; and

(iii) Presence of other skill deficits or specialized training needs that necessitate the availability of trained MR personnel, 24 hours per day, to teach the person functional skills.

§ 431.138 Maintenance of services and availability of FFP.

(a) *Maintenance of services.* If a NF mails a 30 day notice of its intent to transfer or discharge a resident, under § 483.12(a) of this chapter, the agency may not terminate or reduce services until—

(1) The expiration of the notice period; or

(2) A subpart E appeal, if one has been filed, has been resolved.

(b) *Availability of FFP.* FFP is available for expenditures for services provided to Medicaid recipients during—

(1) The 30 day notice period specified in § 483.12(a) of this chapter; or

(2) During the period an appeal is in progress.

4. A new subpart E is added to read as follows:

Subpart E—Appeals of Discharges, Transfers, and Preadmission Screening and Annual Resident Review (PASARR) Determinations

§ 483.200 Basis.

This subpart implements sections 1819(e)(3), 1819(f)(3), 1919(e)(3), 1919(f)(3), and 1919(c)(7) of the Act.

§ 483.202 Definitions.

For purposes of this subpart and subparts B and C—

Discharge means movement from an entity that participates in Medicare as a skilled nursing facility, a Medicare certified distinct part, an entity that participates in Medicaid as a nursing facility, or a Medicaid certified distinct part to a noninstitutional setting when the discharging facility ceases to be legally responsible for the care of the resident.

Individual means an individual or any legal representative of the individual.

Resident means a resident of a SNF or NF or any legal representative of the resident.

Transfer means movement from an entity that participates in Medicare as a skilled nursing facility, a Medicare certified distinct part, an entity that participates in Medicaid as a nursing facility or a Medicaid certified distinct part to another institutional setting when the legal responsibility for the care of the resident changes from the transferring facility to the receiving facility.

§ 483.204 Provision of a hearing and appeal system.

(a) Each State must provide a system for:

(1) A resident of a SNF or a NF to appeal a notice from the SNF or NF of intent to discharge or transfer the resident; and

(2) An individual who has been adversely affected by any PASARR determination (Level I or Level II) made by the State in the context of either a preadmission screening or an annual resident review under subpart C of part 483 to appeal that determination.

(b) The State must provide an appeals system that meets the requirements of this subpart, § 483.12 of this part, and part 431 subpart E of this subchapter.

§ 483.206 Transfers, discharges and relocations subject to appeal.

(a) "Facility" means a certified entity, either a Medicare SNF or a Medicaid NF (See §§ 483.5 and 483.12(a)(1)).

(b) A resident has appeal rights when he or she is transferred from—

(1) A certified bed into a noncertified bed; and

(2) A bed in a certified entity to a bed in an entity which is certified as a different provider.

(c) A resident has no appeal rights when he or she is moved from one bed in the certified entity to another bed in the same certified entity.

Dated: March 14, 1990.

Gail R. Wilensky,

Administrator, Health Care Financing Administration.

Approved: March 16, 1990.

Louis W. Sullivan,

Secretary.

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