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Health Care Financing Administration

**Medicare and medicaid: Nursing facilities; individuals with mental illness and mental
retardation; preadmission screening and annual resident review, 56450**

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RULES

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Vol. 57 No. 230 Monday, November 30, 1992 p 56450 (Rule) 1/8256
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 405, 431, 433, and 483

[BPD-661-FC]

RIN 0938-AE49

Medicare and Medicaid Programs; Preadmission Screening and Annual
Resident Review

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

ACTION: Final rule with comment period.

SUMMARY: This rule sets forth State requirements for preadmission 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 sets forth 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 implement several provisions of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87), Public Law 100-203 and the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), Public Law 101-508.

DATES: Effective Date: These regulations are effective January 29, 1993. However, this effective date does not relieve States and facilities from their obligation to perform certain activities effective on earlier dates specified by the statute. A summary of statutory effective dates is given in the preamble of these regulations. The incorporation by reference of certain publications listed in the regulation is approved by the Director of the

Federal Register as of January 29, 1993.

State agencies have until 90 days after receipt of a revised State plan preprint to submit their plan amendments and required attachments. We will not consider a State plan to be out of compliance with the requirements of these final regulations if the State submits the necessary preprint plan material by that date. We wish to clarify, however, that while we do not intend to hold a State plan out of compliance with these regulatory requirements until final regulations are issued, we cannot waive the statutory requirements and we cannot limit our ability to disallow based on those requirements. Of course, we are precluded from taking compliance actions under section 4801(b)(1) of Public Law 101-508, the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) for failure to meet PASARR requirements before the issuance of guidelines on May 26, 1989. We interpret "compliance actions" to include disallowance actions based on statutory requirements prior to that date.

Comment Date: Written comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on January 29, 1993.

ADDRESSES: Mail written comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD-661-FC, 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.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code BPD-661-FC. Written 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 p.m. (phone: 202-690-7890).

FOR FURTHER INFORMATION CONTACT: Julie Walton, (410) 966-0103.

SUPPLEMENTARY INFORMATION:

I. Background

Proposed Rule

On March 23, 1990, we published in the Federal Register (55 FR 10951) proposed regulations to implement sections 1819(e) and 1919(e) of the Social Security Act (the Act), added by sections 4201(a) and 4211(a) of OBRA '87. Section 1919(e) of the Act requires that States implement preadmission screening and annual review (PASARR) of the need for admitting or retaining individuals

with mental illness (MI) or mental retardation (MR) in nursing facilities (NF) that are certified for Medicaid. Also included was a requirement in sections 1819(e) and 1919(e) of the Act that States institute an appeals system for persons who may be transferred or discharged from Medicare skilled nursing facilities (SNFs) and Medicaid NFs or who wish to dispute a PASARR determination. The purpose of the statutory provisions is to prevent the placement of individuals with MI or MR in a nursing facility unless their medical needs clearly indicate that they require the level of care provided by a nursing facility.

Prior to the enactment of OBRA '87, there was no Federal requirement for screening of individuals with MI or MR prior to admission to a NF to determine if they required the level of care provided by the facility, and, if so, whether they needed specialized services for their MI or MR. Similarly, there was no explicit Federal requirement for annual review of all individuals with MI or MR who reside in nursing facilities, regardless of their method of payment.

Legislative Revisions

On November 6, 1990, the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), Public Law 101-508, was enacted. Section 4801(b) of OBRA '90 contains several revisions to the PASARR requirements in sections 1919(b)(3)(F) and 1919(e)(7) of the Act. These revisions-

- Prohibit the Secretary from taking any compliance action against any State that has made a good faith effort to comply with the PASARR requirements with respect to any period prior to May 26, 1989, the effective date of our program instruction, State Medicaid Manual Transmittal, No. 42.

- Clarify that residents readmitted to a NF from a hospital, and individuals discharged from a hospital directly to a NF for a stay of less than 30 days for treatment of a condition for which the individuals were hospitalized, are not subject to preadmission screening (PAS).

- Clarify that Federal Financial Participation (FFP) is not available in the cost of NF services provided to any individual found not to require the level of services provided by a nursing facility (except certain exempted long-term residents).

- Clarify that a State mental health or mental retardation authority may not subcontract its PASARR responsibilities to a NF or a related entity.

- Require States to report on an annual basis to the Secretary on the number and disposition of short-term residents with mental illness or mental retardation found to require only "specialized services" (formerly known as active treatment) and of any residents with mental illness or mental retardation who are found to need neither specialized services nor NF care. Both of these groups must be discharged, but the first group (those in need of specialized services) may be covered by an alternative disposition plan (ADP). The second group is not eligible for coverage under an ADP and must be discharged immediately.

- Allow States with approved alternative disposition plans to revise those plans, subject to the approval of the Secretary, by October 1, 1991. Any revised plan must provide for disposition of inappropriately placed residents no later than April 1, 1994.

□ Modify the definition of mental illness for purposes of applying the PASARR requirements from "a primary or secondary diagnosis of a mental disorder as defined in the Diagnostic and Statistical Manual, 3rd edition)" to a "serious mental illness (as defined by the Secretary in consultation with the National Institute of Mental Health)." These revisions also exclude from PASARR individuals with a non-primary diagnosis of dementia and a primary diagnosis that is not a serious mental illness.

□ Substitute, for PASARR purposes, the term "specialized services" for the term "active treatment."

The statutory changes that forbid State delegation to NFs, permit ADP revisions, and substitute the term "specialized services" for "active treatment" are effective with enactment (November 5, 1990). All the other PASARR amendments are effective as if they were part of the original OBRA '87 statute.

Section 4801(e)(4) (and the corresponding provision for Medicare) of OBRA '90 also provide clarification of the NF's responsibility for treatment and services required by the mentally ill and mentally retarded that are not otherwise provided or arranged for (or required to be provided or arranged for) by the State. This revision, which amends the list of services that an NF or a SNF is required to provide at section 1819(b)(4) and 1919(b)(4) of the Act, is effective as if it were part of the original OBRA '87.

These amendments represent refinements of the PASARR requirements rather than totally new policy directions. Many of the changes enacted by OBRA '90 were proposed to Congress by the same individuals and organizations which submitted comments to us. In some instances, the statutory changes simply give us the authority to accept those comments. Because Congress did not believe the OBRA '90 nursing home reform changes constituted significant enough redirection of policy to warrant further delays in implementation because of rulemaking requirements, Congress specifically gave us the authority to issue interim final rules.

For these reasons, we have integrated the OBRA '90 changes into these final regulations and discuss the changes in relation to the comments. For purposes of consistency, we have substituted "specialized services" for "active treatment" throughout this preamble even when commenters obviously commented using the old terminology. While these rules are final, we will accept public comment on the way we have implemented those provisions which are new in OBRA '90. Each of these sections is identified in the preamble.

II. Provisions of the Proposed Rule

In accordance with the provisions of sections 1819(e) and 1919(e) of OBRA '87, we proposed that, as a condition for approval of the State plan, each State must establish a program designed to screen all individuals with MI or MR who apply as new admissions to Medicaid NFs on or after January 1, 1989. The screening must determine whether, because of the applicant's physical and mental condition, he or she requires the level of services provided by an NF. If the individual with MI or MR is determined to require an NF level of care, the State must also determine whether the individual requires active treatment (now called specialized services) for the MI or MR. In addition, by April 1, 1990, we

proposed that a State make an initial review of all current residents of NFs who entered the facility prior to January 1, 1989. Effective April 1, 1990, annual reviews would be required of all residents with MI or MR. We proposed that PASARR apply to all individuals, including persons with private pay status.

Funding for State PASARR activities would be available at the 75 percent FFP rate for administrative functions. However, FFP would not be available for active treatment (now called specialized services) of the MI or MR furnished to NF residents as NF services.

Failure by a State to implement a PASARR program in accordance with the proposed requirements would lead to compliance actions against the State under section 1904 of the Act. The failure to implement the clear statutory mandates, such as subjecting all categories of individuals (Medicaid, Medicare, and private pay) with MI or MR to PASARR and requiring that NFs 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. Even in the absence of a compliance action, HCFA could disallow FFP in NF services provided to individuals required to be subject to PASARR review but not, in fact, reviewed.

We proposed that the State mental retardation authority has responsibility for the evaluations of individuals with MR, and that evaluations of individuals with MI must be performed by a person or entity independent of the State mental health authority. Since the State Medicaid agency is charged with administration of the State plan, it is ultimately responsible for assuring that State mental health and mental retardation authorities, who are charged with making the required determinations, fulfill their responsibilities so that the State's PASARR program operates in accordance with the Act and our regulations.

We proposed detailed evaluation criteria for a State PASARR program. We also proposed that the State may make determinations as to whether a NF level of services and active treatment (now called specialized services) for MI or MR are needed based on advance group determinations by category. These categorical determinations would take into account that certain diagnoses or levels of severity of illness clearly indicate that NF services or specialized services are or are not normally needed. Examples of categories that might indicate a need for NF services would be terminal illness as defined for hospice purposes, or severe physical illness such as coma, or ventilator dependence.

We proposed an appeals process for PASARR modeled on the Medicaid fair hearing process specified in 42 CFR part 431, subpart E. The process would provide for the maintenance and the reinstatement of services (and FFP for expenditures for such services) until after the hearing is conducted, if certain conditions are met. This process would apply to hearings for the transfer and discharge of residents from a Medicaid NF or a Medicare SNF and to PASARR determinations. Continued funding would apply only to Medicaid recipients, not for Medicare beneficiaries because funding of Medicare services is available only to the extent it is otherwise available under title XVIII of the Act.

We proposed that the PASARR provisions would be added to our regulations at 42 CFR part 483, which contains requirements for long term care facilities. We would rename the part, Requirements

for States and Long Term Care Facilities, to reflect the States' obligations with respect to PASARR activities, and add new subparts C and E dealing with preadmission screening and review of mentally ill and mentally retarded individuals and appeals of discharges, transfers, and PASARR determinations, respectively.

III. Response to Public Comments

In response to the proposed regulations, we received over 700 comments from States, nursing facilities, hospitals, client advocates, provider groups and members of Congress. The great majority of commenters wrote in response to the proposed PASARR requirements. Consequently, we address those issues first. Later, we address comments on proposed revisions to parts 405, 431 and 433, which deal primarily with appeal procedures and availability of Federal matching funds. Following are specific comments received and our responses to these comments and, where appropriate, to the OBRA '90 statutory amendments.

PART 483-REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

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

Section 483.102-Applicability

We proposed that the PASARR requirements apply to all individuals entering or residing in Medicaid NFs, regardless of the source of payment for their care.

Comment: A large majority of commenters, well over 400 of the 736 responses we received, objected to the application of these PASARR requirements to non-Medicaid eligible NF applicants and residents. Commenters especially disagreed that persons who pay privately for their care should be subject to these requirements. Commenters argued that persons with private pay status have a right to make decisions concerning their health care, free of government barriers to access to facilities an individual can use. They noted that, especially in rural areas, factors such as remaining close to their physician and family play an important role in choosing a NF placement.

Many commenters were concerned about denials of admission and discharge of individuals who pay privately. They argued that our proposal ignores the emotional, financial, and physical disruption in residents' and families' lives when no alternatives exist. One State noted that its pre-existing preadmission screening system screened private pay patients but gave them the choice of entering.

Some commenters asserted that where government has no responsibility for payment, HCFA has no authority to compel disclosure of confidential medical or mental health information. Some States also pointed out that State laws prohibited disclosure of confidential information on non-Medicaid eligible individuals.

A number of commenters questioned whether our proposal reflected Congress' intent, pointing out that the choices that have to be offered a privately paying long-term resident who needs only specialized services make no sense since these are Medicaid-

covered services. Other commenters pointed out that last fall a proposal was seriously considered by Congress to exclude persons with private pay status from PASARR.

By contrast, a number of commenters strongly supported the proposal. They argued that a fundamental public health interest is served by assuring that individuals are not inappropriately admitted to nursing facilities when, instead, they require care of a different type, and that the mental health needs of a sizable segment of the population should be identified and addressed. In addition, commenters noted that failure to apply the system to all individuals would result in discrimination against Medicaid recipients, since privately paying individuals who might not require nursing facility care could occupy beds which might otherwise be filled by Medicaid recipients.

Response: After evaluation of the concerns of commenters both for and against our proposal, we are retaining the requirement that the review system extend to all applicants and residents with mental illness or mental retardation because we believe that the meaning of the law is clear and a statutory change would be needed to limit PASARR to government-funded individuals.

In support of our position we note that the House Energy and Commerce Committee language to accompany the House Budget Reconciliation Bill for 1989 (H.R. Rep. No. 247, 101st Cong., 1st Sess. 463 (1989)) stated that:

Under current law, prior to admission to a nursing facility, States are required to screen all individuals (including those eligible for Medicare and those using private, personal funds or private long-term care insurance) with mental illness or mental retardation to determine whether they require the level of services provided by a nursing facility. Effective January 1, 1989, nursing facilities participating in Medicaid may not admit any individual with mental illness or mental retardation who has been determined not to require such care.

Current law also requires the State to review, on an annual basis, all residents (including those eligible for Medicare and those using private, personal funds or private long-term care insurance) * * *.

This language was repeated almost verbatim in the Report of the House Budget Committee to accompany H.R. 5835, the House bill for 1990 (H.R. Rep. No. 881, 101st Cong., 2nd Sess. 112 (1990)). The 1990 House Budget Reconciliation Bill, like the 1989 House bill, proposed a statutory delay in the application of PASARR to private pay applicants and residents until they become Medicaid eligible. The conference committee report to accompany H.R. 5835 (H.R. Conf. Rep. No. 964, 101st Cong., 2nd Sess. 853 (1990)), however, notes that the conference agreement does not include the House bill.

Thus, for two years in a row, Congress has acknowledged that the PASARR requirements apply to all individuals with MI or MR seeking admission to or residing in Medicaid-certified NFs and has declined to enact a statutory change which would exempt individuals who pay privately from the PASARR requirements. Although some commenters disputed whether Congress originally intended these PASARR provisions to apply to non-Medicaid individuals or not, we believe that, since Congress has now twice spoken

on the matter (by failing to take action when it was proposed), it recognizes the correctness of our interpretation of the law.

The Federal courts have likewise supported our position. In none of the pending cases involving PASARR has a Federal judge disputed that, as currently written, these requirements apply to all residents regardless of the method of payment for their care. We do not believe we have the administrative discretion to exempt non-Medicaid individuals from PASARR.

We note that our requirements for participation in the Medicare and Medicaid programs apply to all residents of certified facilities unless specifically limited by language in the law. To exempt individuals who pay privately from PASARR review without specific statutory language to this effect, we would have to depart significantly from our longstanding interpretation of the meaning of facility certification. The maintenance of this policy is essential to the concept of requirements for participation and is particularly important to the preservation of the resident rights provisions of OBRA '87 for privately paying individuals.

We recognize that commenters have alleged that these rules violate the constitutional rights of privately paying individuals to confidentiality of their medical records and to the freedom to access care of their choice and contract freely for services that they have the means to purchase. Questions as to the constitutionality of these provisions have been raised in many, if not all, of the several PASARR cases that have been entered in Federal courts around the country. No Federal district court, however, has so far agreed with these contentions. We have, therefore, implemented the law, to require the application of these requirements to persons with private pay status.

Comment: A few commenters protested the application of these requirements to Veterans Administration (VA) contract residents. These commenters were concerned that a large number of veterans suffering from well-controlled psychiatric conditions as a secondary diagnosis could be prevented by PASARR from entering or staying in a NF even though the Department of Veteran Affairs has approved the stay and the veteran's physician has certified him or her for NF care.

Response: For the same reasons that we cannot exclude privately paying individuals, we cannot exempt VA eligible individuals from PASARR. We would note, however, that the review system for PASARR described in the proposed regulations would enable individuals such as those discussed by these commenters to be approved for admission to nursing facilities. In our view, the operation of an effective PASARR program would not preclude appropriate nursing facility admissions.

Comment: A few commenters asked if the PASARR requirements still apply when a Medicare beneficiary is receiving covered skilled nursing facility (SNF) care in a facility also approved and participating as a Medicaid NF (i.e., a dually certified facility). They also asked whether time spent in a Medicare SNF, whether or not it is dually certified, can count toward continuous residence in a NF when it comes to calculating whether the resident qualifies for long-term resident protections.

Response: It is clear from the law that PASARR requirements apply to NFs that participate in the Medicaid program and not to SNFs that participate only in the Medicare program. The universe of individuals subject to PASARR consists of all those individuals

who have MI or MR and who apply for admission to, or are residents in an NF, including Medicare beneficiaries as well as veterans and persons with private pay status.

It is also true that a facility that participates as both an SNF under Medicare and an NF under Medicaid must meet the PASARR requirements because Medicaid participation is not possible for a facility that admits individuals who have MI or MR but who have not been screened. In many cases, a single institution may have a "distinct part" which participates in the Medicaid program as an NF and another "distinct part" which participates in Medicare as an SNF. In such a case, the Medicaid "distinct part" would be subject to the PASARR requirements and the Medicare SNF would not be.

With respect to the issue of counting time towards the 30-month minimum for protection of inpatient status, we believe that residence in a Medicare or Medicaid SNF or an intermediate care facility (ICF) would qualify the individual. (Effective October 1, 1990, Medicaid SNFs and ICFs, except for ICFs for the mentally retarded, no longer exist, and facilities must meet requirements as an NF). We believe that it is clear that the 30-month period was not intended to relate to source of payment and it is also clear that Medicare SNF requirements and Medicaid SNF (effective October 1, 1990, NF) requirements are identical. This interpretation is not inconsistent with the distinction between Medicare SNFs and Medicaid NFs drawn above, because the focus of the long-term resident exception is on the resident not the facility. From the resident's viewpoint, time spent in one facility is the same as time spent in the other. Thus, there is no reason why residence in a Medicare-participating SNF could not count towards 30 months of continuous residence.

Comment: A few commenters observed that continuing care retirement communities (CCRCs) with Medicaid-certified nursing facilities must perform preadmission screening (PAS) on all individuals seeking admission to NF care covered by their CCRC contracts, even though these individuals are not, or never will be, eligible for Medicaid. But if admission is denied by PAS, the CCRC is still legally obligated to deliver NF services to its contracting residents, placing them in a breach of contract situation. They asked for an exemption from the PASARR requirements. In their view the effect of PASARR is to inhibit growth of this delivery system because CCRCs are reluctant to admit someone unless they can guarantee the individual an NF bed if the need arises. This is particularly a problem when one spouse has some history of MI or MR or when parents with an adult child with MI or MR seek to enter a CCRC.

Response: We recognize that the PASARR requirements present a difficulty for NFs operated as part of CCRCs; however, we do not believe that, to the extent that they are Medicaid-certified facilities, the law provides a basis for treating CCRC NF residents differently from others. Of course PASARR requirements do not apply to nursing facilities that do not participate in the Medicaid program. CCRCs have the option of not participating. If they do participate in the Medicaid program, they are subject to these rules like any other NF.

We would note, however, that even when there is no economic reason to anticipate Medicaid eligibility, the value of PASARR

reviews in assuring appropriate placement and treatment continues to exist. Individuals who are locked by contract into CCRC arrangements may well benefit from the reviews that are done in such cases when the results of the review indicate the need for treatment which may previously have been overlooked. The issue of the CCRC's liability for failing to provide NF services to a community member determined by preadmission screening not to need such services is one that must be addressed by CCRCs in their contracts.

Comment: A group of commenters from one State responded to our statement in the preamble to the proposed rule that the PASARR requirements do not currently apply to swing beds. A change in the swing bed regulatory requirements would be needed to make them apply. These commenters urged speedy inclusion of PASARR into these requirements.

Response: Concurrently with development of this regulation, we are developing a proposed rule, which includes a proposal for modifying the current swing bed requirements to include requirements included in the nursing home reform provisions of OBRA '87. We are studying the PASARR requirements, among others, to determine whether they should apply in the swing bed setting.

Comment: Several States opposed the application of the PASARR rules to institutions for mental diseases (IMDs) on several grounds. They claimed that since IMDs are one of the potentially appropriate settings to which applicants or residents are to be deflected, it makes no sense to screen individuals entering or residing there. One commenter stated that IMDs are by definition specialized facilities for the treatment of mental illness. Therefore, by definition they provide specialized services. Furthermore, NF/IMDs re regulated by their own conditions of participation. Another commenter believed that only individuals leaving IMDs for regular NFs should be screened. Several States attested that they had completed their reviews of these facilities and found absolutely no inappropriately placed residents in them.

Response: We continue to believe that the law requires PASARR to be performed for individuals who are proposed for admission to or who are residents in IMDs that are also NFs. There are two Medicaid benefits which may be provided in IMDs: Inpatient psychiatric services for persons under age 22 and IMD services for persons over age 65. Both these benefits provide for payment on behalf of persons who are patients in IMDs. IMD patients between the ages of 22 and 64 are ineligible for any Medicaid benefits. In the case of persons under age 22, the law clearly requires the need for and provision of specialized services. For persons over age 65 there is no such requirement in connection with the benefit. For the two benefits that may be provided in IMDs, there are program, but not special facility, requirements. The facilities by which these benefits are provided do not participate in Medicaid as a class of providers known as IMDs. They participate as NFs or psychiatric hospitals which offer these benefits. Therefore, the view of some commenters that IMDs have their own conditions of participation and that IMDs, by definition, provide specialized services does not reflect an accurate understanding of Medicaid policy.

On the issue of whether an IMD is subject to PASARR, the IMD designation is used for facilities that provide services

under Medicaid under the two benefits described above as well as for facilities which do not participate. PASARR would not, of course, be required for facilities that do not participate in Medicaid. Among IMDs that do participate in Medicaid, the PASARR requirements apply only to those facilities that are NFs. Neither of the benefits described above is required to be provided in NFs and both of them could also be provided in hospitals. There is nothing in the law that distinguishes one setting from the other or creates an exemption from PASARR for any NF. In the absence of any statutory language to the contrary, we believe we must require PASARR for all NFs, including those which have been designated as IMDs.

There is some utility in these reviews since they will likely identify individuals who might otherwise be inappropriately placed and may well assist the facility in the assessment and treatment of the individuals reviewed. As noted above concerning the benefit for those 65 and older, specialized services is not a program requirement. Therefore, absent a facility requirement, an individual in an IMD may not be receiving needed specialized services. In addition, an IMD may contain a strong minority (up to 49 percent) of residents who might be classed as "regular geriatric" residents. If IMD/NFs were excluded from PASARR, residents in this group who actually have MI or MR would be missed. Therefore, the statutory application of the PASARR requirements to IMDs is not without logical basis.

Comment: A few commenters, citing section 1919(a)(1) of the Act, which states that a NF is not primarily for the care and treatment of mental diseases," disputed our interpretation that a facility could be both a NF and an IMD.

Response: The commenters identify an inconsistency in the Act. On the one hand, section 1919(a)(1) of the Act, which was added by OBRA '87, prohibits a NF from being an IMD. On the other hand, section 1905(a)(14) of the Act explicitly provides that medical assistance may include "inpatient hospital and nursing facility services for individuals 65 years of age and over in an institution for mental diseases. . . ." OBRA '87 changed the terms "skilled nursing facility" and "intermediate care facility" to the new designation, "nursing facility," which OBRA '87 instituted for all Medicaid long term care facilities. Because of this latter change, we conclude that Congress did not intend to exclude the possibility that this Medicaid benefit could be provided in a NF.

It is clear to us that, despite the language in section 1919(a)(1) of the Act, Congress intended NF/IMDs to be able to participate in the Medicaid program in order to provide the benefits authorized in section 1905(a)(14) of the Act. As noted in the above response, it is also clear that Congress intended that all NFs fall within the purview of the PASARR provisions. Therefore, we are unable to accept the suggestions of the commenters.

Comment: Associated with the requirement in §483.120(d) that the NF must provide mental health or mental retardation services which are of a lesser intensity than specialized services to all residents who need them, a sizable number of commenters from both the States and the nursing home industry requested changes in the IMD guidelines so that NFs that meet the mental health needs of their residents will not risk reclassification as IMDs.

Response: We agree with the commenters that the criteria used to identify IMDs may need to be reconsidered in the light of OBRA '87 requirements. We would note that the Congress also made this an objective in the Omnibus Budget Reconciliation Act of 1989 (OBRA '89), Public Law 101-239. Section 6408(a) of that Act requires the Secretary to undertake a study both of the IMD exclusion itself and of its implementation to determine if changes in either the exclusion itself or the implementation guidelines are appropriate, given the changes in medical practice. The report of the study was due to the Congress in late 1990, but has not yet been completed. Because we believe this report will provide a useful baseline for our work, we have deferred revision of the IMD criteria now contained in section 4390 of the State Medicaid Manual until the report has been prepared and we have the benefit of its findings.

In the near term, we would expect our regional offices to take nursing home reform requirements relating to mental health and mental retardation services into consideration when applying the guidelines to determine whether a facility is an IMD. We do not expect the implementation of the nursing home reform provisions to result in inappropriate IMD determinations by HCFA auditors, especially since we note that OBRA '90 contains a clarification concerning responsibility for services for residents with MI or MR which explicitly states the concept reflected in §483.120(d) of the Act itself.

Comment: A group of commenters representing individuals with related conditions such as cerebral palsy believed that the proposed regulations do not sufficiently address the needs of persons with their conditions. They questioned the assumption that applicants and residents who qualify for specialized services need to be in an ICF/MR regardless of their concomitant need for SNF services. Another commenter expressed the belief that HCFA should not limit options of the States or localities to offer programs specifically designed to meet the special needs of persons with related conditions.

Response: This regulation is not intended to limit the options States have for providing appropriate services for individuals with cerebral palsy or other conditions for which Medicaid ICF/MR coverage may be appropriate. The key to appropriate treatment for these individuals, as for other individuals with unusual service needs, is development of appropriate care settings, both institutional and non-institutional.

The PASARR requirements include individuals with "related conditions," as used in section 1905(d) of the Act, and defined in regulations at 42 CFR 435.1009. The statutory use of the term is to describe the range of services to be offered by an "Intermediate Care Facility for the Mentally Retarded And Persons With Related Conditions." There is no assumption that such individuals must always need ICF/MR care, or even inpatient care; however, the Medicaid law provides coverage of care in an ICF/MR for such individuals who do need it, as it provides coverage in nursing facilities for others who need the level of care in such settings, and as it provides States with the option to provide other services for such individuals in the home and community setting.

We would expect States to exhibit special sensitivity to the needs of persons with related conditions when they are reviewed

under PASARR, both with respect to their need for nursing facility (as opposed to other inpatient or home or community-based) care, and with respect to the need for specialized services. While we do not have specific guidelines adapted to the review of such individuals, we believe that the regulations are flexible enough to permit States to continue to operate review and service systems that are sensitive to the needs of this population.

Regardless of Known Diagnosis

Section 483.102(a)-Applicability

Comment: Some commenters, especially organizations representing physicians, objected strongly to the suggestion that the PASARR process could overturn a physician's diagnoses or recommendations of what is best for his or her patients. Commenters disputed our interpretation of sections 1919(b)(3)(F) and 1919(e)(7) of the Act to cover all individuals applying to and residing in a Medicaid NF who actually have MI or MR, whether or not there is a diagnosis to this effect on record. They objected to our suggestion that PASARR evaluators should look behind the diagnostic labels for presenting evidence of MI or MR, and to our suggestion that a diagnosis of dementia should be supported by evidence of a thorough mental status examination. (See the later discussion of dementia in §483.102(b)).

One of these organizations indicated that it is seeking congressional repeal of the PASARR provisions on the grounds that PASARR process is an affront to their professional standing. In the meantime, this commenter asked that we amend the rule to require State mental health and mental retardation authorities to follow the determinations of an individual's personal physician before the appropriateness of NF services is decided.

Response: We believe the strong reaction of some physicians to the suggestion that PASARR evaluators look behind existing diagnostic labels results from the misplaced concern that the suggestion is intended to reflect adversely upon the honesty or professionalism of physicians. This is not the case. We know from comments we have received from physicians among other persons that some physicians may be reluctant to record a diagnosis of mental illness or mental retardation out of consideration for the patient or the family or out of a sense of reticence generally. In fact, a reluctance to diagnose mental illness or mental retardation has sometimes been given both as an argument against the PASARR legislation generally because it stigmatizes individuals with these conditions and as an argument for the need for these screenings to identify these individuals so that their needs will be served.

We understand these concerns and recognize that a physician may well avoid making (or recording) a diagnosis for reasons which reflect neither on the physician's integrity or abilities. Nonetheless, the requirement for screening of all persons with mental illness or mental retardation makes it necessary for the State to identify such individuals if possible. This necessity gives rise to our suggestion that the screener look beyond the presenting diagnosis in some cases.

As we are noting in a subsequent comment and response, we

have reexamined our views on the identification of individuals with dementia on the basis of the comments we received.

Comment: A number of commenters expressed the fundamental view that the entire screening process overrides the doctor/patient relationship and inappropriately questions the physician's judgments. On the other hand, other commenters thought the regulation should contain specific information on how to deal with the physician's refusal to accept a PASARR determination. Some reported that NFs were encountering considerable difficulty in getting physicians to comply with their requests for data needed to perform Level I evaluations, particularly on applicants coming from the community.

Response: As noted in the response to the comment above, we believe there is good and adequate reason to support the detailed screening requirements we have instituted and these are not intended in any way to impugn the professionals involved in diagnosing and treating patients. We would hope that a clearer understanding of our purpose would overcome any reluctance to fully comply with the best needs of the patients, which we believe will be served by these rules. We reiterate that because mental illness/mental retardation diagnoses may be withheld from individuals or their families because of family preferences or the medical discretion of the physician, we do not believe it is appropriate to accept existing diagnostic information without question.

Comment: Some commenters noted that, while the preamble suggests that the Level I evaluator should not just rely on "known diagnosis" but should "use discretion in reviewing client data and look behind diagnostic labels...for any presenting evidence of MI," it did not mention psychotropic drugs as an identifier of MI. Such a reference was included in the May 1989 State Medicaid Manual issuance. These commenters recommended that we retain the Manual guidance relating to psychotropic drugs in the final rule. In their view, this guidance suggested that evaluators review the use of these medications in relation to the reason they were prescribed. For example, if an individual is taking such medication for a reason other than MI, the mere presence of the medication in the person's medical history should not by itself cause a person to be sent for a Level II evaluation.

Response: While we recognize the concern that gave rise to this comment, we believe emphasizing the possibility that psychotropic drugs might be an identifier of MI could lead to misunderstanding. The criterion relating to psychotropic drugs in the State Medicaid Manual instruction was included because we believed at the time it was issued that the use of such drugs could be construed, at the least, as a basis for further consideration as to whether an individual may have mental illness. A large number of comments and complaints about the instruction elicited examples of cases in which psychotropic drugs were prescribed for the control of certain physical, nonpsychiatric conditions. They also cited examples of cases in which the use of a psychotropic drug in the relatively distant past resulted in referral of an individual's case for Level II review. The thrust of the comments was that the use of this criterion as a mandatory criterion for selection of individuals for Level II screening cast too broad a net and resulted in unnecessary screenings. The omission of this criterion from the regulation does not prevent a State from using it, either as a general criterion, despite the criticisms discussed above, or on a more selective basis, based on a more refined

application. We are omitting it from this final regulation because we want to avoid the potential for misunderstanding that arose when we included it in the manual instruction.

Section 483.102(b)-Definitions

Comment: Some commenters objected to the breadth of our definition of mental illness as a primary or secondary diagnosis of a mental disorder described in the Diagnostic and Statistical Manual, 3rd edition, revised (DSM-III-R), which was based on the statute as enacted by OBRA '87.

Response: OBRA '90 changed the first part of the definition of mental illness from "a primary or secondary diagnosis of a mental disorder (as defined in the Diagnostic and Statistical Manual of Mental Disorders, 3rd edition)" to a "serious mental illness (as defined by the Secretary in consultation with the National Institute of Mental Health)." This statutory change permits us to narrow the definition considerably, thereby reducing the number of individuals to whom PASARR applies and eliminating much needless screening. The previous definition cast a very broad net by encompassing individuals who, for example, may be experiencing "normal" anxiety or depressive reactions to a terminal or chronic debilitating condition or suffering from such things as tobacco addiction. While such individuals might need occasional mental health services, they would probably never need services of the intensity characterized by the term "specialized services."

The Conference Committee agreement on H.R. 5835 (H.R. Rep. No. 101-964, 101st Cong., 2nd Sess. 850 (1990)) instructs us, in defining serious mental illness, to consult with the National Institute of Mental Health (NIMH). The Report of the House Committee on the Budget to accompany H.R. 5835 (H.R. Rep. No. 881, 101st Cong., 2nd Sess. 118 (1990)) further indicates that the House Energy and Commerce Committee, where this provision originated, intends that in developing this definition of MI we should refer to the term "serious mental illness" as that term is defined and used in the Community Support Program operated under the NIMH. We, therefore, used this definition as a basis for discussions with NIMH staff. The definition which resulted from these consultations is presented at §483.102(b)(1).

The NIMH Community Support Program's definition of serious mental illness defines its population along three dimensions: diagnosis, level of disability, and duration of the illness. We followed this general approach. Some aspects of the NIMH definition, however, had to be rejected. First, the NIMH Community Support Program limits its population to adults aged 18 and over. Because Medicaid provides inpatient psychiatric services (sometimes in the NF setting) to individuals aged 21 and under, we could not place any age restriction on the seriously mentally ill population for PASARR purposes.

Second, under the diagnosis dimension, the NIMH definition includes organic disorders. Section 1919(e)(7)(G), which defines mental illness, contains a second clause (as amended by OBRA '90) which states: "and does not have a primary diagnosis of dementia (including Alzheimer's disease or a related disorder) or a diagnosis (other than a primary diagnosis) of dementia and a primary diagnosis that is not a serious mental illness."

Since various types of dementia form the bulk of disorders classified in DSM-III-R as organic disorders, we rejected NIMH's inclusion of organic disorders within the definition of serious MI for PASARR purposes.

Third, to adapt the NIMH definition to the NF population, we made modifications to the level of severity and duration criteria. For example, among NF residents, being unemployed or unable to work, is not necessarily an indication of the severity of a mental impairment. Likewise, difficulty in maintaining or establishing a personal support system describes many NF residents, including those with dementia, not just those with serious mental illness.

While this is a final rule, we will accept comments on this definition of serious mental illness which we developed in response to Congress' commission to us in OBRA '90.

Comment: A number of commenters responded to the definition of dementia as we had proposed it in section 483.102(b)(2). Commenters asserted that distinctions between primary and secondary diagnoses of dementia are artificial, confusing, clinically inaccurate, and unimportant. They observed that the typical person with dementia entering an NF has multiple coexisting physical and mental problems that together create the need for NF services. While commenters proposed various definitions of "primary" and "secondary" diagnosis, all agreed that the condition has the same relative impact upon its victim and must be addressed. They also noted that once dementia has been diagnosed, further screening is not relevant. One commenter, nevertheless, cautioned that if the dementia exclusion were to be applied broadly it should not extend to individuals with a noncomitant mental illness.

Response: We note that in OBRA '90 Congress, apparently agreeing with our commenters, expanded the dementia exclusion from MI to include non-primary dementias so long as there is not a concurrent primary diagnosis of a serious MI. This statutory change is reflected at section 483.102(b)(1)(i)(B).

Comment: Some commenters believed that we took an unnecessarily literal reading of the Act in proposing in section 483.102(b)(2)(ii) that the dementia exclusion could not apply to individuals with MR even though we recognize the special aging needs of some segments of the MR population. Commenters who addressed this issue of dementia/MR strongly advocated that we extend the dementia exclusion to individuals with MR.

A few commenters suggested that States be allowed to use the system of categorical determinations at §483.130 to make PASARR determinations for all individuals with non-primary dementias and individuals with both MR and dementia without the need for performing individual reviews. Categorical determinations would still be determinations made by the State for individuals meeting the statutory definitions of MI or MR.

Response: We found considerable merit in the suggestion of some commenters that we permit use of non-primary dementia and dementia/MR group categorical determinations and had planned to adopt such a course of action prior to the enactment of OBRA '90. As noted in the previous response, the OBRA '90 revisions concerning dementias permit exemption of individuals with non-primary dementias (and a primary diagnosis which is not a serious mental illness) from PASARR on the basis that these individuals are not mentally ill. OBRA '90, thus, resolved the issue with

respect to non-primary dementia exclusions from the definition of MI.

Nevertheless, the dementia/MR issue remained. The statutory change does not provide a specific basis for a dementia exclusion from the definition of MR. Moreover, it is clear throughout the relevant discussions in the conference committee and House budget committee reports that the expanded dementia exclusion is an exclusion from the definition of MI, not a general exclusion from PASARR. There are no grounds for inferring that Congress intended that individuals with dementia and MR or a related condition should be exempted from PASARR or that there should be a generic dementia exclusion limited only by presence of a concurrent primary diagnosis of MI. (H.R. Rep. No. 964, 101st Cong. 2nd Sess. 850 (1990) and H.R. Rep. No. 881, 101st Cong. 2nd Sess. 118 (1990)).

The lack of support from the statutory language and legislative history was critical in our decision not to alter the definition of MR to exclude dementias. We also reasoned that much the same end could be achieved by permitting categorical determinations in dementia/MR cases. We have therefore added a dementia/MR categorical determination in a new §483.130(h). While this approach is a more complicated method of achieving a similar result, it does ensure that individuals with both conditions will be reviewed in at least a preliminary fashion rather than being exempted totally from PASARR.

Since this decision represents a discretionary action taken on our part in response to OBRA '90, we specifically solicit comments on this portion of the final regulation.

Comment: Approximately 25 commenters responded to our invitation to share their ideas on how stringent the diagnostic screening requirements for applying a dementia exclusion from further screening should be. Twenty commenters believed that our proposed standard that the dementia exclusion should only be applied when a primary diagnosis of dementia was supported by "positive evidence from a thorough mental status exam focusing on cognitive functioning and performed in the context of a complete neurological or neuropsychiatric exam." was too restrictive. They claimed that having to complete such extensive screenings would result in extended hospital stays, especially in rural areas, and would result in the exclusion of people with dementia from NFs. While they did not want to encourage the glib use of dementia diagnoses as a means of avoiding PASARR, these commenters recommended that we drop all references to a "complete neurological" or a "complete neuropsychiatric" examination and rely solely on a physician's diagnosis of dementia which is reasonably established on the basis of a prior examination and a patient's medical records.

Some commenters noted that the National Institutes of Health (NIH) developed a consensus document on Differential Diagnosis of Dementing Disease in 1987. They recommended that in future revisions to our program instruction we incorporate the method suggested in that document to identify key benchmarks that indicate dementia versus another condition. They felt that the State Medicaid Manual would serve as the appropriate vehicle for giving direction to States on how the Level I function, as it relates to dementias, should be conducted.

As noted earlier, some commenters, notably physicians' associations,

objected to our suggestion that Level I evaluators should be required to look behind a physician's diagnosis. This group of commenters believed that the PASARR evaluator, who usually does not know the individual being screened, should not be able to overturn a diagnosis of dementia made by the patient's own physician.

Other commenters, who advocated less restrictive requirements for accepting a diagnosis of dementia than we proposed, believe that PASARR is not the appropriate vehicle for assessing a person's needs in order to design appropriate care and services. The comprehensive resident assessment for all nursing home residents should determine that. They recommended that Level I determinations that an individual has dementia and therefore need not go through Level II evaluation should be made more simply on prevailing evidence.

The remaining commenters supported the position we took in the NPRM.

Response: We believe that the commenters have made a number of valid points relating to screening of individuals for dementia. To some extent, the comments on this condition throw into relief the problems of designing a set of criteria to govern the implementation of a PASARR program by a State. We note that the statutory purpose of the criteria contained in this rule is not expressly to tell States how to conduct such reviews but to measure the appropriateness of State systems developed for that purpose. On the one hand, there are no doubt cases in which some pains must be taken in order to discern whether an individual has dementia or whether the dementia is complicated by another mental condition. On the other hand, there are apparently many cases in which such a determination is more readily made or has already been made by the individual's physician. While we do not want to require routinely burdensome procedures for making such determinations, we also wish to avoid what one of the commenters called the prospect of having dementia become the diagnosis of choice. Nor do we wish to tie the States to the Consensus Statement methodology referred to above. The Statement was prepared by a non-Federal panel convened on a single occasion and was an independent report of the panel. It did not constitute a policy statement of the NIH or the Government.

Ultimately, however, we believe that States must have the flexibility to deal with situations in which the conditions of individuals presented for admission and the amount and reliability of the medical information available to assist in determining their diagnoses vary considerably from case to case. Thus, we no longer believe that it is necessary for a State to gather positive evidence of a thorough mental status exam focusing on cognitive functioning and performed in the context of a complete neurological or neuro-psychiatric exam in every case where a diagnosis of dementia is made. On the other hand, we do expect States to take reasonable measures to assure that diagnoses are accurate and we expect that such measures will vary for some patients. When we develop specific protocols to monitor State PASARR implementation, we will include features to look behind the determinations made to assure that inappropriate dementia diagnoses were not routinely used to avoid the need for review.

Section 483.106(b)-New Admissions, Readmissions, and Interfacility Transfers

We proposed that a patient be considered a new admission when an individual is being admitted to any NF in which he or she had not recently resided and to which he or she could not qualify as a readmission. We proposed to define a readmission as an individual being readmitted, following a temporary absence for hospitalization or for therapeutic leave, to a NF in which he or she has resided. In the proposed rule we suggested that States could define "recently resided" and "temporary absence" as they saw fit. If the State had a bedhold policy, we suggested that the State could use that time period or a longer one, if it chose, in defining these terms. We further suggested that States that did not have a bedhold policy ought to devise a definition for these terms.

Comment: We received a number of comments concerning our suggested use of the bedhold period in defining temporary absence for readmission purposes. Believing that the bedhold period was too short, commenters generally argued that the legislative intent was to eliminate as much duplicative testing as possible. While some commenters suggested defining a temporary absence as 30 days or less, the majority favored subjecting a returning resident who had a PAS or annual resident review (ARR) during the preceding year to a new PAS only when there is a hospital admitting diagnosis of MI or MR (i.e., the MI or MR condition is a cause for the hospital admission), a first time identification of MI or MR, or a change in the resident's physical condition which has a direct bearing on patient's mental health needs.

Response: Since we issued the proposed rule on March 23, 1990, Congress has acted on the issue of readmissions through OBRA '90. Specifically, section 4801(b)(2) clarifies that the PAS program required at revised section 1919(e)(7)(A)(i) need not apply to readmission to a NF of an individual who, after being admitted to the NF, was transferred for care in a hospital. This provision places no specific time limit on the length of absence from the NF. Nor does it qualify the exemption from PAS based on the type of care received in the hospital or the reason for the hospital transfer. Ostensibly, readmissions to a NF following transfer to a psychiatric unit in an acute hospital or to a psychiatric hospital for treatment of an acute episode of serious mental illness would be equally exempt for PAS as would be, for example, transfers for treatment of pneumonia or a broken hip caused by a fall. The statute also does not appear to clearly limit readmission to the same NF in which the resident previously resided. That is, it speaks of readmission to "a" (or "any") NF of an individual who, after being admitted to "the" (or a specific) NF, was transferred to a hospital for any type of care.

We have incorporated the new OBRA '90 language on readmissions into §483.106(b)(1)(iii) of the regulation. We note, however, that while any readmission to a NF from a hospital is not subject to PAS, the individual is still subject to ARR which would normally be due some time over the next 12 months. If the ARR falls due during the hospital stay, the ARR must be performed within the quarter after return to the facility. If the ARR is not due for some time, but there has been a significant change in the

resident's condition an earlier ARR is required by these regulations. As discussed elsewhere in this preamble, at the time of a resident's readmission to a NF, the facility must perform a new resident assessment (RA) within the first 14 days of readmission. If this RA indicates a substantial change in the resident's condition which would have a bearing on his or her mental health needs, the NF must refer the resident immediately for an ARR. Thus, we believe, the very legitimate concerns of commenters that some hospitalizations ought to trigger a new review by the State mental health or mental retardation authority should be satisfied.

Comment: Concerning interfacility transfers, most commenters objected to our interpretation that a new resident is someone unknown to the receiving NF. We had proposed that in such cases, a PAS was required. In the preamble we had suggested, however, that a PAS or ARR of record within the preceding year could be simply updated if there had been no significant change in the resident's condition. Commenters proposed an alternative view of a "new" admission as an individual who is initially seeking NF services, and not necessarily someone who is new to a specific NF. They reasoned that residents transfer fairly frequently from one NF to another, with or without an intervening hospital stay, for any number of reasons. They believed that to require a new PAS at every juncture would only waste scarce resources and discriminate against residents with MI or MR. Several commenters also objected that because of our definition of transfer in the provisions of the rule dealing with appeals, a transfer from one type of certified bed to another type of certified bed within the same physical plant would be an interfacility, rather than an intrafacility, transfer which would be subject to a new PAS.

Response: We are persuaded by commenters that the statutory phrase "new resident" can arguably be interpreted to mean an individual being admitted for the first time to a NF rather than to a specific NF. We have therefore revised §483.106(b) so as to require PAS only at first entry into the NF system. This provision allows essentially continuing residents to be subjected only to ARR even though they may transfer among NFs, need hospitalization, or take therapeutic leave during the course of the year from their most recent PAS or ARR. As noted above, however, in the case of a change in the resident's condition we assure timely attention by requiring an earlier ARR for continuing residents.

Because a facility is defined at section 483.5 as a certified entity, transfers from one certified entity to another are interfacility transfers. This fact, however, should cause no undue difficulties for nursing homes with distinct parts because, as noted above, we are not requiring a PAS at the time of transfer.

Comment: A number of commenters favored by the flexibility we gave States in devising categorical groups to deal with such situations as the need for convalescent care following a hospital stay. However, some commenters objected to the proposed requirement that the PASARR/MI or PASARR/MR cannot automatically be waived when a categorical determination on the need for NF care is made under the PASSAR/NF portion of the screening. They wanted the categorical determinations to function as exemptions from any further screening. (See discussion of §483.130(d)).

Response: We are revising §483.106(b) to include a new OBRA

'90 provision concerning certain hospital discharges which are exempt from PAS. To qualify for this exemption, the individual must meet three pre-conditions. First, he or she must be admitted to any NF directly from a hospital after receiving acute inpatient care at the hospital. Second, the individual must require NF services for the condition for which he or she received care in the hospital. Third, the attending physician must have certified before admission to the facility that the individual is likely to require less than 30 days of NF services. Such a hospital discharge is exempt from PAS.

The statute does not specify what should happen if the stay exceeds 30 days. We must provide for this possibility in order to assure that this exemption could not be misused to avoid PAS. Therefore, we are adding that, if it becomes apparent during the 30 days that a longer stay is needed, the individual must receive an ARR within 40 calendar days of admission.

Because not all convalescent care admissions from hospitals will be able to fit the prerequisites for a PAS-exempt hospital discharge, we are retaining the categorical group determination at §483.130(d)(1). For instance, convalescence from a broken hip would normally be expected to require longer than 30 days. In such a case, the person could not qualify from the new statutory exemption from preadmission screening. The individual could still be admitted, however, under a convalescent care categorical determination that NF services were needed, accompanied by determination of specialized service needs. Since the definition of mental illness has now been restricted to serious mental illnesses, it is extremely important that such individuals not be admitted to NFs for extended periods of time without having their need for specialized services reviewed.

We will accept comments on the way we have implemented the new OBRA '90 provisions on readmissions and PAS-exempt hospital discharges.

Section 483.106(d)-Responsibility for Evaluations and Determinations

Independent Evaluations

We proposed in §483.106 that PASARR determinations for individuals with MI 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. For individuals with mental retardation, the PASARR determinations must be made by the State mental retardation authority without any requirement for independent evaluation.

Comment: Several commenters questioned why independent evaluations are required for individuals with MI but not for individuals with MR. Some developmental disabilities advocates felt that if independent evaluations offer some measure of protection to individuals with MI, this same protection should be extended to individuals with MR. They believed that the physical and fiscal constraints imposed on State mental retardation authorities by PASARR could compromise the authorities' performance of this responsibility.

On the other hand, several States objected to the proposed requirement that, for individuals with MI, the State mental

health authority base its determinations on an independent evaluation. They claim that having to use independent evaluators is very inefficient and time consuming, especially given the credential and data requirements proposed. These States indicated that their State mental health authorities are just as capable of doing their own evaluations as their State mental retardation authorities. They argued that making the use of independent evaluators optional rather than mandatory would be more efficient.

Response: Section 1919(e)(7)(B)(i) of the Act requires that the State mental health authority base its determinations on an independent evaluation performed by a person or entity other than the State mental health authority. To allow the State mental health to do its own evaluations would require a statutory change. Therefore, States must use independent evaluators to perform all evaluations on individuals with MI. The Act places no similar requirement on the State mental retardation authority to base its determinations on independent evaluations. In the State Medicaid Manual, Transmittal No. 42, which we published in May 1989, we indicated that State mental retardation authorities are free to use independent evaluators if they so choose.

Comment: We also received a few comments asking who in the State was responsible for hiring the independent MI evaluators, the State mental health authority or the State Medicaid agency.

Response: States are free to use the Medicaid agency, the mental health authority, or some central contracting office to contract with independent evaluators so long as the terms of the contract specify that the evaluations are to be performed independently. We wish to allow States latitude in organizing their administrative structures to respond to the PASARR requirements. The law, however, makes the State Medicaid agency ultimately responsible for seeing that MI determinations are based on independent evaluations. We are also requiring that the interagency agreement designate the independent evaluator and ensure that all the requirements of these regulations are met. (See preamble discussion of interagency agreements.)

Section 483.106(e)-Delegation of Authority To Perform Evaluations

In §483.106(e), we proposed that the State mental health and mental retardation authorities may delegate the evaluation and determination functions for which they are responsible to another entity: (1) If the respective authorities retain ultimate control and responsibility; and (2) if the determinations of need for NF services and for specialized services are based on a consistent analysis of the data. The State mental retardation authority would have responsibility for both evaluation and determination functions, while the State mental health authority would have responsibility only for the determination function. We proposed that the evaluation of individuals with MI cannot be delegated by the State mental health authority because the law provides that it must be performed by a person or entity other than the State mental health authority. The State, not the mental health authority, must see that an independent entity is used. (See discussion of interagency agreements.)

Comment: One commenter objected to the fact that, if a State mental retardation authority delegates its responsibility to perform evaluations, we do not require that agents be adequately

prepared to perform the evaluations. This commenter felt that more safeguards were needed. The commenter noted that for MR evaluations we proposed only one credential requirement (i.e., that a licensed psychologist who is a qualified mental retardation professional must measure the level of intellectual functioning).

Response: This issue is dealt with under a later response to personnel issues. We believe that requiring the State mental health and mental retardation authorities to be ultimately responsible for the performance of their functions, if they delegate them, is a sufficient safeguard.

Comment: One commenter objected to the delegation provision in §483.106(e) on the grounds that he found an inherent conflict of interest in allowing the Medicaid agency to conduct the evaluations. A second commenter objected to allowing the State mental health and mental retardation authorities to delegate their determination functions in cases in which a conflict of interest may exist. Several other commenters indicated that NFs in a few States may currently be expected to arrange for Level II evaluations, transport applicants or residents to screenings, and otherwise carry out the administrative functions of the State to see that Level II evaluations are performed, tasks which are beyond the scope of the NF's responsibility for doing a Level I identification.

One commenter protested an arrangement in his State that does not provide for an "independent" evaluation (i.e., the evaluation and determination functions are not performed by two separate entities, the one independent of the other). He also contended that a further conflict of interest exists in that the local boards, in some cases, own, operate, fund or otherwise have control over public NFs. The commenter urged us to prohibit the entity which has responsibility for performing evaluations from also making the determinations and urged that we prohibit delegation of either the evaluation or determination function to any entity that owns, operates, funds, or otherwise has control over a nursing facility.

Response: Sections 1919(b)(3)(f) and 1919(e)(7)(B)(i) of the Act require that the State mental health authority make the required determinations for individuals with MI based on an independent physical and mental evaluation performed by a person or entity other than the State mental health authority. In determining the meaning of "independent" we note that the Act requires only that the person or entity performing the evaluation be independent of the State mental health authority. It does not require that the evaluation and determination functions be performed by two separate entities acting independently of each other. This provision, as originally enacted, did not preclude delegation to any other entity—either to the State Medicaid Agency or to a nursing facility, the two delegations to which commenters objected. We note, however, that OBRA '90 contains a new provision which prohibits State mental health and mental retardation authorities from delegating, by subcontract or otherwise, their responsibilities for PAS and ARR to a nursing facility or any entity that has a direct or indirect affiliation or relationship with such a facility.

Despite the fact that the heading for section 4801(b)(4) of OBRA '90 broadly states "No delegation of authority to conduct screening and reviews," the actual text of this provision only prohibits delegation of the State mental health or mental retardation

authority responsibilities to NFs or like entities. It does not prohibit other types of delegations such as to the State Medicaid agency or to individual persons (as opposed to entities), such as physicians, who in some rural areas might be the only available personnel to perform the evaluations.

We believe that this position-that the only delegations which are prohibited are those which involve NFs or like entities-is consistent with Congressional intent. The House Energy and Commerce Committee language incorporated in the House budget committee report states:

Although OBRA 1987 did not specifically prohibit States from delegating these responsibilities to nursing facilities themselves, it was never the law's intention to allow facilities to be able to conduct these activities. Since nursing facilities have a direct interest in the eligibility determinations that are to be made for those individuals subject to the PASARR requirements, there is a potential conflict of interest in permitting them to make these determinations. Thus, it was the Committee's view in 1987-as it is today-to prohibit nursing facilities (or their related entities) to participate, in any way, in the PASARR process.

It has come to the attention of the Committee, however, that some State mental health and mental retardation agencies (or other appropriate State authorities) may be circumventing the intent of OBRA 1987 that PASARR determinations be made independent of a nursing facility by entering into subcontracts with nursing facilities (or related entities) to carry out the State's responsibility with respect to the PASARR requirements. Under the Committee bill, such subcontracts * * * are specifically prohibited.

Based on the new statutory prohibition against delegation to NFs, we have revised §483.106(e) to include a third prerequisite for an approvable delegation of either the evaluation or determination function under PAS or ARR to another person or entity. This precondition is that the entity to which the delegation is made may not be a NF or an entity that has a direct or indirect affiliation or relationship with a NF. Because State mental health authorities technically do not have authority to conduct (and therefore to delegate) PASARR evaluations, we have added a further provision at the end of §483.106(e)(3) to require that in designating an independent person or entity to perform MI evaluations, the State must not use a NF or an entity that has a direct or indirect affiliation or relationship with a NF.

We believe it is necessary to clarify that this new provision in no way impairs our authority to require that NFs conduct Level I screenings. Level I identification is, in effect, a pre-PASARR activity designed to determine who is subject to PASARR. We also wish to clarify that the statute prohibits NFs and similar "entities" from conducting PASARR. Individual physicians or mental health professionals (unless they are owners, operators, or employees of the NF) would not be precluded from performing those portions of the PASARR evaluation which they are qualified to perform.

In response to the two specific comments on delegations, we note that this change in the law has resolved the concerns of the commenter who objected to one State's delegation of responsibilities

to local boards which own or operate public nursing facilities. Such types of delegations are now barred. Because the scope of the congressional action is so specific, we did not accommodate the commenter who objected to delegation to the State Medicaid agencies on the grounds that this also represented a conflict of interest. This type of delegation is very common because it often occurs in States that had screening programs in operation prior to OBRA '87. Since Congress singled out one less frequent type of delegation for prohibition and remained silent on the issue of delegation to State Medicaid agencies, we believe that such delegations remain permissible.

Section 431.621-Interagency Agreements

and

Section 483.108(a)-Relationship of PASARR to Other Medicaid Processes

In §431.621, we proposed that 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 certain specified requirements. In §483.108, we proposed that PASARR determinations made by the State mental health or mental retardation authorities cannot be countermanded by the State Medicaid agency or by the State survey and certification agency. We also proposed that determinations made by the State mental health and mental retardation authorities must be based on criteria relating to NF level of care and specialized services that are consistent with this regulation and any supplementary criteria adopted by the State Medicaid agency. To avoid duplicative testing and effort, PASARR must be coordinated with the routine resident assessments required under §483.20(b).

Comment: Approximately 25 State agencies responded to proposed §483.108(a) or §431.621, usually in combination. The primary concern of most of the State Medicaid agencies was their objection to having responsibility for the results of the PASARR process in the State without having any control over that process. Specifically, they objected to the requirement that the Medicaid agency not countermand determinations of the State mental health and mental retardation authorities (SMHMRAs). In their view, the SMHMRAs have no training in making NF level of care determinations. They recommended that PASARR determinations be shared by the Medicaid agency and the SMHMRAs: the Medicaid agency should handle the NF question and the SMHMRAs should handle the specialized services question. Some pointed out that many of the approximately 35 States that had pre-existing screening programs have set their systems up this way, through delegation, so as not to disrupt a working system.

Response: The issue of control is a sensitive one; however, State Medicaid agency concerns must give way to the plain requirement in the law that some of the PASARR functions be conducted and determinations be made by the SMHMRAs. This is not a requirement subject to administrative alteration. Of course, the SMHMRAs are not free to make determinations that are inconsistent with the law and regulations. Both the proposed regulation and this

final regulation make it clear that the determinations of the SMHMRAs with respect to the need for NF care and specialized services must be consistent with the Medicaid program's law and regulations. The requirements relating to interagency agreements that we have included in this regulation were for the express purpose of ensuring that the Medicaid agency would assure that the appropriate relationships were established formally, including the bases for determinations by the SMHMRAs.

The law clearly requires that the State comply with the PASARR requirements as a condition of approval for the State's Medicaid plan and our regulations do what we believe is appropriate with respect to assuring that the State government is aware that the determinations of the SMHMRAs must be consistent with Medicaid requirements, and the responsibilities must be spelled out in interagency agreements. These agreements provide the means by which the Medicaid agency achieves the control it needs to assure that its plan is in compliance.

Although some commenters opined that the Medicaid agency can make more appropriate determinations about the need for NF care and recommended that we delegate this function to them, the law requires that both the NF and specialized services determinations must be made by the SMHMRAs. Any delegation of responsibility back to the Medicaid agency would need to be done through an interagency agreement. We also note that, consistent with the legislative history, we have adopted the Medicaid fair hearing system for PASARR appeals and appeals of transfers and discharges. We have amended §483.108(a) to clarify that only an appeals determination made through the system designated in Part 483 Subpart E may overturn a PASARR determination made by the SMHMRAs.

Comment: Several Medicaid agencies amplified upon the problem of having responsibility without control. They objected to the fact that the regulation would require the Medicaid agency to withhold payment for unscreened individuals but would not give the Medicaid agency any way to find out who these individuals are. Some stated that the elimination of inspections of care (IOCs) put the Medicaid agency at a distinct disadvantage. Noting that the preamble to the proposed rule stated that the State survey agency would identify individuals who should have been screened but were not, they asserted that the surveys will only look at a sample. They asked for clarification of how the Medicaid agency is supposed to ensure PASARR compliance if it cannot do IOCs and cannot control the survey process. Some States asked that we specify the extent to which the survey process will be responsible for identifying missed PASARRs. Others asked for clarification of the role of the Peer Review Organization (PRO) with respect to PASARR.

Response: Commenters who complained that the elimination of IOC deprives them of the means to validate the proper working of the PASARR system misread the law and our regulations. While IOC will no longer be required after the State has implemented the minimum data set and has begun conducting surveys under the new survey procedures, the law does nothing to limit the ability of the State to monitor its own programs. While we have not specified a method for monitoring PASARR compliance, we have not prohibited States from establishing systems for doing so. While neither we nor the Act established a specific role for PROs in connection with PASARR, States have the latitude

to contract with them for services. For example, the State might contract with a PRO to perform the assessment of persons with MI, which must be performed by an entity independent of the State mental health authority.

Comment: Concerning the interagency agreement proposed at §431.621, several States, while complaining that they had no control over the PASARR process, stated that the interagency agreement requirements were too prescriptive. They felt that although the Medicaid agency is the funding vehicle for PASARR, that agency should not have to do accounting, auditing and enforcing functions. In their opinion, the interagency coordination requirements would double State administrative cost. Several States indicated that they favored a less prescriptive approach which simply measures outcomes instead of placing the Medicaid agency in the position of having to supervise the SMHMRAs. These commenters also believed that the regulation should make the SMHMRAs bear responsibility for PASARR outcomes.

By contrast, one State mental health authority applauded the fact that we required the Medicaid agency to be responsible for the PASARR system. They requested that the regulations require that this statement be included in the interagency agreement.

Other comments concerning the interagency agreement were:

HCFA has exceeded the requirements in the Act by requiring an interagency agreement.

HCFA should allow each State to determine if it needs an interagency agreement.

The interagency agreement requirement should be expanded to explain what the State is to do if both the Medicaid agency and the SMHMRA are under the same umbrella agency within the State or the overarching agency is the single State agency.

Response: State complaints about the burdensome nature of the required interagency agreements are somewhat at odds with earlier comments about the need to assure better control of circumstances by the Medicaid agency. We do not believe that Medicaid is a mere conduit of funds to the SMHMRAs for PASARR functions. We believe that the law makes the Medicaid agency responsible for the functioning of the process and that it is important for the details to be spelled out in the interagency agreements we require. In cases where components involved in the PASARR process are within the same umbrella agency, this requirement may be met by establishing written procedures governing how those components will accomplish the required tasks.

Comment: One commenter claimed that in many passages the proposed rule is unclear because of the use of the term, "the State." He noted that usually this term means the single State Medicaid agency, but in the PASARR context this is uncertain. He, therefore, urged us to specify that "the State" means the single State Medicaid agency and that "State authorities" means the SMHMRAs.

Response: We recognize that the term, "the State," is used throughout the regulation. In our proposal, we followed the specific wording of the Act, which requires many functions be accomplished by "the State," specifies that some responsibilities be carried out specifically by the Medicaid agency or SMHMRAs, and makes compliance with the requirements generally a condition of approval for the State's Medicaid plan. In this final rule, we have attempted to assure that our usage also follows the

Act and have made corrections when necessary.

Section 483.108-Relationship of PASARR to Other Medicaid Processes;
Coordination of PASARR and Resident Assessments in NFs

Comment: Stating their intention to eliminate as much duplication of testing as possible, virtually all of the approximately 15 commenters who responded to this requirement strongly supported the concept of coordination between the NF's resident assessment (RA) process and the State's PASARR program. Many asked for clarification of how the RA should interplay with Levels I and II of the PASARR. Others gave their opinions on how the two processes should interrelate. Several commenters expressed the view that the RA should suffice for at least Level I of ARR, thus eliminating one step.

Response: In both the preamble to the proposed rule and in the earlier program instruction, we indicated that the NF's resident assessment could serve as a Level I for ARR. If an individual had been identified as having MI or MR through PAS but was approved for NF admission and was subsequently admitted, that individual should already be in the State's PASARR tracking system. Similarly, the initial resident reviews, which were required to have been completed by April 1, 1990, should have added many more individuals with MI or MR to the tracking system. In fact, the population being tracked should be nearly complete except for new entrants through PAS or through the discovery of new or newly diagnosed conditions. RAs subsequently performed by the NF on these individuals on at least an annual basis would likely only confirm the continued need for these individuals to be retained in the State's tracking system and subjected to ARR as required on at least an annual basis. For this fixed population of residents with MI and MR, one could conceive of the Level I screen as not really being necessary since the State has already been alerted to its responsibility to rescreen the individual annually.

Both RAs and ARRs, however, are required to be performed more frequently than annually if a significant change in the resident's condition occurs. We envision that an earlier RA (i.e., one which is performed between annual RAs in response to a significant change in the resident's condition) should trigger a similarly expedited ARR. In such cases, the RA should function actively as a Level I to identify residents with new or newly discovered conditions of MI or MR.

It is also possible that, particularly with residents with MI, who constitute a somewhat more fluid population than residents with MR (although the statutory change in the definition of MI to more serious and chronic forms of mental disorders reduces this fluidity), the RA could indicate that an individual in the State's tracking system is found no longer to have MI. Such a finding by the NF should serve as a negative Level I to the State. When doing the next ARR, the State may agree that the individual should be removed from the State's tracking system because he or she does not have MI or MR.

Comment: One commenter was concerned that if the resident assessment instrument (RAI) were to be used for Level I it would result in large numbers of referrals for Level II ARRs because nearly anyone with some aspect of a possible mental health problem

would trigger an ARR on the grounds that the resident was identified as having MI or MR. Consequently, this commenter asked for clarification of the types of data that would trigger a Level II.

Response: We agree and, in fact, hope that individuals with MI who have previously had needs that were ignored and unmet will be identified through the RA process. The statutory change in the definition of MI reduces the likelihood that large numbers of individuals who had previously been unidentified as mentally ill will be discovered. Only data that indicate a serious mental illness would trigger a Level II review (we discuss the definition of serious mental illness below).

Comment: Some commenters thought that the RA should function more broadly in the PASARR process than serving as a Level I identifier. A few questioned the need for a Level II ARR once the NF's RA process is in place because they viewed the RA as more thorough and complete than the ARR. Others saw ARR as performing a different but somewhat subordinate role, e.g., one commenter favored coordination of PASARR with resident assessment, but not vice versa, asserting that the minimum data set (MDS) is meant to be the centerpiece of care planning and quality of care while PASARR should simply signal whether admission or residence in the NF is or continues to be appropriate.

Response: The requirement that ARRs be performed on all individuals in NFs who have MI or MR is statutory and, hence, cannot be eliminated. There must be two processes for these two populations, the mentally ill and the mentally retarded. We have no authority to allow the NF process to substitute for the State process. Although they may share a common core of data, PASARR and RA are different processes which serve different purposes. As explained in a later response, they offer the opportunity of providing differing perspectives on the resident, each of which has its own value.

The OBRA '90 provision prohibiting delegation of the SMHMRAs' authority to conduct PASARR to the NF does not preclude the use of NF-developed RA data by PASARR evaluators. It does prevent the NF's staff from performing the PASARR evaluations rather than simply supplying data for use by the State's PASARR system.

Comment: Several commenters believed that the information collected through the RA should form the database for the ARR. One commenter recommended that we delete the phrase, "to the maximum extent practicable" from the coordination requirement. Another noted that IOCs formerly made level of care determinations, but that the NF's RA will replace the IOC process, hence the State mental health and mental retardation authorities should look at the RA when doing the ARR.

Response: We agree with the commenters who suggested that ARR evaluators should use the most recent RA as the basis for their review. The RA and the ARR have as a core a common set of resident examinations and evaluations. We believe there is little utility in replicating, for purposes of the ARR, the physical, functional, and mental status assessments contained in the RAI unless the evaluator has some reason to suspect that the information contained in the most recent RA is inaccurate or no longer current. As we indicate in section 483.128(e), existing data may usually be used for PASARR. However, each process also has some specific requirements which are in addition to the core of common evaluations. While the RA may supply most

of the data required for the ARR, some additional data may be needed for ARR purposes in some cases.

While we are maximizing opportunities for having a very recent RA by the NF available to serve as the basis for the ARR, we cannot guarantee that total coordination always will be possible. Because sections 1819(b)(3)(E) and 1919(b)(3)(E) of the Act require coordination to "to the maximum extent practicable," we retain this phrase in our regulations. (Section 483.20(b)(7) in the February 2, 1989 long term care final rule repeats this coordination requirement. In the discussion of 483.114, below, we also respond to comments concerning the scheduling of ARRs.)

Comment: Several State commenters recommended having the minimum data set (MDS) well in advance of the effective date of the final PASARR regulations so that the State Medicaid agencies would have time to build coordination strategies into the process. These sentiments were echoed by several other commenters who stressed the need for consistency between the two instruments. One recommended that the PASARR evaluation process and criteria-used in determining the level, intensity, and types of services which are needed-be linked to the criteria in the MDS for the resident assessment and development of plan of care. This commenter felt strongly that there must be consistency between the information gathered for the two processes, that common definitions of service should be used, and that the individualized plan of care for residents with MI or MR should result from a combination of the two processes.

Along the same line, another commenter noted that the resident assessment instrument (RAI) should function as a continuum where care planning interventions for psychosocial needs trigger further mental health evaluation when there is a deficit. Attesting that the current version of the MDS would trigger at least 6 areas which would require further investigation into mental health needs, this commenter believed that the RAI may constitute a sufficient mental status examination for ARR purposes, even without the additional domains on the MDS. This commenter noted, however, that while the RAI contains federally-mandated data requirements, the PASARR screening tools, developed by States in response to the emerging Federal PASARR criteria, have comparatively few data requirements. Without additional guidelines on coordination of the two instruments, this commenter believed that coordination will not occur.

Response: The MDS was distributed in draft form to the State Medicaid agencies several times, beginning in April 1990 (i.e., during the comment period on this regulation). It was also distributed as a program instruction in early September 1990 in both the State Medicaid Manual (HCFA Pub. 45-4, Transmittal 49) and the State Operations Manual (HCFA Pub. 7, Transmittal 241). Additionally, it is scheduled for publication in the near future as a proposed rule. While it is not feasible to delay establishment of these requirements until the completion of rulemaking on MDS, States were given the opportunity to specify an RAI well before the effective date of this regulation. If a State specified an RAI before December 31, 1990 and implemented it by March 31, 1991, it would have been relieved of the responsibility for filing a quarterly IOC report for the fourth quarter of 1990 and for subsequent periods.

We recognize that the content of the MDS must be closely

related to the assessment requirements in the nursing facility requirements and that PASARR requirements, as well, will need to be coordinated with this data. It is our intention to propose any necessary revisions in these processes in connection with the rulemaking process for the MDS.

Since this rule is being published as a final rule with comment, we formally invite comments from readers on how best to coordinate the resident assessment process with PASARR. Because we expect to issue the MDS as a proposed rule in the near future, commenters may wish to comment on that rule as well.

We agree with the commenter who indicated that the individualized plan of care for residents with MI or MR should result from a combination of the 2 processes. We envision an interactive process. Information and findings from the PAS process, which precedes the NF assessment process, should supply data to the NF for use in performing its assessment and care planning. Information and findings from the ARR, which can and should utilize data developed in conjunction with the RA, should be fed back into the NF's care planning. For this reason we indicated in the preamble to the proposed rule and reaffirm in this final rule that the State's PASARR evaluation report should identify NF service needs (including the need for mental health services which are of less intensity than specialized services) and specialized services needs, if these are determined to exist.

As discussed later under comments in response to proposed §483.128(g)(3-5), we do not anticipate that the PASARR process should replicate the NF's RA process. Rather, it should support it and build on it. Since PASARR is performed by mental health and mental retardation specialists, their professional views on the individual's service needs, while not constituting as comprehensive an analysis of all the resident's needs as the RA should provide, can provide the NF with insights into care planning as it relates to the resident's mental health or mental retardation needs. In this sense, information provided by the PAS or ARR should provide another perspective on the resident's needs. The PAS can serve as a starting point for the first RA after admission and subsequent RAs should supply data for ARRs. The ARR should supplement the RA, either corroborating it or providing conflicting views. Both instruments, thus, should contribute to the care planning process.

So that the NF can utilize PASARR findings in its care planning, the NF obviously must receive a copy of the PASARR report. We have therefore added a new §483.128(l), to require that the admitting or retaining NF receive a copy of the PASARR evaluative report. We are not specifying whether we mean the individualized or categorical evaluative report. We are primarily concerned that the NF receive a copy of the more detailed evaluative reports which result from individualized evaluations. However, if an agent other than the NF performs the Level I identification and applies to the case a categorical determination made by the State in its rules at this point, the NF should receive a copy of the abbreviated report. In most cases, we envision that the NF discerns that the categorical determination developed by the State applies to the individual on the basis of the evaluative data the NF has available. A NF that does the evaluation in these categorical cases does not need to send a copy of the evaluative report. However, some States may be using other mechanisms

for applying the categorical determinations. We want to ensure that the NF receives copies of PASARR reports on their residents, regardless of who issues them.

It is especially critical that the NF receive a copy of the report in cases in which an individual who needs specialized services is approved for NF admission or continued residence and is admitted or remains in the NF because care planning will need to be coordinated between the NF and the State which must provide or arrange for the provision of specialized services. The PASARR report, in such cases, should serve as a starting point for working out between the NF and the State which entity should provide which service so that integrated care results.

Section 483.110-Out-of-State Arrangements

In §483.110, we proposed that for an individual eligible for Medicaid, the State in which an individual is a legal resident must pay for the PASARR and make the required determinations. For an individual not eligible for Medicaid, the State in which the facility is located would be responsible for paying for the PASARR determination unless the States have mutually agreed to another arrangement. Also, a State would have the option to include arrangements for PASARR in its provider agreements with out-of-State facilities or reciprocal interstate agreements.

Comment: About a dozen State agencies responded to the requirements on out-of-State arrangements stating that this section was confusing. States favored a single way of treating all out-of-State residents: Either the home State pays for everybody or the host State does. Moreover, they preferred the same rule to apply for both PAS and ARR, with the State working out the rest of the details through interstate agreements.

Although commenters were divided on the issue of whether the home State or the host State should have responsibility in all cases, a slim majority of commenters favored having the home State pay. A few commenters also asked that we cross-reference this section to our regulations at section 435.403 governing State residence for purposes of Medicaid eligibility.

Response: We appreciate the commenters' desire for a single rule for both Medicaid-eligible and other individuals and for both PAS and ARR purposes. We have, therefore, attempted to simplify this requirement. We have also accepted commenters' suggestion that we cross-reference the regulations defining State residence at §435.403. We are amending the basic rule to require that the State in which the individual is a State resident (or would be a State resident at the time he or she becomes eligible for Medicaid), as defined in §435.403, must pay for the PASARR and make the required determinations, in accordance with §431.52(b)(1). We note, however, that while simplified, this "home State pays" rule may result in different outcomes for Medicaid and non-Medicaid individuals.

The rules at §435.403 define State residence for the purposes of Medicaid eligibility. In most cases, State residence is determined by where the Medicaid recipient (or his or her guardian) physically resides. In other cases, an individual may be eligible for Medicaid in a State other than the one in which the individual is physically present and receiving care. For example, the home State may arrange for an individual to be placed in an out-of-State NF.

In such cases, the home State pays for the individual, although the State may enter into inter-State compacts under 41 CFR 435.403(k) under which the host State agrees to accept some or all out-of-State Medicaid recipients as their own.

For non-Medicaid eligible individuals, however, the issue of State residency is not determined until the individual applies for Medicaid. In most cases, an individual who has entered a NF in State different from the one in which he resided prior to institutionalization, would claim residence in the facility's State at the time he or she had spent down to Medicaid levels. Therefore, the State in which the facility is located would become the NF resident's home State.

The cardinal principle that we believe must be preserved is that the State that bears financial responsibility for the individual (or would bear responsibility, if the individual becomes Medicaid eligible in the future) should pay for both the PAS and ARR and should make the required determinations. Our reason for believing this is that the State that bears financial responsibility (which we call the home State) must be able to control its utilization. It must know about and have in its tracking system those State residents for which it is obligated to provide services (or would be obligated if they become Medicaid-eligible).

We are leaving to the home State's discretion how it chooses to work out the arrangements for seeing that its State residents are screened. For Medicaid recipients receiving care in an out-of-State NF, the State may prefer to perform the screenings and make the determinations itself through its own PASARR program or may choose to contract with the facility's State program to perform all or part of the work. For instance, the home State might choose to contract out the evaluation phase while retaining the determination phase. Alternatively, it could contract out the entire process to the host State in which the home State resident seeks admission or physically resides in a NF.

A PAS could often be performed more easily by the home State while the Medicaid recipient is still physically present in the home State before entering the out-of-State NF. An ARR, on the other hand, may more easily be performed by the host State and be simply paid for by the home State. States may therefore wish to make one set of arrangements for PAS and another for ARR.

A NF accepting an applicant or having a Medicaid-eligible resident who is the responsibility of another State is responsible for seeing that the applicant's or resident's home State has made the required determinations. Under this rule, State survey agencies in the facility's State should know that it is the responsibility of a Medicaid recipient's home State to provide for the PAS or ARR. All other NF residents with MI or MR should be screened by the facility's State PASARR program. The survey process, to the extent that it is able, using samples, can, thus, serve as the means of detecting residents who might otherwise be missed.

We acknowledge that States will, in practice, find it advantageous to work out interstate agreements and include PASARR arrangements with out-of-State providers to deal with their Medicaid-eligible recipients who receive care out-of-State. However, we are not requiring such agreements and are providing States with maximum

flexibility to arrange the out-of-State procedures which best suit their needs so long as they maintain the principle that the home State retains control over and responsibility for its State residents. We may, however, provide further guidance on out-of-State arrangement issues when we revise our program instruction.

Comment: One commenter noted that the proposed rule required that the State "must pay" for PASARRs performed on Medicaid recipients but stated simply that "the State . . . pays" for non-Medicaid eligible individuals. The commenter believed that, in addition to designating which State should pay in certain situations, we should require States to pay the screening costs of its residents with private pay status.

Response: We are requiring that the NF resident's or applicant's home State must pay for and make the determinations. The cost of the PASARR screening itself is a State responsibility as an administrative expense of operating the Medicaid program. Therefore, the home State must pay the cost for PASARR for all individuals, including non-Medicaid eligible individuals.

Section 483.112(c)-Timeliness

We proposed in §483.112(c) that 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 to the State mental health or mental retardation authority.

More than 150 commenters addressed the timeliness standard proposed in §483.112(c) for PAS. These commenters represented several different perspectives: hospitals and hospital associations; State mental health and mental retardation authorities; State Medicaid agencies; screener/contractors; consumer advocacy organizations; physicians' and mental health professional associations; and nursing facilities and their organizations. The positions taken by each group reflect their perspectives and interests in the process.

Hospitals commented generally that very short time frames should be mandatory and that special payment provisions should be made to compensate them for costs they may incur in cases where a patient remains in the hospital while a screening determination is made. Hospitals commenting provided a variety of anecdotes relating to delays in screenings, both generally and in specific cases, to support their contentions. Even the 7-day standard, many hospital commenters claimed, ignores the question of who pays for patients awaiting placement and leaves them with days of uncompensated care. They also alleged that early referral by the hospital discharge planner to the State does not solve the problem. They explained that under Medicare few diagnoses allow for a 7-day stay and outliers (see 42 CFR part 412, subpart F) are not really a help in most cases. Under Medicaid, they asserted, assistance is only available if the State pays for administratively necessary days. Private patients must either go home or pay to continue care in the hospital while awaiting placement. Hospitals generally favored specific additional payments from the Medicare or Medicaid programs to cover days of care necessitated by the operation of the PASARR program.

At the opposite end of the spectrum, State Medicaid agencies and State mental health and mental retardation authorities,

along with some consumer advocacy groups, asserted that the timeliness standard we proposed was unrealistic. Moreover, combined with the denial of FFP for the entire stay if a PAS were not performed timely, they felt the standard was both arbitrary and punitive. In the view of many of the State agencies, we were asking for too much detailed information about clients, expecting determinations to be made by too highly credentialed (and unavailable) personnel, wanting determinations made too fast, and then applying strong penalties when the States failed.

Among those commenters who thought the 7-day standard was unfair or unattainable there was, however, very little agreement on what the timeliness standard should be. A few commenters thought that States should be allowed to set their own standards based on their own unique circumstances. Of those who suggested alternative timeframes, some were willing to concede that the 7-day standard should be kept for admissions from hospitals or for emergency placement cases, but believed that more time should be allowed for admissions from other settings.

The distribution of suggested standards ranged from the 7 we had proposed to 30 days or longer for exceptional cases, with the largest number of commenters favoring the greatest time. Some commenters wanted a standard based on flat aggregate averages, averages with outer day limits, differential limits based on the location of the client, or limits with exceptions.

We also received a number of requests for a different and longer timeframe for PASs on individuals with MR. One screening contractor reported that to distinguish developmental disabilities from other causes of disability often requires an investigation that could not be done quickly. For example, this often requires sending for records from previous treatment programs or schools. Another disabilities advocate noted that only a small percentage of NF applicants who require PAS as a result of MR or related condition are residing in an acute care hospital when they apply. For those few seeking NF admission from hospitals or experiencing a crisis (current residence in an out-of-home setting that cannot meet his or her needs or the sudden loss of caregiver), the 7-day standard should apply. Otherwise this commenter believed the regulation should allow 30 days. Still another contractor performing PASs/MR stated that obtaining adequate histories on individuals with MR, particularly those of advanced age with no living relatives to substantiate an early history of MR/DD, is one of their biggest problems. In their view, substantiating a diagnosis of MR of any age is a serious matter and requires more consideration than just testing. They urged that the regulation allow adequate time to obtain as much previous information and history as is needed to do a thorough job and reach a responsible decision.

For both MI and MR populations, however, State agencies presented a variety of more general reasons for needing a longer timeframe than the proposed 7 working days:

- Many States use contracts to complete necessary assessments and can't always get the evaluations done when they would like.

- Especially on individuals coming from the community, data are not always in place and records must be requested or testing by appropriate professionals arranged.

- A State has no way of compelling physicians to cooperate in filling out forms, especially on applicants from the community.

□ It takes time to schedule the evaluation once referral is received. Contractor schedules have to be accommodated. Also, transportation has to be arranged which can be troublesome, especially in rural areas.

By contrast, a small number of States indicated support for a minimum standard of 7-days. Often these States alluded to having very high occupancy rates and a need for the fastest PAS system possible. Some consumer advocate groups were also concerned that without timeframes for emergency, priority and routine situations, individuals could lose a bed in high occupancy States while awaiting placement. We also heard from a number of NFs in States in which PASARR appears to be working well. These commenters saw no problem with the 7-day timeframe. We also heard from one private PASARR screening contractor who has successfully developed regional networks of professionals to do the screenings and has fully computerized its operation so that it is able to provide a 72-hour turn-around.

Response: The commenters raise a variety of valid points with respect to the different types of situations in which the screening may need to occur. In selecting a response to the comments, we recognized that the overall purpose of the timeliness standard was not necessarily to assure that each screening be accomplished very quickly but, rather, to assure that States operate an efficient process under which individuals are screened as quickly as possible.

The variety of views provided by the commenters convinced us that it would not be possible to establish alternative timeliness standards for all of the types of situations raised by them. We therefore rejected this approach in favor of a single timeliness standard which would nonetheless provide flexibility in individual cases. We are replacing the requirement that each determination be made in writing within 7 working days of referral to the State mental health or mental retardation agency with a standard that requires that the State's determinations reflect a maximum annual average timeliness of between 7 and 9 working days from the date of referral to the State mental health or mental retardation authority to the date of a written determination.

A standard requiring an annual average makes it possible for States to allow longer time periods for more difficult cases and permits it to take advantage of simpler cases to keep its average processing time in line with the requirement. We received enough comments in support of the proposed 7 day standard to persuade us that it is achievable. Nothing in the regulation would penalize an efficient State if screenings were performed more quickly than the required average. We would also encourage States to set their own timeliness standards within the limits we have identified. In particular, they may wish to establish categories of cases in which they require expedited review.

We have also rejected the idea suggested by some commenters of an outer time limit for individual PASs which would constrain the system of aggregate averages. We believe that setting an outer limit would induce some States to view reaching that limit in some cases as sanctioned behavior. We prefer to emphasize solely the goal of reaching an acceptable mean. States may wish, however, to set their own outer limits.

Because we recognize that in some States the SMHA and the SMRA are different agencies which may want to each keep their

own records on timeliness, we have added a provision at §483.128(c)(3) which permits separate averages for individuals with MI and MR. Both averages, however, would have to meet the same standard of an annual average of 7 to 9 days. Even in cases where two different agencies are involved, however, the State may wish to combine their averages if MR evaluations, on an average, take longer than MI evaluations. We leave it to the State to determine how it chooses to calculate its averages for the purpose of complying with the standard.

We are also adding a provision to the regulation indicating that an exception to the timeliness standard may be granted by the Secretary in cases where the State exceeds the average and provides justifications satisfactory to the Secretary that the longer period of time was necessary. We are including this provision to assure that we do not penalize a State when the average processing standard is exceeded for good cause.

We recognize that a number of the commenters were concerned about the timeframes involved in screening out of concern about payment for care, primarily continued inpatient hospital care, that may be necessitated during the time screening takes place. As we have noted, delays can be minimized in cases where the need for screening is identified at or near the time of admission and requested immediately. Moreover, there are existing provisions in both the law and regulations that permit States to make payment to hospitals in situations where individuals remain in the hospitals for lack of an NF bed and a number of States make such payments. FFP is available under Medicaid when States make such payments in accordance with the law and regulations. In the case of a Medicare patient who is a hospital inpatient and awaiting discharge to an SNF (which also participates in Medicaid as an NF), there is a similar provision of law which provides coverage for the days of care in question. (Whether actual per diem payments are made for such days depends upon whether the patient is in a hospital paid on a cost basis or, if in a PPS hospital, whether the patient is in outlier status.)

We note that a number of other changes made in this final regulation and discussed elsewhere in this preamble will have the effect of reducing the number of individuals being screened and decreasing to some extent the time it takes to perform some screening examinations.

It is not within the scope of this regulation to deal with the payment issues that arise from this provision and we have not done so here.

Comment: Various commenters touched on a number of other aspects of the timeliness standard than simply the timeframe. Several commenters supported the use of telephone calls to relay requests and announce results which we had presented in the preamble to the proposed rule. One commenter recommended that phone calls be required to be followed by written confirmation.

Response: We recognize the potential for errors to be made when determinations are relayed by telephone in advance of their reduction to writing; however, we are permitting this method of conveying determinations because we believe that the need for efficiency demands the use of quick methods. Our revisions to the timeliness standard, discussed above, no longer require that the average processing time be calculated from the date of referral to the date of a written determination but, rather,

simply measure the elapsed time between referral and determination.

Comment: A few commenters appeared confused about whether the 5-day limit we proposed in §483.128(j) for completion of the evaluation was included within the 7-day timeframe or in addition to it. Other commenters requested that the regulation not specify a separate timeframe for the evaluation, but leave it to States to work out how much time for evaluation and how much for determination. Still another commenter asked for further clarification as to when the clock starts in terms of timeframes for which States will be held accountable.

Response: Because we have revised the overall timeframe requirement to reflect annual averages, we are deleting the 5-day limit for completion of the evaluation in §483.128(j). As we noted in §483.112(c), as revised, PAS timeliness will be judged from the date of referral to the State MI or MR authority to the date of the determination.

Comment: Several States indicated that they would like the regulation to permit a categorical protective services determination for emergency cases similar to provisional admissions for delirium or short respite care (See §483.130(d)(4) through (6)).

Response: We recognize that an emergency may necessitate an immediate admission, to be followed as soon as possible with a PAS and appropriate assessment and care planning and we are revising §483.130(d)(4) relating to categorical determinations to permit such determinations to be made for a period of time not to exceed 7 days.

Comment: One commenter asked us to clarify in the preamble that this timeliness standard applies only to PAS, not to ARR. Because it was placed in the §483.112, the PAS section, and not in §483.114, the commenter thought that this timeliness standard applied only to PAS. However, he cited language in the preamble on p. 10962 (discussion of denial of FFP) which he believed suggests there is a timeliness standard for ARRs.

Response: Annual resident reviews are also subject to an FFP penalty if they are not performed timely. In a later comment and response discussion we note that we will permit ARRs to be performed in the quarter in which they are due in order to permit States to take advantage of annual facility reassessments required under §483.20(b)(4)(v). Accordingly, we would view an ARR as late, and therefore subject to the FFP penalty, if it were not performed by the first day in the subsequent calendar quarter. Since we have adopted the policy that ARRs may be conducted any time in the calendar quarter in which they are required, we do not see the need for further requirements relating to timeliness.

Comment: Few commenters responded to our request in the preamble to the proposed rule for information on whether a timeliness standard is needed for Level I. Most of them stated that they did not believe a Level I standard was needed. One commenter suggested a 3-working day limit while another suggested that a time frame for Level I is unnecessary if done by hospital discharge planners. However, if a State agency is doing Level I, the commenter felt a time frame is needed to assure prompt action. This commenter also felt that States should be required to reimburse hospitals for services furnished if patients must await Level I screening by a party other than the hospital. Another commenter noted that the Level I process in place in

his State has not created any delays.

Response: We do not believe that it is appropriate to establish a time frame for Level I screenings. Hospitals and nursing facilities have a clear incentive to perform such screens as soon as possible since they have an interest in prompt discharge and prompt admission approval, respectively. We received no information from the commenters that indicates the lack of a timeframe for this review has created a current problem. Therefore, we have not instituted a timeliness standard for Level I review.

Section 483.114-Annual Review of NF Residents

The proposal was that for each resident of a NF with MI or MR who entered the NF before January 1, 1989, the State must have made an initial review of that person's need for NF services and specialized services by April 1, 1990. Also, we proposed that the State must have in operation as of April 1, 1990, an ongoing ARR program for making such determinations for all residents with MI or MR regardless of whether they were first screened under PAS or the initial resident review.

Comment: Several commenters, noting that the proposed rule drew no distinction between screens for PAS and ARR purposes, objected to having to replicate the entire screening process every year. They believed that most of the people affected are elderly and not much change can be expected. They asked about the possibility of updating previous records or of performing abbreviated reviews for those residents who do not need specialized services. One commenter felt that the NF's mandatory annual resident assessment should suffice.

Response: Section 1919(e)(7)(B) of the Act requires that the State mental health or mental retardation authority review every resident with MI or MR on at least an annual basis. There is no way of avoiding this statutory requirement that the same questions relating to appropriateness of placement and service needs must be asked year after year if the individual continues to have MI or MR. However, we have never suggested that a completely new work up must be done on an individual every year. Indeed, in §483.128(g) we indicate that evaluators may use relevant evaluative data obtained prior to the initiation of PAS or ARR if the data are considered valid and accurate and they reflect the current functional status of the individual. Some further testing may be called for to verify the currency and accuracy of existing data, but zero-based screening is not required. Since a full medical history is an important part of any review, careful attention should be given to updating this history. This process should indicate whatever else, if anything, needs to be done.

As noted above in our discussion of the required coordination between the NF's resident assessment process and the State's PASARR process, the two processes should support each other and allow for interchange of data. If a significant change in the resident's condition has occurred during the year, it should have triggered a speedier ARR. As discussed in the response to the following comment, by allowing ARRs to be performed on a facility-by-facility basis within the quarter in which the anniversary date of the individual's ARR falls, we have increased the likelihood that a recent NF resident assessment has been

performed and will be available for the State ARR evaluators to use.

Comment: Several State agencies proposed that we allow ARRs to be done on a facility-by-facility basis rather than on the basis of the anniversary date of the PAS or initial review for each individual resident. Citing the inspection of care (IOC) review process and the utilization review regulations as precedents, they argued that scheduling ARRs on a routine basis would reduce costs and allow reviews to be done in an orderly manner. A few commenters asked that we allow ARRs to be done any time within the quarter in which the individual resident's anniversary date occurs while another few commenters requested that we allow ARRs to be done within 30 days of the anniversary date of last review. In asking for clarification of the meaning of "annual," these commenters sought to avoid disputes between NFs and the State mental health and mental retardation authorities as to deadlines.

Response: We agree that one feasible way for evaluators to accomplish the task of performing ARRs on all residents with MI or MR is for the State to establish a schedule of regular visits to each facility to review those residents who will come due for an ARR within a specified timeframe. We also want our requirements to allow for the maximum degree of coordination between PASARR and the NF's resident assessment. In the preamble to the proposed rule we indicated that the NF resident assessment could serve as the Level I screen although the resident would probably already be included in the State's tracking system if he or she received a previous PAS or ARR which confirmed the diagnosis of MI or MR. If a previously undetected condition of MI or MR were to be uncovered through the facility's resident assessment, this assessment should serve as a trigger for a Level II screen. If a Level II evaluation confirms the diagnosis of MI or MR, the resident would then be brought into the loop of the State's tracking system on all residents with MI or MR.

Because the PAS is performed prior to admission and, the first resident assessment is performed within 14 days of admission, there will always be a slight lag between the anniversary date of the PAS and the next annual resident assessment done by the NF. Adhering firmly to the anniversary date of PAS would mean that the most recent resident assessment available would always be, unless the resident had experienced a significant change in condition, nearly a year old. The Act requires coordination of PASARR processes with the mandatory resident assessment to the maximum extent feasible, and we believe it would be contrary to the intent of Congress to enforce a rigid ARR schedule that results in duplication of effort. We, therefore, find the proposal that ARRs be performed within the quarter in which the anniversary date falls to be an appropriate means of ensuring maximum coordination between the two processes. Subsequent AARRs would always fall, according to the facility visitation schedule, 4 quarters later. If a resident experienced a change in condition during the year, his annual review date could be readjusted using the date of this resident review.

We recognize that allowing a quarter's tolerance in which to schedule screenings might be viewed by some as not meeting the literal requirements of the law (i.e., that the ARR must be performed "not less often than annually"), we believe that

other parts of section 1919(e)(7)(B) of the Act provide a basis for allowing this amount of flexibility. Sections 1919(b)(3)(F) and 1919(e)(7)(A) of the Act require PAS to have commenced on January 1, 1989. Section 1919(e)(7)(B)(i) requires the on-going ARR to have been in effect as of April 1, 1990. Since the on-going system of ARR was not required to be fully operational until April 1, 1990, for the first quarter of 1990 the two processes were still not totally synchronized in terms of the Act. Furthermore, section 1919(e)(7)(B)(iii) provides that the ARR on an individual admitted after a PAS need not be done until the resident has resided in the NF for one year (i.e., not until one year after admission, not one year after the initial PAS which normally would have occurred some days prior to admission). Added to these facts is the requirement that the NF resident assessment process and the PASARR process should be coordinated to the maximum extent possible. This cannot be accomplished unless the ARR occurs after the annual NF resident assessment. We believe the quarter's lag may have been intended by Congress to avoid needless duplication of effort.

We are therefore interpreting "annual" to mean occurring within every fourth quarter after the previous PAS or ARR and are revising §483.114(c) to reflect this change.

Comment: Approximately 25 commenters representing both the States and NFs expressed various concerns relating to the April 1, 1990 deadline for the completion of initial resident reviews on all residents with MI or MR who entered NFs prior to the commencement of PAS on January 1, 1989. Most of these commenters asked that we include in the regulation a hold harmless clause with respect to the penalties proposed in §483.122, for recognition of States' good faith efforts to meet the deadline, or for a postponement of the deadline from April 1, 1990 to October 1, 1990.

A number of States felt that they should not be penalized for failing to meet the deadline, noting the lack of timely Federal guidelines. Other State commenters complained that until the resident assessment instrument based on the minimum data set is in place, it is impossible for NFs to do a good job of identifying individuals with MI and MR. Therefore, the States cannot be sure of having identified all individuals with MI or MR. On the other hand, several NFs in one State complained that they were impeded in performing their responsibilities because their State did not release its PASARR policy until February 1, 1990 due to lack of direction for HCFA. Some State agency commenters also expressed fears that when a final regulation is published, they would have to rescreen everybody done under their old PASARR processes which were based on previous drafts of the Federal criteria.

Nursing facilities, anticipating loss of FFP (see comments on §483.122), believed that they and their residents should not be penalized in the way proposed in the NPRM for the State's failure to complete all initial reviews by the deadline. For their part, States were concerned about the possibility of future disallowances through post-audits and disputes about dates and whether screening was complete enough to meet requirements. States also professed concern that the quality of services would suffer for those residents for whom disallowances are made.

Response: We have consistently indicated that our criteria

are advisory until we issue final regulations and that, when published, the standards contained in the final regulations will be applied only for prospective periods. The States are bound in the meantime by the statutory requirements alone. Completion of the initial resident reviews by April 1, 1990 is a statutory requirement. While we do not plan to focus our enforcement efforts on periods of time before the final regulations become effective, States are subject by law to FFP penalties if reviews have not been performed. Thus, we cannot by regulation hold harmless States which have failed to complete their reviews by the deadline. Some States may well be subject to disallowances in the future, as a result of audits done by HCFA or the Inspector General's Office.

Section 483.118 (b) and (c)-Persons Determined Not To Need NF Services

In §483.118(b), we proposed that, for a resident who requires neither NF services nor specialized services, the State must arrange for the resident's discharge from the facility and prepare the resident for discharge. In §483.118(c), we specified requirements for residents who do not require NF services but require specialized services. For an individual who continuously resided in the NF for at least 30 months before the date of the determination, we proposed that the State must arrange to provide specialized services, offer the resident the choice of whether to remain in the facility or receive services in an alternative setting, inform the resident of institutional and non-institutional settings, and if the resident chooses to leave the facility, clarify the effect on Medicaid eligibility. For an individual who has not resided continuously in the NF for at least 30 months, we proposed that the State must arrange for the discharge of the resident, prepare the resident and provide specialized services.

Comment: One State questioned the statement in §483.118(c)(1) that the State must, in consultation with the resident's family or legal representative and caregivers, undertake certain steps aimed at allowing the long term resident to choose between staying in the NF or moving to an alternative appropriate setting. They asked us to clarify the meaning of "consultation with the family," to inform them of what notice requirements are involved, and to specify that the placement decision can only be made by the resident or legal representative.

Response: Concerning the resident's choice of where he or she would like to live, the Act presents a decision-making process which involves a number of parties: The resident and any legal representative, State representatives, the resident's family, and the resident's caregivers who would presumably be the NF staff and the resident's physician. We do not believe that any special notice requirements are required. Rather we would expect this decision-making process to take place within the context of the regular care planning conference in the NF to which any legal representative and interested family members would be invited and encouraged to attend. The invitation to the legal representative and family members should, of course, explain the nature and importance of the discussions to be held and the fact that the Act requires that the family or legal representative be consulted. Efforts should be made to hold the conference(s)

at a time when all parties involved can attend.

In regulations published in the Federal Register on February 2, 1989 (54 FR 5316) we dealt extensively with the question of who may exercise the rights of residents, including residents who are incompetent or incapacitated. We clarified in that rule that only the resident or a legally appointed surrogate decisionmaker can exercise a resident's rights. Others may, however, assist a resident to exercise his or her rights. In the designation of legal surrogates by either judicial or non-judicial means, we deferred entirely to State laws. We would, therefore, allow the choice decision to be made, in the case of an incompetent or incapacitated resident, by any duly designated legal representative, whether this representative be a court-appointed guardian or conservator or someone operating under some non-adjudicative instrument authorized by the State such as a durable power of attorney.

Comment: A few States asked us to address the issue of permanency of resident's choice. Section §483.118(c)(2)(iv) requires the State to clarify for the resident the effect of choosing to leave the NF on his or her eligibility for Medicaid services under the State plan, including its effect on readmission to the facility. These commenters believed that residents choosing to stay or go should be allowed to change their minds.

Response: We do not agree. The language used in this section of the regulation is taken directly from section 1919(e)(7)(C)(i)(III) of the Act. The House Budget Committee language gives little further clarification concerning this requirement. It simply states that the State must "make clear to the individual and his legal representative whether he will lose Medicaid eligibility if he leaves the facility" (H.R. Rep. No. 391, 100th Cong., 1st Sess. 461 (1987)).

We believe that this language was included specifically because the choice a resident or his or her representative makes could be significant. We do not believe that it should be revocable. For one thing, we believe that the provision permitting longstanding residents to remain in a facility was intended to accommodate longstanding arrangements that a resident or family might not want to change. We believe it was intended to be a single, one time choice.

We would note, however, that a State might permit a longstanding resident of a nursing facility to take a therapeutic leave of absence for a limited period of time in order to determine if a different arrangement was more desirable. This regulation would not prohibit this type of action if the State elected to offer it. Once the choice is made, however, any future choices are subject to Medicaid rules in effect at the time of the choice.

Comment: Concerning the requirements at §483.118 (b) and (c)(2), several States objected to being required to arrange for the discharge of NF residents on the grounds that discharge planning and resident preparation and orientation for discharge are NF functions and requirements. Some commenters saw no way that the State could have a central discharge process while others asked for clarification of how the State is to work with the NF in discharge planning.

Response: Section 1919(e)(7)(C) of the Act places certain discharge responsibilities on the State as a condition of approval of its State plan. However, since 46 States have alternative

disposition plans (ADPs) covering NF residents who are in need of relocation to alternative appropriate settings, discussion of the State's responsibilities concerning discharge planning must be framed in the ADP context, at least for two of the three groups for whom the statute gives the State discharge responsibilities. ADPs may cover the long-term residents identified in §483.118(c)(1) who elect to move and the short-term residents identified in §483.118(c)(2) all of whom must move. Section 1919(e)(7)(E) of the Act, which permits ADPs, does not permit inclusion of the third group of potential discharges, those residents who are found to need neither NF nor specialized services who are identified in §483.118(b).

The NF can only discharge residents to already existing placements. The State, on the other hand, has statutory responsibility for making available the appropriate alternative settings to which residents can move. To deal with these residents, the State must have a master plan which, based on assessed needs, provides for the expansion or creation of the placement options, in the right numbers and types, as have been determined to be needed. This is the essence of the ADP process. Discharge planning cannot begin until residents have some place to go; seeing that they have some place to go is the State's role.

The States are correct, however, in asserting that the actual act of discharging the resident and the preparation and orientation activities which normally occur shortly before the discharge are the NF's responsibility, as identified in §483.12(a) of the regulation. The NF must abide by the requirements of this section.

Comment: Some States were concerned that 30 days for discharge is not enough time to work out relocation plans for those residents needing to be moved.

Response: In response to concerns raised by some commenters that 30 days is an inadequate period in which to make alternative living arrangements, we would assert that, depending on the timetable which the State has set for itself in its ADP, it has time in which to make the necessary arrangements before discharge can take place for most residents who are slated for discharge. Only in the case of residents identified in §483.118(b) (i.e., those who require neither NF nor specialized services and are thus not protected by an ADP) would discharge have to be accomplished speedily under the terms identified in section 1919(c)(2) of the Act and §483.12(a) of the February 2, 1989 rule. We note, however, that the 30 days begin from the date of the NF's issuance of a discharge notice to the resident, not from the date of the State authority's determination letter.

Comment: A number of NFs were concerned that some of their residents, whom they believe need the more structured setting of the NF to function, would be harmed by discharge into poorly supervised community settings or to non-existent alternatives. They wanted to have an opportunity to make recommendations concerning placement options for these residents.

Response: We recognize the interests of NFs who commented that they know their residents well enough to believe that continued NF placement is the most appropriate course. As noted in a previous response, the State is required to include the resident's caregivers among those with whom it consults in the process of allowing the long-term resident to select the placement option he or

she wants and in arranging for the safe and orderly discharge of the short-term resident who needs only specialized services. In fact, if a long-term resident elects to stay in the NF, such discussions are critical, given the need for the State and NF to coordinate with respect to the issue of specialized services.

As to the issue of alternatives, we would note that the law absolutely requires that the States make appropriate alternatives available and we would not anticipate a State ordering a discharge where a placement is not available. We cannot, however, provide formally for the NFs to participate in the State's decision-making process concerning the types of alternative appropriate placements it chooses to develop. Informally, however, NFs may be able to influence the decision-making process for the residents about whom they have special concerns by supplying information about the residents' needs.

Comment: Both NFs and States expressed concern over how the costs of discharge activities associated with ARR determinations would be covered. States asked if the 75 percent Federal financial participation (FFP) for PASARR activities would be available for the State's discharge planning activities. NFs, who generally expressed disfavor over our previous program instruction which prevented States from paying NFs for PASARR costs, except through the regular NF per diem rate, enumerated their cost factors resulting from having to handle ARR discharges. They claimed that if the State makes a decision to remove a resident from a facility because of ARR, the time and cost involved for the NF will be considerable. For none of these costs does the NF receive any extra reimbursement even though it is acting as the State's agent in carrying out the discharge.

Response: Both of these questions concerning the availability of the 75 percent FFP for discharge planning activities of the State and the status of NFs are discussed under §§483.122 and 483.124 where other FFP issues are dealt with. We would note, however, that there is nothing to prevent a State from paying NFs for the services they perform in accordance with the State plan. In fact, section 1902(a)(13) of the Act and §447.250 of our regulations require such payments to be made. It is up to the State to determine its nursing home payment rates, subject to approval by the Secretary, and so we have not specified how such costs should be taken into account in rate-setting.

Comment: One commenter asked whether the right to stay in a NF, which is available to residents who have resided in a NF for 30 months or longer, is a portable benefit that moves with the resident if he or she wishes to transfer to another NF. Because we had proposed that interfacility transfers would require PAS, the commenter further asked whether the right applies only to ARR situations or whether it would also apply to PAS situations when the resident wishes to move to another NF.

Response: It is clear that Congress intended not to disrupt long-standing care arrangements by granting an exception for long-term residents who do not need NF services, but do need specialized services. It is not quite so clear whether this exception is specific to the NF in which the resident was located at the time of the determination or whether the exception can be more broadly interpreted to mean that the resident has the right to elect to remain at the NF level of care and receive the specialized services he or she needs in that setting rather

than being compelled to relocate to a more appropriate setting.

We believe that one can readily argue that Congress exempted this long-term population in the belief that these residents should not be forced to suffer for placement mistakes made by others in the distant past. It can also be argued that Congress believed such individuals, having been institutionalized in the NF for a long time, would have lost all ties with the community and would not be able to cope in a community placement if that were the State's preferred treatment setting. In order not to subject them to the trauma of involuntary transfer or forced adaptation to an unfamiliar treatment setting, Congress allowed these residents the option of choosing to be inappropriately placed.

Under this line of reasoning, that freedom from coercion was Congress' objective in dealing with these long-term inappropriately placed residents, the decision to be inappropriately placed is permanent and should be portable. To require the resident to remain in the particular NF in which he or she was located at the time of the determination or to require him or her to move involuntarily to a setting which is not of his or her choice--perhaps years later--because of the closure of the original NF, would be a strange form of bondage indeed. Freedom from coercion, in this case, from involuntary transfer cannot be turned into another form of coercion, the denial of a right to voluntarily transfer.

We believe, therefore, that Congress intended the choice for long-term residents to be a general, portable benefit rather than one specific to a particular NF. While it is likely that most residents will want to remain in the same facility for reasons of familiarity or convenience, it is also likely that some residents may need or want to transfer to other nursing facilities. For example, beds may become available in a facility nearer to the homes of family members, or one facility may close or cease to participate in the Medicaid program, thus necessitating a transfer. As previously discussed, we are revising §483.106(b) to exempt these individuals in most cases from PAS requirements when they transfer from one facility to another.

Comment: Other commenters, chiefly advocates for individuals with MI and MR, responded to §483.118(c)(1) by asserting that there would be no real reform if there are no new more appropriate placement options created. These commenters claimed that ADPs began to address the need to create more community placements, but they were concerned that the regulation did not really provide any treatment of ADPs, giving just passing references to them. This group of commenters was distressed that at various points we discussed discharge to alternative settings, without specifying that these alternative settings must be appropriate (e.g., at §§483.118(c)(1)(iii) and 483.130(o)(3)). These commenters were particularly concerned about the possible discharge of short term residents to homelessness or inadequate and inappropriate settings.

Other disabilities advocates felt that the proposed regulations at §483.118(c) did not clearly reflect the intent of section 1919(e)(7)(C)(i) of the Act that a long-term resident who requires only specialized services can receive those services in a non-institutional setting. They believed we had failed to take into proper account the phrase, "regardless of the resident's choice"

of institutional or noninstitutional settings, which would require the State to provide specialized services in non-institutional settings. They urged us to require by regulation that the State must provide specialized services in non-institutional settings. Without this requirement, these commenters believed, the State mental health authorities could simply move these residents with MI back to the State mental institutions from which they had been deinstitutionalized a decade ago.

Response: We agree with the commenters that the provisions of the law will not have been implemented if the alternative placements required under it are not made available by the States. We also agree that the placement opportunities created by the States under this law must be appropriate. We would note, however, that the States themselves have considerable latitude in devising such placements and we do not believe it is proper for us to enumerate or describe the various alternatives a State may choose. On the other hand, the law does require that the States provide appropriate treatment both in and outside NFs in order for their State Medicaid plans to be in compliance with the law, and a failure to do so would subject a State to a compliance action under section 1904 of the Act.

We also agree with the commenters who wanted us to add the statutory words "regardless of the resident's choice" to the language in §483.118(c)(1)(i). While we believe that the language carries the meaning desired by the commenters in its proposed form, we have clarified it further by adding the phrase desired. The law clearly requires that the State provide specialized services to the individuals who require it both inside and outside of institutional settings. (See also the discussion of §483.132(a).)

Comment: One commenter was concerned about the impact on the board and care industry of our requirements to discharge residents who do not need NF care. They asserted that States should not evict elderly individuals with mental illness from the medical model of care (which they believe the NF embodies) until there is funding for a social model within which the board and care industry plays a part. This commenter believed that personal care homes could provide a social model at great savings, but they must have adequate funding if they are to assume this role.

Response: While the PASARR statutory provisions require that States ensure placements for those to be discharged from a NF, the nature and funding of alternative placements is determined by the States. Whether personal care homes would be a suitable alternative placement for some individuals being discharged and what funding sources would be available for that placement are questions that are beyond the scope of these regulations.

Comment: Only a few commenters addressed our discussion in the preamble to the proposed rule of "temporary absence" from a NF as it relates to determining whether a resident has continuously resided in a NF for 30 months for purposes of eligibility for the right to choose to stay in the NF. More commenters were concerned with the use of this term as it relates to determining if a resident who underwent a hospital stay or therapeutic leave could be considered a readmission of a new resident (see discussion of §483.106). The few commenters who responded to the concept of a temporary absence as counting toward a continuous residence believed that the State's bedhold period, if one exists, is

too short a time period. Some commenters suggested 30 days.

Response: Because the OBRA '90 changes concerning readmissions contain no time limits on the period of absence from the NF, we have removed references to "temporary absence" from our definition of readmissions in §483.106(b). Although readmissions are not subject to PAS, they continue to be subject to ARR. This fact effectively sets an outside limit of one year on what can reasonably be called a temporary absence for hospitalization or therapeutic leave.

We do not believe it is appropriate to set a more precise limit on the length of a temporary absence from a NF for purposes of counting periods of continuous residence than the one year outer limit implied in §483.106(b) for readmissions. We agree with commenters that a State's bedhold period is likely to be too short. We also reject the 30-day limit suggested by some commenters. We believe, instead, that the issue should be resolved on a case-by-case basis by review of the resident's records. For example, a long-term resident may well be granted a therapeutic leave for a period longer than 30 days with the expectation that he or she will return to the facility. In other cases, residents may sustain periods of hospitalization of longer than 30 days even though there is continuing expectation that the patient will return to the NF (or another NF, if the resident's bed has not been held or if there is no bed available at the time of the hospital discharge). The key, we believe, is a finding by the State that when the individual left the NF, there was an expectation that he or she would return to the facility (or another facility) at the end of the absence.

Comment: Commenters also asked whether time spent in a Medicare SNF bed could count toward the 30 months of continuous residence.

Response: This comment is addressed previously under the discussion of proposed §483.102, applicability to Medicare beneficiaries.

Comment: One commenter asked whether §483.118(c)(3) applies only to the initial review of residents who entered the NF prior to the start-up of PAS on January 1, 1989 or whether the 30 months could be counted back from subsequent determinations performed on individuals covered under an alternative disposition plan (ADP).

Response: The initial resident reviews were required by the Act to be completed by April 1, 1990. Short-term residents who were found under the initial resident reviews to need only specialized services were eligible for inclusion under an ADP. At subsequent ARRs, these residents would eventually reach 30 months residency if they remained in the NF awaiting relocation under the terms of the ADP. If we permitted the second interpretation (i.e., that the 30 months could be counted back from subsequent determinations), these residents would be eligible to choose to stay in the NF once they had resided in the NF for 30 months. In other words, eventually no one would have to be moved as all would have attained long-term resident status.

Clearly, this interpretation is unacceptable. We have, therefore, amended §483.118(c) to state that the 30 months residence is calculated back from the date of the first annual resident review determination which finds that the individual is not in need of NF level of services. This means that if the resident were found through the initial resident review performed prior to April 1, 1990 not to need NF care, his or her status concerning

the right to choose to stay would be permanently established based on the number of months of residence the resident had attained at that time. Subsequent reviews would not alter his or her status as a short- or long-term resident. However, another resident could be found through the initial resident review to need both NF care and specialized services but, upon subsequent review, be found to need only specialized services. For instance, such a result could occur if there was an improvement in a physical impairment. The subsequent determination, in this case, would be the first time an ARR found the individual to need only specialized services. Length of residence would then be calculated back from this subsequent review.

Section 483.120(a)(1)(i)-Definition of Specialized Services for Mental Illness

In §483.120(a)(1), we proposed to define specialized services (formerly known as active treatment) for mental illness as the continuous and aggressive implementation of an individualized plan of care that is (i) 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 behavioral 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 specialized services level of services at the earliest possible time.

In §483.120(b), we proposed that, for mental illness, specialized services do not include intermittent or periodic psychiatric services for residents who do not require 24-hour supervision by qualified mental health personnel.

Comment: Although a few commenters favored a broader definition of specialized services than we proposed, the overwhelming majority of commenters who responded to this section on the definition of specialized services for MI supported the definition which restricted specialized services to the level of intensity of services and degree of supervision that might be found in an inpatient psychiatric setting. Some of those who supported the definition in general principle had, however, some refinements to suggest. Those who objected to the definition were afraid that individuals with serious mental illnesses which are not in an acute phase currently might not get the intensity of services they need, even though they do not need specialized services for the moment. A very few commenters, thinking that what was called active treatment is active and anything less than active treatment is passive or non-existent, wanted the definition of what is now called specialized services to be broadened to include all MI conditions except non-reversible degenerative disorders such as dementia.

Those who supported the narrow definition did so largely because it allows the vast majority of individuals with mental disorders to enter and reside in NFs. Coupled with the strengthening of the requirements that the NF meet the mental health needs

of its residents, if these needs are below the specialized services level, these commenters were satisfied that the needs of these residents could be served and stood a better chance than ever before of being served.

For example, one commenter believed that the vast majority of people in NFs with mental disorders have not been in public institutions. They are either individuals with late onset mental health problems such as Alzheimer's disease or the physically ill elderly who develop associated psychiatric, emotional or behavioral conditions. Most common among these are depression, wandering, confusion, disorientation, withdrawal lethargy agitation, stress reaction, dependency, apathy, and irritability. While individuals who exhibit such conditions and behavior clearly need some form of treatment, which should be identified in the care planning process, the treatment will not be so intensive that it should be considered specialized services.

Another commenter noted that removal from the NF should be restricted to those individuals whose needs are so severe that they cannot be adequately provided for within the NF. This commenter was happy that, under this clear definition, there would be no question that most individuals with mental disorders would be able to be admitted to or remain in the NF.

A mental health professional organization expressed support for the separation of the definitions of specialized services for MI and MR. While it liked the definition which restricts specialized services (formerly known as active treatment) for MI to an acute episode of MI (now defined as a serious mental illness), the organization recognized that the old statutory term "active treatment" had created problems in implementing these PASARR provisions. The commenter indicated that his organization, like a number of others, favored a statutory change in the term to "specialized and intensive treatment" with separate applications to persons with MI and MR instead of the term active treatment.

Response: We believe that the comments as a whole support the approach we have taken to specialized services. We agree generally with the commenters that the statutory use of the term "active treatment," as opposed to a term such as "specialized service," made it difficult to discuss the concepts involved without some confusion over issues of institutional versus noninstitutional services and without creating concern with respect to individuals whose needs fall in the middle of the continuum of mental health care rather than at either of the ends. Congress has solved this problem for us, however, by substituting the term "specialized services" for "active treatment." The supporting committee language from the House Energy and Commerce Committee (H.R. Rept. 101-881, 101st Cong., 2nd Sess. 118 (1990)) indicates that we are free to define this concept as we see fit with only one restriction. The report notes:

As under current law, the term 'specialized services' is to be defined by the Secretary. And like current law, the Secretary cannot define 'specialized services' to include those services within the scope of services that a nursing facility must provide or arrange for its residents under the OBRA '87 requirements relating to the provision of services and activities.

We are choosing to define "specialized services" for MI in

the same fashion in which we defined active treatment for MI in the NPRM and have modified the definition to take account of commenters' suggestions as described in this section of the preamble. Essentially we are simply substituting one term for another. We believe this is the intent of Congress as well as of those groups which sought the legislative change from Congress. However, we recognize that there may be other views on this issue and will accept comments on it in response to this final regulation.

As will be explained more thoroughly in §483.120 (c) and (d), specialized services are a State-and not a NF-responsibility. Nursing facilities are responsible for all mental health services needed by residents with mental disorders who are determined under the new definition of MI not to have MI as well as for those services needed by residents who are determined under the new MI definition to have MI but which are not, because of their intensity and scope, classed as "specialized services" and provided separately by the State.

Originally, the term active treatment referred to a mode of treatment rather than a set of treatments. By exchanging the term "specialized services" for "active treatment," we are substituting terms and not concepts. We wish to preserve the original intent of emphasizing the mode and intensity of treatment rather than the separate and distinct nature of these specialized services.

Since enactment of OBRA '90, we have been asked by some members of the interested public to develop lists of services which are considered to be specialized services which the State would be responsible for providing. (This request has also been made with respect to specialized services for individuals with MR and is also discussed under that topic).

As a practical matter, we find that we cannot list certain discrete services as separate and distinct from nursing facility services. As we noted in the NPRM, with respect to active treatment for MI, "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." (55 FR 10951, March 23, 1990, p. 10961). The requirement of OBRA '90 that the NF is responsible for providing mental health or mental retardation services not provided or required to be provided for by the State, implies that the same types of services will be provided by both the State and the NF. The difference is a matter of intensity and frequency.

The PASARR report, as discussed later, becomes the key, for each individual with MI or MR, to determining who does what and who is responsible if services are not being supplied. As discussed in §483.128, the PASARR report must identify, if specialized services are needed, what those services are. The report must also identify, whether specialized services are needed or not, what mental health or mental retardation services are needed which are below the level of specialized services and are to be considered NF services. Thus, on the individual level, a list of specialized services for which the State is responsible and a list of other mental health or mental retardation services for which the NF is responsible is developed as a result of the PASARR process. Based on the PASARR report a NF can make

admission decisions on prospective residents with MI or MR. State surveyors will also be able to tell which services are the NF's responsibility and which are the State's.

We are leaving it open to States to craft a list of services which they believe are "specialized services," if they so choose. The State plan preprint will provide States with an opportunity to list these specialized services, if the State selects this option. Such a list could serve as a fixed menu from which specific choices could be made for each individual and listed in his or her PASARR report. Since mental health and mental retardation services delivery systems vary from State to State, we believe it is preferable to allow States the flexibility to define specialized services within the context of their own systems rather than prescribing a uniform national list of what these services should be.

Comment: Among those commenters who supported the basic idea of a definition that characterizes specialized services as an intensive level of services, some commenters objected to what they characterized as the institutional character of the definition we provided. One group, which otherwise supported the approach, stated that one of its few major disagreements with the proposed rule was that the definition of specialized services failed to recognize that the law authorizes the provision of these services in a non-institutional setting. Apparently, our proposed definition was viewed as implicitly relating to inpatient services. This commenter recommended some slight modifications in the definition, including removal of the reference to 24-hour care, to make it refer more clearly to community-based services as well. Another mental health professionals' organization concurred with this view stating that it is unrealistic to require 24-hour care in a community setting or a nursing home. Although residents experiencing an acute episode of MI certainly require close supervision, the professionals asserted, these residents may not require 24-hour care. Another commenter asserted that the focus in our description on 24-hour care implied that persons with more moderate symptoms never need specialized services.

On the other hand, another commenter stated that the need for 24-hour care should be included in the definition of specialized services for MI rather than just in the definition of what specialized services is not. Still another commenter suggested that this section, which aims at a functional definition of the need for specialized services, needs to be supported by clinical and functional indicators rather than time indicators.

Response: In general, the commenters on intensity of services (i.e., in need of 24-hour supervision) and institutional bias in the definition make some of the same points made in connection with the term specialized services for persons with MR. As we noted in the response to those comments, we do not believe that the definition reflects an institutional bias, since it requires such services on an inpatient basis only for persons who require it or under the limited exception available to persons who have resided in the NF for more than 30 months. The definition stresses the treatment, not the setting in which it is furnished. As we have noted elsewhere in this preamble, the term 24-hour supervision does not require 24-hour treatment programs but, rather, the availability on a 24-hour basis of staff who are prepared to intervene as appropriate to deal with symptoms that may arise.

That is, we mean to identify individuals whose needs are such that constant supervision is needed to assure proper care.

The language in the proposed regulation concerning what specialized services are not was taken in part from our ICF/MR regulations, where it was designed to distinguish between clients whose needs should be met outside the facility and those clients whose needs would be appropriately met inside the facility to assure that inappropriate placements were not made. We believe that the NF context is one in which resident needs are sufficiently heterogeneous that this restriction is not helpful to the definition. Moreover, the comments persuade us that the term "24-hour a day supervision" has given rise to the erroneous impression that actual treatment must proceed throughout each 24-hour period. We are, therefore, deleting that portion of §483.120(b) that characterizes what specialized services are not. We believe that this change will eliminate the impression of institutional bias and the misunderstanding of the term "continuous" for both the MI and MR populations.

Comment: Among those commenters who wanted a somewhat less stringent definition of specialized services, one organization stated that while they agreed that the statute intends something more intensive than would normally be appropriate in a NF setting, they believe that the proposed definition leaves too much out. This commenter was concerned that a large range of mental disorders and treatments would remain undistinguished and unaddressed by the PASARR process. Chronically mentally ill residents who have acute episodes of illness and require intensive but intermittent psychiatric care would not be distinguished under PASARR from those who suffer milder depressive disorders that are controllable and readily treatable within the NF setting. The commenter recommended that the definition of specialized services be expanded to include those chronically ill individuals who need intensive, though intermittent, psychiatric treatment. Under such a definition, the State would be required to pay for the psychiatric care of these people.

In a similar vein, another consumer advocacy group objected that the narrow proposed definition sets individuals up to be shifted back and forth between settings with every swing in their condition. This same commenter argued that we are using the definition mainly to perform a gatekeeper function. By limiting the definition to very extreme circumstances, the commenter argued that we restrict the number of people to whom it applies and therefore reduce the number of people who will be found to need specialized services (which the commenter felt would, at least by implication, bar them from NF placement). Yet, the commenter maintained, the statute allows for a combination of needs and seems to direct evaluators to look at those needs in combination and send people to the right setting accordingly. In the commenter's opinion, we may prevent people from being served by using such a stringent definition.

This commenter believed that our efforts to require the NF to provide all mental health services short of specialized services might accomplish the desired end, but only if the definition of services which are less than specialized services clearly addresses the needs of people with serious MI who are not in an acute phase of their illness. The commenter urged us to find a way for persons likely to be gravely affected by continuous transfers from one setting to another to receive the care they

need without disruption.

Response: We agree with the commenters who indicated that some individuals may function quite well in a NF setting but may occasionally need specialized services for the management of an episode of MI or to adjust medication. We believe that such individuals would likely be found not to need specialized services when screened and we believe that it can be appropriate for such individuals to reside in NFs even though occasional hospital admissions may be necessary for symptom management. In response to comments about individuals whose condition may necessitate frequent inpatient hospital stays for treatment, we note that knowledge of such a need would likely affect the State's view of whether the individual's needs could be met in a NF and result in a determination that NF care is not appropriate.

These, like a number of other comments, appeared to be directed towards the conclusion that the possibility of inappropriate screening determinations would give rise to inappropriate placements which would result in inappropriate treatment. While we agree that the effect of errors in the operation of PASARR systems may be inappropriate placements, we do not believe that these regulations can totally prevent the possibility of errors.

We do not believe that this regulation will result in the routine admission of individuals with serious mental illness (MI as it is currently defined as a result of OBRA '90) because such individuals are not likely to be able to receive appropriate treatment in that setting. The regulations clearly require that all individuals who are admitted to NFs receive the services they require, so we do not believe that the regulations themselves envision admission of individuals with needs that will go unmet. As we have said earlier, it is difficult to discuss these issues without reference to specific cases for discussion. When a State determines that an individual requires NF services and specialized services, the State must do so in anticipation that it will provide the treatment. When a NF considers admission of an individual approved by the State it must determine if it agrees his or her needs can be met in the facility and must meet those needs (in conjunction with the State, if the needs include the need for specialized services) if it elects to accept the individual for admission.

Comment: A large group of commenters, particularly doctoral-level psychologists, objected to the requirement that a physician must supervise the plan of care in the provision of specialized services for MI. Feeling that this requirement puts non-physician team members in a subordinate position, these commenters noted that physicians rarely see NF residents. They contended that mental health professionals, in collaboration with physicians, should provide the bulk of specialized services in an NF. These commenters understood that we had borrowed this language concerning the role of the physician from the context of the psychiatric services for individuals under 21 benefit. They asserted that physician supervision of the interdisciplinary team is generally not necessary for NF residents with MI because pharmacological treatment is often not required (and, if anything, is overused). They believed that for NF residents with MI less invasive interventions are often more effective. For these reasons they requested that we change section 483.120(a)(1)(i) to make it consistent with the requirements in the ICF/MR regulations which state that

the plan of care is "developed by an interdisciplinary team that represents a physician, other qualified mental health professionals, disciplines or service areas."

Response: We agree that this provision requiring physician supervision of the specialized services plan of care needs revision. As we discuss more fully under credentialing issues, recent legislative changes affecting a number of Federal health care programs have granted doctoral-level psychologists increased autonomy in both inpatient and outpatient settings. Specifically, doctoral-level psychologists, operating within the scope of practice permitted by State law, are now authorized to admit patients to inpatient psychiatric settings under Medicare as if these services were provided by a physician and to supervise their plan of care while there, so long as the patient's physician is informed of the treatment being provided.

The definition of specialized services (formally called active treatment) for MI which we proposed in the NPRM grew out of the existing definitions of active treatment in the regulations governing the inpatient psychiatric services for individuals under 21 benefit and in manual instructions relating to inpatient psychiatric hospital services. These regulations and instructions require physician supervision of the active treatment plan of care for these benefits. Because of the above-cited recent legislative changes and because we agree with other points made concerning treatment needs of NF residents with MI, we believe that for our purposes here the specialized services plan of care should be developed and supervised by an interdisciplinary team rather than by a physician. The team should include a physician and qualified mental health professionals and other professionals as appropriate. We have therefore revised the regulation accordingly.

Comment: Another organization of mental health professionals, while supporting the general character of the specialized services definition for MI, recommended that we change the word "psychotic" in (iii) to "behavioral" or "psychiatric."

Response: We are replacing the term "psychotic" in §483.120(a)(1)(iii) with the term "behavioral" because we agree that this word better expresses our intention.

Section 483.120(a)(2)-Definition of Specialized Services for Mental Retardation

In §483.120(a)(2), we proposed to define specialized services (formerly active treatment) for mental retardation as treatment that meets the requirements of §483.440(a)(1). That section defines active treatment for residents of intermediate care facilities for the mentally retarded (ICFs/MR).

Comment: Several advocates for individuals with developmental disabilities objected strongly to our cross-referencing of the definition of specialized services for individuals with MR to the definition of active treatment contained in the ICF/MR regulations. Some of their views can be summarized as follows:

□ PASARR presents an opportunity to take a fresh look at specialized services needs of individuals with MR. Instead HCFA has relied on a medical model with its inherent institutional bias and which is narrow, inflexible, and outdated. It does not accommodate the variation and complexity of needs among individuals.

□ By tying care to a model which requires 24 hours of supervision a day, HCFA is discouraging clients from achieving a degree of independence or success. Needing 23 instead of 24 hours of supervision a day, could result in loss of eligibility for services. This discourages clients from acquiring independent skills.

□ HCFA's reasons for adhering to this definition-that the Act requires active treatment to mean what the Secretary defines it to be in regulations and the ICF/MR setting is the only context in which such a definition of active treatment for MR currently exists-are unconvincing.

Noting that the ultimate solution was to get a statutory change which would delete the reference to active treatment and require instead "specialized services," commenters, in the meantime, requested a separate definition of specialized services, which would leave the NF responsible for providing basic services that any NF resident would be entitled to receive. Supplementary services that are necessary to help the individual achieve appropriate developmental goals would then be provided by the State. This solution would focus on the types of adjunctive services and assistance persons with developmental disabilities may require while living in a NF. By contrast, only a few commenters, representing NFs, supported restricting the definition of specialized services for persons with MR to within the parameters of the ICF/MR.

Response: We believe that to a large extent these commenters' concerns arise from a misunderstanding of the definition of active treatment that we have referenced in the proposed regulations. We believe that the definition of active treatment contained in §483.440(a)(1) is not tied to institutional care. The key to this definition, as stated in that regulation, is-

The acquisition of the behaviors necessary for the client to function with as much self-determination and independence as possible; and the prevention or deceleration of regression of current optimal functional status.

The program of active treatment is described as "continuous" and includes an "aggressive, consistent implementation of a program of specialized and generic training, treatment, health services and related services" that is directed toward that result. We believe that this definition is as relevant to services outside an institution as it is to services inside an institution. It is undeniable that, in many cases, an ICF/MR may be the only place where such services are available and, when that is true, an ICF/MR is the appropriate placement. It is also true that hundreds of persons with MR/DD diagnoses are served in the home and community under waivers which, as a condition of being granted, require that the client be in need of institutional care under Medicaid definitions.

One source of concern to the commenters, apparently, was the additional language in the referenced definition that indicated-

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.

This statement is intended to assure that persons with MR/DD diagnoses who require fewer services because of their independence

and functional status are not inappropriately retained in an institutional setting. It does not exclude non-institutional settings. The comments on the need for a 24-hour a day program and suggestions that individuals who require 23 or fewer hours are excluded reflect a misunderstanding of the concept generally. It is not that treatment itself must occur on a 24-hour a day basis. Rather, it is that individuals who lack the independence to function without constant supervision have such supervision available to them in the event that it is required. It also means that there is continuous competent interaction among all facility staff who come in contact with the individual so that treatment modalities identified in the plan of care can be properly implemented and reinforced as needed on a 24-hour a day basis. If the need for supervision or treatment is not predictable because of the individual's condition, then clearly it needs to be available at all times. However, while we believed this language is useful in understanding the meaning of the term we were defining, "specialized services" we now recognize that it gives rise to misunderstanding and we are therefore removing it from our cross-reference. The reference now includes only the positive language describing the treatment program.

A remaining concern of the commenters was the use of what they call a "medical model" for the treatment of persons with MR/DD. We understand their concern to be that such a definition does not enable Medicaid funds to be used for general social and community support of individuals who are generally independent, leaving this area of support to other Federal and State programs. We believe that this focus on individuals with greater needs is consistent with the purpose of the Medicaid program.

We note that the most recent Congressional consideration of this concept occurred in connection with H.R. 3299, the version of the 1989 reconciliation act adopted by the House Budget Committee. Section 4231 of that bill would have renamed ICFs/MR as habilitation facilities and codified in law many of the requirements in current regulations. Among them would have been the concept of continuous active treatment. Thus, we believe that the current definition represents an accurate interpretation of the Medicaid program's mandate and we have not changed it.

The decision as to whether an individual requires specialized services while in a NF is a complex one related to that individual's general independence and functional status and the concomitant presence of a mental or physical condition in connection with the MR/DD diagnosis. The concomitant illness might temporarily limit an individual's ability to benefit from specialized services or require modification in a specialized services program. Once the decision is made, however, we believe that the treatment may be furnished both inside and outside of institutions.

In response to those commenters who requested a separate definition of specialized services which focuses on supplementary services that are necessary to help the individual achieve appropriate developmental goals, we refer to the discussion under the previous section on specialized services for MI. In that discussion, we point out that, as a practical matter, it is not possible for us to develop a uniform list of certain discrete services that are not also part of NF services which now, as a result of OBRA '90, include mental health and mental retardation services that are less than specialized services.

As we indicated in the previous section, we are allowing States the option of developing such a list. Whether the State develops such a list or not, however, we anticipate that the individual PASARR report will identify which services the individual needs are specialized services for which the State bears responsibility and which are NF services.

For these reasons, we have not revised the specialized services definition for persons with MR, except to substitute terms and to remove paragraph (b)(2) on what specialized services are not, which was a source of confusion.

We recognize, however, that some readers may not agree with the manner in which we have adopted the term "specialized services." We will, therefore, consider public comments on this issue.

Comment: Some disabilities advocates also claimed that designing and implementing a specialized services plan as defined in the ICF/MR regulations does nothing to promote the goal of community living and maximum independence for people with MR. In their view, the present ICF/MR regulations do not approach what are considered best practices in the field of developmental disabilities. They believe that adopting these regulations as a model for specialized services frustrates the goal of the legislation which is to provide quality lives. They requested that the definition be broadened to allow for and, in fact, encourage transfers to settings in the community.

Response: Because these concerns are similar to comments discussed under §483.118(c)(1), we have addressed them at that location.

Comment: Disabilities advocates also argued that the ICF/MR definition of active treatment is a global concept, which assumes that all persons with severe, complex developmental disabilities, regardless of medical complications, can benefit from active treatment services. Everything they need and get, whether the services attend to physical or developmental needs, is part of active treatment. The result, they claimed, is that for individuals who require both NF and specialized services there are no benchmarks for judging when NF care is or is not appropriate. Advocates also claimed that this definition puts the NF in the business of being an ICF/MR.

Response: These comments are similar to those raised by States over the practical difficulty in drawing a line between the State's responsibility to provide specialized services and the NF's responsibility to provide all mental health and mental retardation services below the specialized services level to individuals who need these services. We are addressing these concerns in our discussion of §483.120(d).

Section 483.120(c)-States Must Provide Specialized Services

In §483.120(c), we proposed that the State must provide or arrange for the provision of specialized services (previously known as active treatment) 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.

Comment: In response to the requirement that the State must provide specialized services to all residents who are determined to need them, a number of States protested that there is no

way to do this short of bringing qualified mental retardation and mental health professionals into NFs. They strongly objected to having to make NFs into ICFs/MR or psychiatric treatment facilities. Terming this impossible, they noted that a statutory change is needed to absolve them of this onerous responsibility.

Response: We have discussed the substitution of the term "specialized services" for "active treatment" elsewhere in this preamble. There is little we can add to that discussion. Congress did not see fit to alter in any way the States' responsibility to provide these services, however they are called. When the need for specialized services is great, a State may need to examine whether, in fact, an ICF/MR, psychiatric hospital, or other setting may be a more appropriate placement. As we have noted elsewhere in this preamble, determinations as to the need for NF services and the need for specialized services in a PASARR program should be related to one another and sensitive, where appropriate, to the range of available services.

Comment: One State asked whether, in the case of an individual who requires NF services and specialized services, the individual can insist on admission to the NF of his or her choice or whether the State can dictate where it can effectively provide it. A related question was raised by another commenter who represented a group of disabled residents in one State which apparently attempted to preclude NF residence for persons with related conditions who needed both NF services and specialized services. This commenter urged us to revise the regulation so that the State would be prohibited from requiring anyone with MR or a related condition who needs specialized services to go to an ICF/MR or from requiring the NF to be responsible for providing specialized services. In this commenter's view, the regulation should explicitly state that NFs are not and cannot be made responsible for providing specialized services which the State determines to be necessary.

Response: We believe that PASARR determinations are virtually always made when an individual is proposed for admission to a specific NF. We also believe that many PASARR determinations, to be accurate, must take into account not only the specialized needs of the patient but also the ability of a specific NF to provide the services. If, in the State's view, the needs of an individual can only be met appropriately in specific facilities, whether NFs or ICFs/MR, then this view would be reflected in the State's PASARR determination relating to the need for NF care at the NF to which admission is proposed. Also, this type of determination is best done at a State, rather, than a Federal level, since NFs and mental health care systems may vary from State to State.

While our NF requirements are general, some NFs may specialize in treating specific types of residents, for example, by concentrating on physical rehabilitation or on residents with Alzheimer's Disease or other persons. We do not discourage such specialization, since it works to the advantage of the residents, and we do not believe that States should be prevented from considering such factors when they make PASARR determinations.

We would assume that when an individual has been considered appropriate for placement or continued stay only in a specific NF because of special capabilities of that NF to meet his or her care needs, any future contemplation of a transfer to another

NF (which would normally occur without a new PAS) should involve consideration by the facilities of the needs that led to the previous PAS or ARR decision. We would expect the two NFs to be sensitive to these needs in arranging such a transfer. If necessary, the facility to which transfer is proposed may request a new PAS to determine whether placement in the new NF is appropriate. The next ARR would also evaluate the appropriateness of care in the new setting.

Comment: A few States also asked technical questions concerning how they might deliver specialized services in the NF. They wanted us to clarify if other available Medicaid services, such as targeted case management, can be used to deliver specialized services to NF residents.

Response: As we noted in the proposed rule, there are a variety of other possibilities beyond the NF benefit itself for providing services to persons who require specialized services, whether they are residents of NFs or are in the home and community setting. Because the Medicaid program provides so many options for creativity in providing services consistent with our regulations, it is not possible to discuss specific issues without reference to a specific proposal to amend a State's Medicaid plan. We are therefore unable to respond to commenters who pose theoretical questions about services. The responses to their questions must take account both the Federal regulations governing services and the choices individual States make in fashioning their Medicaid programs.

Comment: A couple of States objected to the requirement that States must provide specialized services to those who need both NF services and specialized services. They noted that section 1919(e)(7)(C) explicitly requires the State to provide specialized services only to those residents who do not need NF services but do need specialized services. They argued that, since the Act does not explicitly require provision of specialized services in dual need cases, we are exceeding our statutory authority. Moreover, these commenters were of the opinion that we should not require provision of specialized services in these cases unless we are willing to pay the full cost.

Response: We do not agree with the commenters. In our view, the law does require that the States provide specialized services to persons in NFs who have been determined through their PASARR programs to require both NF services and specialized services. While the statute contains no explicit reference to provision of specialized services to those residents with dual needs, we are, in placing this requirement on States, relying on the central theme of all the OBRA '87 nursing home reform provisions which is that all of a resident's needs must be identified and served. Congress could not possibly have intended that the specialized services needs of those residents who also need NF services, and are therefore approved for NF residence, should be ignored or go unmet. Since the description of specialized services at section 1919(e)(7)(G) clearly indicates that specialized services is beyond the scope of NF services, the NF cannot be required to provide it. Both the statute and the legislative history indicate that the provision of specialized services is solely a State responsibility (see the House Committee Report language quoted in the preamble to the proposed rule on p. 10962). The logical corollary is that the State must provide specialized

services to residents with dual needs.

It is also clearly the intent of Congress to assure that NF placements are appropriate and that the States supply the specialized services needed for persons who are residents of NFs. We note that States have some latitude in determining whether individuals need NF care and may determine that individuals who need specialized services do not need NF care, in which case the issue of payment would not arise. We suggest that the commenters review their PASARR criteria to determine whether the issue they raised may be resolved internally.

Comment: Over 250 NFs were concerned about the lack of accountability on the part of the State for the provision of specialized services. They complained that the regulations do not address the issue of a State's liability should it fail to arrange for or provide specialized services to an individual who is determined to need it. Asking for a hold harmless clause, they wanted the regulation to ensure that FFP could not be withheld from a resident or facility due to State's failure to provide specialized services. They recommended that the State be required to continue paying the facility if FFP is terminated.

Response: We understand the concern raised by the commenters, however, we do not believe that the law provides for a specific remedy for States that fail to provide the specialized services required by the law. Absent a specific remedy, the enforcement of the requirement would be done under section 1904 of the Act, which supports compliance actions. Such actions may be taken when the State Plan is out of compliance with the law. Withholding of FFP in compliance actions is prospective, effective only after the State has had reasonable notice and opportunity for a hearing.

With respect to FFP for NF services, we would note that the regulation does not hold the NF accountable for providing specialized services and failure of a NF to do so would not be cause for a sanction relating to the facility. This conclusion is now supported explicitly by sections 4008(h)(2)(D) (for Medicare) and 4801(e)(4) (for Medicaid) which explicitly makes MI and MR care a NF responsibility except to the extent services are provided (or required to be provided) by the State. We also note that compliance actions taken under section 1904 of the Act relate to the State and not to facilities. The FFP relationship is between us and the States. NF payments are, on the other hand, governed by agreements between the State and the NF. It is beyond the scope of these regulations to interfere with these contractual relationships.

Comment: Nursing facilities also feared that if the State fails to provide specialized services they would be held accountable if they attempted to provide psychiatric rehabilitation, which would be inadequate to meet the residents' full needs.

Response: As noted above, we do not envision holding a facility accountable for deficiencies in the State's actions with respect to specialized services. We believe the law would need to be changed for us to do so. Facilities attempting to address a resident's needs would not be in jeopardy of sanctions unless they were otherwise out of compliance with the NF requirements.

Section 483.120(d)-NFs Must Provide Mental Health Services of Lesser Intensity Than Specialized Services

Section 483.120(d) proposed that a NF must provide mental health or mental retardation services which are of a lesser intensity than specialized services to all residents who need such services. In the preamble, we noted that specialized services are not services that a NF is required to provide under section 1919(e)(7)(iii) of the Act. However, the law requires that specialized rehabilitative services be provided by SNFs and NFs. We indicated in the preamble to the proposed PASARR rule that, based on comments received on the long term care facility requirements, published on February 2, 1989 at 54 FR 5316, we intended to amend that rule (i.e., the long term care requirements) to include psychiatric rehabilitation among the specialized rehabilitative services which are required to NFs at section 483.45. Since that time, OBRA '90 has added language to sections 1819 and 1919(b)(4) of the Act, which supports our decision (see sections 4008(h)(2)(D) and 4801(e)(4)).

Comment: A large majority of commenters, over 400 of the 736 responses we received, objected to what they perceived to be an expanded definition of covered mental health services under Medicaid. Many of the letters enumerated 3 grounds for complaint. In their view:

□ Psychiatric rehabilitation constitutes a new category of services that is far more intensive than those provided under the existing psychosocial services currently required of NFs under Medicaid;

□ The new category exceeds the scope of psychiatric services as currently defined under Medicaid. Existing Medicaid regulations define psychiatric rehabilitative services as those which are intended to restore an individual to a prior functional level. These are not "maintenance" activities. The new category speaks of "intermittent or maintenance" services; and

□ We have not addressed the question of funding for the expanded services. By narrowly defining specialized services, we have shifted responsibility for the provision of mental health services from the States to NFs. They noted that as it is currently defined, very few residents would need specialized services. Requiring NFs to be responsible for everything short of specialized services would place a great hardship on the NF and its resources. They believed the costs involved in such a rule would be over \$100 million.

In contrast to the adverse reaction by many NFs to the psychiatric rehabilitation proposal, a number of NF commenters supported our view that NFs should be held accountable for a certain level of mental health care. A few suggested that we use another term for psychiatric rehabilitation because they believed "psychiatric" is too narrow and medically oriented a term. As discussed more fully at §483.120, several commenters also suggested that we substitute the term specialized and intensive psychiatric treatment for active treatment.

Response: Sections 1819 and 1919(b)(4) of the Act, as originally enacted by OBRA '87, both require that a nursing facility must provide-

* * * nursing and related services and specialized rehabilitative services to attain and maintain the highest practicable physical, mental, and psychosocial well-being of each resident;

and the term "highest practicable physical, mental, and psychosocial well-being" is also used in connection with social services and activities. In addition, sections 4008(h)(2)(D) and 4801(e)(4) of OBRA '90 further clarify NF responsibilities by adding an identical sentence (vii) to sections 1819(b)(4)(A) and 1919(b)(4)(A). These new provisions require that, to the extent needed to fulfill all plans of care described in sections 1819(b)(2) and 1919(b)(2), the NF must provide or arrange for the provision of "treatment and services required by mentally ill and mentally retarded residents not otherwise provided or arranged for (or required to be provided or arranged for) by the State." "Mentally ill," as used here in 1819 and 1919(b)(4)(A), we note, is broader than the new statutory definition of MI at section 1919(e)(7)(G) (See later discussion in this preamble). That more restrictive definition of MI (i.e., a serious mental illness (as defined by the Secretary in consultation with the National Institute of Mental Health)) applies only to sections 1919(b)(3)(F) and 1919(e)(7) of the Act.

In light of this specific statutory direction, there is no doubt that both mental and physical health services are mandatory components of nursing facility care. The same requirement appears in our regulations at the beginning of the quality of care section at §483.25. Given these requirements, it is not possible to mount a credible argument that mental health services are not required.

We note, in fact, that those commenters whose reaction to this requirement was positive stressed that NFs should be held accountable for these essential services and made it clear that such services are an integral part of appropriate care in a facility. NFs traditionally have admitted and cared for individuals in need of mental health services, as evidenced by studies showing that diagnoses of mental illness are relatively prevalent in this setting. Evidence that such individuals are often treated inappropriately through the use of psychoactive drugs and restraints also demonstrates that facilities have long admitted and cared for such individuals. The principal issue appears to be whether such individuals must be appropriately diagnosed and treated or whether their problems can continue to be addressed improperly or incompletely.

Commenters who objected to the term "psychiatric rehabilitation" raised a number of valid points although we note that the term appeared in the preamble to the proposed rule and did not appear in the proposed regulation itself. We concede that the term "psychiatric" connotes a level of services which is both intensive and narrowly focused on psychiatric needs. We did not intend to convey that impression; such treatment is inherently distinct from NF services generally focused on rehabilitation. In the final regulation on Requirements for Long Term Care Facilities, which responds to public comments on the rule published on February 2, 1989 at 54 FR 5316 we intend to include in the specialized rehabilitation requirement the words "including mental health rehabilitative services" in recognition of the fact that they are an integral part of overall care. This change would meet our and commenters' objectives to require that the full range of physical, mental, and psychosocial needs of residents be

met by the nursing facility which chooses to admit and treat them.

In this connection, we believe that commenters who asserted that a requirement for mental health services is a new requirement misread the law. While it is true that there is a statutory exclusion of coverage for any person who is a "patient in an institution for mental diseases," there is no other restriction on mental health services. Moreover, section 1905(a), which lists those services which are defined as medical assistance under Medicaid, includes nursing facility services. These services are defined in section 1919(b)(4) of the Act in the manner noted above to include nursing and related services and specialized rehabilitative services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident. Thus, the services in question are an integral part of NF services under Medicaid. This point was made in the February 2, 1989 regulation. Our intention in discussing it here is to deal with the obvious confusion that has arisen over it and to clarify the requirement, not to institute a new requirement. Similarly, OBRA '90 adds further clarification on this point. As we discuss in the following response, this is not to say that a particular NF must admit individuals with MI or MR and provide these services. However, if a NF admits such individuals, it must provide services appropriate to their needs.

In response to the large number of comments dealing with the issue of payment for services, OBRA '87 included a requirement for States to amend their Medicaid payment plans to include funding for services required by the nursing home reform provisions of that act. While the statute excludes specialized services for MI and MR from NF services, Medicaid funding would remain available for some services under other benefits (for example, physical therapy, if a State plan provides such services). This may help States fund specialized services for those residents who need these services. We do not agree with commenters who argued that these requirements should not be implemented because the cost of remedying past neglect of this treatment area may be high. Moreover, while we do not believe that nursing homes generally neglect the mental health needs of their residents, an underlying assumption of the legislation is that there are residents who are either inappropriately placed or, if properly placed, who are receiving inadequate treatment. One purpose of the legislation is to effect changes in this behavior.

Comment: States raised the issue of how payment should be made and how much should be paid. Some asked if States would have to pay for psychiatric rehabilitation as a vendor service or as part of their NF per diem rate. In addition, they noted, States would have to pay for specialized services. A few States wanted the regulation to allow the State Medicaid agency to require the NF to provide psychiatric rehabilitation either through in-house or contracted personnel or by referral to community mental health clinics (CMHCs).

Response: The issue of payment for services provided to NF residents is a complex one because it involves issues as to what services are included in the nursing facility's payment rate as well as what services might be furnished by providers of other services under the State's Medicaid Plan (e.g., physical therapy, physician services, rehabilitative services, etc.).

We are currently in the process of rulemaking with respect to the services included within the NF rate. We published an NPRM on March 20, 1990, at 55 FR 10256, dealing with the issue and are currently in the process of analyzing comments and developing a final regulation. As to the services that may be provided under other Medicaid benefits, we would note that regulations governing these services are currently published, primarily in 42 CFR Part 440, and have not been affected by these final regulations. States have considerable flexibility in developing their Medicaid benefit packages and that flexibility provides them with differing options for dealing with these issues, as well.

Comment: Many commenters who responded to the psychiatric rehabilitation issue questioned the effect of this proposed rule on the role and character of the NF. They argued that NFs are not prepared to offer the psychiatric rehabilitation outlined in the NPRM. They held that NFs have never been IMDs or ICFs/MR, nor were they intended to be. Rural facilities particularly indicated that they would not be able to obtain or train the staff necessary to provide the level of mental health services we suggested even if they were to receive additional funding. In the view of many of these commenters, we should require the State mental health authorities to provide mental health treatment in State or private mental health facilities, not NFs.

A number of commenters believed that the role of the NF is to provide a homelike, peaceful environment for "normal" elderly people. They stated that residents with a psychiatric history require a different level of care than the geriatric population with a medical history. To take in residents with serious mental disturbances would require closer professional monitoring and documentation of activities than NFs can provide. Moreover, they argued, the presence of such individuals would be very frightening to other residents who do not understand that this is an illness. One commenter also noted that NFs are trying to reduce the use of psychotropic medications but that taking in more individuals with MI would result in increased use of these drugs.

Some commenters also noted a contradiction between the espoused view that NFs are inappropriate places for individuals with MI and our position that NFs are capable of providing psychiatric rehabilitation. They claimed OBRA '87 required PASARR because Congress wanted inappropriately placed people out of NFs. They argued that Congress did not raise the issue only to have responsibility for providing these services shifted from the State's mental health system to the NFs.

Response: Studies have shown that a high percentage of nursing home patients have diagnoses of mental disorders. By far the preponderance of these individuals appear to have Alzheimer's Disease or dementia, but there are other diagnoses as well and many individuals have more than one diagnosis. It is this population which the commenters apparently allude to as "normal." We agree that the current population is the one to which the requirements are addressed, but we believe that the misperception that these individuals are "normal" is a fundamental part of the problem intended to be addressed by OBRA '87, through PASARR reviews, resident assessment, care planning, and provision of services.

Some of the commenters appear to have misunderstood the PASARR

requirements and incorrectly assumed that NFs might be required to accept persons with MI or MR. Nothing in the PASARR process requires that an individual be admitted to a nursing facility. The requirements simply prohibit the admission of an individual who has not been screened and who has not been determined to need NF care. A positive determination as to the need for NF care by the PASARR process simply creates the option for an NF to admit an individual. It does not require it.

A nursing facility still may determine which applicants to admit. The nursing facility requirements create a set of rules designed to ensure that those individuals who are admitted are properly assessed and treated, including rules to prevent inappropriate discharges or transfers. One way to view these requirements is to see them as a means of assuring that NFs treat the whole person. We would note that nursing facilities, like other types of health care providers, may well specialize in certain types of care—for example, the care of Alzheimer's victims—and may focus admission criteria so that applicants are selected who may benefit best from their specialty. Our concern is not to prevent facilities from specializing but to assure that individuals who are admitted for treatment are fully assessed and treated once they are admitted.

Comment: Many commenters sought clarification of what specific services are included in "mental health and mental retardation services that are of a lesser intensity than [specialized services]" and requested that any definition of these services be put forth in a proposed rule so that the industry may comment on the parameters of the defined services. They objected to our plan to revise the February 2, 1989 rule in response to comments on that regulation to require NFs to meet any mental health needs of their residents that are below the specialized services level. They felt that the promulgation of any definition of psychiatric rehabilitation or covered mental health services in an NF is too important to be adopted without public comment.

Similarly, approximately 20 State agencies argued that the States should have a chance to comment on the definitions of both terms, psychiatric rehabilitation and specialized services. They questioned how they could discriminate between the two services and what criteria would be used to determine who does what between the core NF services and the wrap-around specialized services. From a financial standpoint, they wanted to know which services would be billable as psychiatric rehabilitation and which would not be billable as specialized services. They noted that, particularly for individuals with MR, virtually all services in 1919(b)(4) are elements of what was formerly called active treatment. States were also concerned about how their survey agencies could tell the two services apart. Their general view was that we were creating an unsurveyable situation, one which is totally lacking in guidelines and measures.

Response: We do not believe that it is necessary to describe in detail all the services that are needed to meet the mental health rehabilitation needs of NF residents and do not agree with the commenters that this particular issue requires specific notice and comment. As we noted, the February 2, 1989 regulation already requires services to meet the "the highest practicable physical, mental, and psychosocial well-being" of the residents, as does the law. The regulations do list, and have listed for

many years, other specialized rehabilitative services quite generally, such as physical therapy and speech therapy. Specific definitions are not appropriate because the nature of the services may vary depending on the specific need of a particular individual. In this case, we are simply clarifying a general requirement in the law and the current regulations, we are not expanding or defining a new benefit. Similarly, OBRA '90, as noted earlier, contains provisions that fully support our conclusions as to SNF and NF responsibilities for MR and MI care and which are characterized in the legislative report language as clarifications rather than new requirements.

Commenters who focused on the difficulty of drawing a dividing line between specialized services and mental health services generally and commenters who more specifically advocated either a prohibition against admissions of individuals who need specialized services or recommended that specialized services be included as a nursing facility service, raise a challenging issue. It is possible to define a term such as "specialized services" but as a practical matter it is a very difficult to bisect a continuum of care with such precision that there is a clear line between one type of care and another when the guidelines are applied to the cases of individuals whose needs cluster around the dividing point. For example, it is difficult to write guidelines to distinguish the point at which the need for hospital care ends and the need for NF or SNF care begins. Much depends upon the condition of the individual and the capacity of one or another facility to meet his or her needs. While many decisions are clear, the close decisions must be made with close attention both to the condition of the individual and the capacity of the facility to provide care. That is one reason why nursing facilities continue to have discretion in accepting applicants. We have attempted to make the policy as clear as possible in this regulation but we acknowledge that many determinations require close medical judgment the particulars of which cannot be specified in regulations.

Comment: Going beyond the level of service intensity involved in providing psychiatric rehabilitation, approximately 40 NF commenters believed that NFs should be allowed to provide specialized services, if they can meet the program requirements. They reasoned that this approach to service delivery would be better monetarily and programmatically and would be less traumatic for the resident. They believed that when a resident's mental condition has been resolved and he or she can maintain relative mental stability on a low maintenance psychotropic drug, he or she should be allowed to enter or remain in a NF of his or her choice. In those rare cases where a resident experiences an acute episode, they felt the NF should be permitted to provide the specialized services required. Only if a resident becomes violent, did they believe he or she should be transferred, by contract, to an appropriate inpatient psychiatric setting. Consistent with the other NF comments, of course, these commenters noted that NFs which elected to provide these services would need to receive adequate funding to do both psychiatric rehabilitation and specialized services.

Response: Commenters who believed that NFs were prohibited by the proposed rule from providing specialized services misunderstood our intent in stating that specialized services is not a NF

responsibility. We meant to prevent NFs from being required by States to provide specialized services, not to bar them from providing it if they choose to do so and are staffed and equipped to provide these services. Nothing in this rule should be interpreted to prohibit the State from arranging with a consenting NF for the provision of specialized services to its residents who need these services. However, NFs may not be required to take on these responsibilities against their will. We would also note that, under the existing IMD guidelines, NFs which undertake provision of specialized services to large numbers of residents do so at the risk of becoming IMDs.

Comment: A final set of concerns of the States, with respect to the psychiatric rehabilitation issue, centered around whether the NF can discharge or not admit someone so as not to have to provide psychiatric rehabilitation. They noted that PASARR only indicates who may be admitted or retained by a NF. There is no requirement that the NF admit or retain those whom the State's PASARR approves for NF residence. They believed that requiring psychiatric rehabilitation while allowing NFs to exclude residents who need such services would increase access problems for patients with mental illnesses. They, therefore, asked who has the ultimate decision-making power concerning whether a NF can meet a resident's needs, the NF or the State Medicaid agency? They also noted that the proposed system of wrapping specialized services around the NF core of services can work only if the NF cooperates. States feared that NFs could use the excuse that "the State has to provide it" and that anything the State expects the NF to do by way of mental health services would be viewed by the NF as being beyond "the practical limitations" of what can be provided in a NF, given its staffing and funding.

Response: We believe that the commenters overestimate both the ability and inclination of NFs to avoid residents who may require mental health rehabilitation services and fail to take account of the protections available to residents and prospective residents. Finally, we do not believe that commenters' assertions about limited access to care have been documented.

While facilities do have some latitude in determining who they will admit, they are bound by Federal, State, and local laws against discrimination. The law and our regulations limit the reasons for which a resident may be transferred, and the law provides for an appeal to the State when a resident (or his or her representative) questions the appropriateness of a facility's decision. Moreover, the survey process we design to implement the regulations will enable surveyors of the State (and Federal surveyors, where a Federal survey is done) to determine whether the residents were properly assessed, had proper care planning, and, where specialized rehabilitation is needed, whether it was provided. Thus, as a practical matter, these issues are subject to oversight by both the States and the Federal government.

On the issue of specialized services, we would note that States are subject to Federal oversight to determine if they are meeting their obligations with respect to the provision of services to residents of nursing facilities and individuals who have been discharged to receive specialized services in other settings. States which fail to meet these requirements are subject to the compliance process established under section 1904 of the Act to deal with situations in which the State is

out of compliance with its plan.

Sections 483.122 and 483.124-Availability of FFP

Proposed §483.122 provided that, except as otherwise provided in an ADP, FFP is available for NF services provided to a Medicaid eligible individual only if the individual has been determined to need NF care, or not to need NF services but to need specialized services under §483.118(c)(1) and elects to stay in the NF. Also, FFP cannot remain available if the State has not conducted a timely annual review of an individual with MI or MR to reevaluate NF and specialized services needs.

In §483.124, we proposed that FFP is not available for specialized services furnished to NF residents as NF services.

Comment: A large number of States requested that, in addition to specifying the conditions under which FFP is available for NF services, the regulation specify that 75 percent FFP is available under administration for PASARR costs. Several commenters also asked that the regulation clarify that FFP is available for screening non-Medicaid, especially private pay, individuals. Others wanted us to specifically prohibit charging private pay individuals for screening costs.

Response: We agree with the commenters. Our omission was inadvertent and we are amending 42 CFR 433.15(b) to add a new paragraph which specifies that expenditures for PASARR activities conducted by the State (including the use of subcontractors) are matchable at 75 percent. Because the regulations governing PASARR require that the system be operated by the State and apply to all individuals with MI or MR who are seeking admission to or residing in NFs that participate in Medicaid, this matching authority extends to State expenditures for the entire PASARR population. It does not, however, extend to activities not required under these regulations.

On the issue of whether States are prohibited from charging private pay individuals for costs associated with PASARR evaluations, we believe that the State Medicaid program must pay the unique costs of PASARR evaluations. Operating a PASARR system for all applicants and residents with MI or MR is a Medicaid requirement, and the expense must be borne by that program. Of course, a State need not pay for the cost of underlying examinations which would have been performed in any case (and the State may have general requirements for examinations applicable to all NF applicants or residents).

Comment: Funding for Level I activities raised considerable controversy. Some States asked that we clarify in the regulation that if Level I is done by a NF, the costs may be included in the NF rate. It was not clear from their comments, however, whether these States did or did not wish to supplement the NF's per diem for these Level I activities. By contrast, some State commenters asserted that there is no justification for making different levels of FFP available for Level I screens. These commenters believed that Medicaid should pay NFs separately for doing them and that the State should get 75 percent FFP no matter who the State designates to do the Level I screens.

A number of NFs objected strenuously to having to do Level I screens without specific reimbursement for these activities. They attested that their costs for performing Level I are substantial.

They felt that if NFs are required to do Level I there must be a mechanism for payment for these additional services.

A number of hospitals also complained that, apart from the costs produced by delays in placement, the cost of doing Level I has been significant for acute care hospitals. One hospital reported that in the first year its hospital staff and physicians completed 350 Level I screens and that the staff time required to complete these was significant. Another large hospital concurred in the view that doing Level I screens consumes considerable staff time, involving social workers, nurses, physicians, and on a consulting basis, psychiatrists, neurologists and neuro-psychologists. None of the Level I screening costs are reimbursed, they claimed. Other hospital commenters noted that State Medicaid Manual, Transmittal 63, which we quoted in the proposed rule at length, says that if hospital dischargers do Level I screens, the State's reimbursement rate is 75 percent. Their States have, however, refused to reimburse hospitals for doing Level I screens. Like the NFs, these commenters believed there should be a mechanism for them to bill the State for this service when they have contracted to do it.

Response: With regard to whether a State may require a facility to perform a Level I screen, we believe it is well within the authority of a State to require that hospitals and NFs identify individuals who require screening under PASARR. Thus, we do not agree with the commenters who challenged States' ability to do so. As to whether a facility must be paid for doing so, and, if so, whether the State's matching payment would be at 75 percent or 50 percent (the usual administrative match) if it made an explicit payment for the service, we believe that section 1903(a)(3)(C) of the Act indicates that the enhanced matching rate is for PASARR activities "conducted by the State." Thus, the enhanced matching rate is not available for activities of NFs, even if in support of a PASARR program. On the other hand, such costs can be built into the State's NF rates where they will be recognized at the Federal Medical Assistance Percentage (FMAP), the matching rate applied to the State's Medicaid benefit payments.

Comment: Commenters had numerous questions about the availability of the 75 percent FFP for various other PASARR-related activities such as discharging residents who are determined not to need NF care, handling appeals, and record keeping/tracking activities. Both the NFs and the States claimed that these activities created costs for them. Transmittal No. 63 to the State Medicaid Manual clarified the State's eligibility for FFP for some types of PASARR-related activities but not others. NFs, however, felt they were disadvantaged because they are being expected to absorb all these extra activities within their per diem payment rates.

Response: It is neither possible nor appropriate to answer all the questions that may arise in this context in this preamble.

Commenters cannot assume that functions required by this and other regulations must be separately priced and separately recognized for payment in the context of the rule. A number of the expenses associated with the operation of a PASARR program are appropriate Medicaid administrative costs as, for example, appeals of determinations and the record-keeping and tracking needed to operate the program. NF expenses associated with discharge planning and required under the NF requirements and funding

for these services would be an expected part of the State's payment rates for NF care. Other expenses may well be outside the Medicaid program entirely, for example, provision of specialized services to individuals who are permitted to remain in NFs because they have resided there for more than 30 months. We expect that we will be clarifying a number of these issues in the State Medicaid Manual, which is the appropriate vehicle for such detailed discussions. Basic existing procedures for administering State Plans, including payment for medical assistance, embrace the whole range of allowable expenses even though they are not specifically discussed in this or other regulations.

Comment: For both the States and NFs, the proposed denial of FFP for the entire stay was a very heated issue, eliciting responses which referred to these penalties as "draconian," "grossly unfair," or "punitive." Over 150 NF and hospital commenters and nearly all of the States, sometimes through more than one State agency, responded. These groups were joined by a number of consumer advocates and a variety of other commenters.

As noted in the comments discussed under the timeliness standard at §483.112(c), States believed that our requests were excessive and timeframes unrealistic, resulting in our punishing the States for failing to meet our expectations. They felt that we should provide for occasional lapses that occur for legitimate reasons.

As discussed under §483.114(c), some States were very concerned about the possibility of future disallowances for their continuing resident population (all those with MI or MR who entered NFs prior to January 1, 1989 and were not subjected PAS) if they had not completed their initial reviews by April 1, 1990. If the group that a State had not yet screened by that date were sizable, denial of all FFP for these residents from April 1, 1990 henceforth to the time of some future disallowance could be great. They felt that the application of penalties to the first year of implementation of ARR would be highly unrealistic and unfair.

A number of commenters noted that such harsh penalties would be unwise because of the adverse impacts they would produce. Some said the residents would suffer from the denial of FFP for their care. Others asserted that the penalties would only drive the NF to discharge a resident whose stay had been disallowed and then readmit him or her to get FFP. NFs were concerned that they might honestly miss identifying someone with MI or MR in doing a Level I because they must rely on records from the referral facility until they can thoroughly assess all transferring information on the resident through their own assessment. They also believed it is unfair to penalize the resident or the facility for the failure of the State to complete ARRs on time. For their part, hospitals were concerned that the threat of these penalties would paralyze the system and would exacerbate the hospital back up problem.

A number of State commenters noted that while Congress did not specifically permit intermediate penalties, it did not preclude them. Nor, they also argued, does the statute even discuss timeliness. It only says there shall be no FFP if a PASARR which is required is not done. They believed that the use of the present tense is significant. The law does not say there can be no FFP if a PAS or an ARR was not done at some point in the past when it should have been performed, without any possibility of ever

rectifying an error. In their view, HCFA should take a broad and proactive view of what is best for NF applicants and residents, NFs, and State agencies.

A number of States, therefore, indicated that we should either restrict the loss of FFP to days beyond the allowable time period until the PASARR is done or devise some type of intermediate sanctions or plans of correction. Some proposed that FFP should be available absent a finding of substantial non-compliance by the State. One commenter suggested that penalties should only be applied if a person is inappropriately placed. Another proposed that FFP be denied for twice the number of days that the PAS or ARR was late.

NFs overwhelmingly agree that provision of FFP should begin or resume as soon as the PASARR has been done. They felt that in the event of a PAS error, loss of income for the penalty days only would be punishment enough. One NF thought that FFP should start as soon as a PAS is done and be retroactive to admission if the PAS is done within 14 days of admission. Another mentioned that emergency admissions are sometimes necessary for the well-being of the resident and screening is done as soon after admission as possible. This should not result in permanent denial of FFP. A large number of NFs recommended that the rules allow PAS to be conducted after admission if it is anticipated that the individual will meet requirements for admission.

Response: While we believe that the proposed language is supportable under the law in that the statute requires "preadmission" screening which, by definition, can only occur prior to admission, we have been persuaded by the counter-arguments presented by commenters. We found particularly compelling their contention that the present tense in which the statutory language is written is significant. That is, the law only says there shall be no FFP if a determination that is required is not done. It does not prohibit FFP if a PAS or an ARR was not done when it should have been performed but the error has been corrected. Furthermore, the use of the term "determination" to refer to both the PAS and the ARR implies that Congress meant to refer to the underlying questions of need for NF services and for specialized services, rather than to the specific timing requirements. We also agree with the commenters that the proposal, under which FFP would not be available at all if a preadmission screen was not performed before admission or a resident review was not performed timely, would create financial difficulties for States and facilities to the detriment of residents. By adopting this interpretation, we allow past errors and omissions to be rectified.

Having, thus, reconsidered the issue in light of the comments, we have added a new paragraph (b) to §483.122 to read as follows-

(b) When a preadmission screening has not been performed prior to admission or an annual review is not performed timely, in accordance with section 483.114(c), but either is performed at a later date, FFP is available only for services furnished after the screening or review has been performed, subject to the provisions of paragraph (a) of this section.

We do not believe that the law provides for any intermediate sanctions save for the denial of FFP for the period during which a review has not been performed and so we have not attempted

to develop such sanctions. Given the revised language, a State which fails to perform a PAS would lose FFP from the date of admission until the date the review is performed, and for an ARR, from the end of the quarter in which it is due until the date it is performed.

We recognize that adoption of this policy does allow States to receive FFP for persons admitted without the required preadmission screening but we do not believe that this change will materially affect the incentives States have to comply with these regulations for the following reasons. First, NFs themselves continue to be subject to the requirement that they not admit any individual for whom a screening is required but for whom it has not been accomplished. Thus, an admission may jeopardize the NF's certification. Second, a State which permits such admissions to occur as a matter of policy would be in violation of these regulations and would be subject to a compliance action under section 1904 of the Act. We view this change primarily as an incentive to States and facilities to rectify any errors as soon as possible and as a means to assure that FFP is available for necessary NF care, the need for which is identified by such screenings.

We note that OBRA '90 contained revisions to section 1919(e)(7)(D) concerning denial of payment for failure to conduct PAS and ARR and for certain residents not requiring NF care. The original OBRA '87 language provided explicitly only for denial of payment in cases in which no PAS was performed; our proposed rule also indicated FFP would be unavailable for individuals who did not need NF care. This statutory change confirms the correctness of our proposed FFP exclusion.

Comment: A large number of commenters objected to the fact that FFP is not available for specialized services. Most of these commenters recognized that this provision is statutory; however, they registered their objections for the record.

Response: We understand the concern of the commenters but we believe that the law is clear on this issue. As we noted in the proposed rule the prohibition against FFP for specialized services relates to NF services specifically, not to other services that may be covered under the State plan. Thus, a State may be able to obtain FFP for otherwise covered services provided to NF residents as part of a specialized services program.

Section 483.126-Definition of Appropriate Placement

In §483.126, we proposed 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 which 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 specialized services provided by or arranged by the State.

Comment: A number of commenters expressed appreciation for the elaboration on the definition of appropriate placement which we provided in §483.126 and the preamble discussion which accompanied it. These commenters particularly welcomed the discussion of the concept of a vertical continuum of care in which the NF level of care is analogous to a layer in a layer cake, being joined above and below by other levels of care which are more

or less intensive than that which is capable of being provided by the NF. Noting the change from some of the previous drafts of the criteria, some of these commenters also applauded clarification of the point that the need for specialized services should not bar a person from NF admission.

By contrast, another group of commenters, appeared to believe that if the individual needs specialized services, he or she should not be in NF except under very limited circumstances. This was the position that was taken in the PASARR draft criteria, which were circulated informally in September 1988. However, the subsequent Manual issuance and proposed rule did not take this position. These commenters wished us to return to our earlier position.

Taking a broad view across several different points in the regulation, they believed that we were, instead, sending out mixed messages. One commenter claimed that §§483.126 and 483.116 appeared to contradict each other. Section 483.116 permits (but does not require) an individual to be admitted or retained in a NF if he or she needs a NF level of care, whether or not specialized services are needed. Section 483.126 states that an individual can only be appropriately placed in a NF if his or her needs can be met in that setting, with or without the provision of extra services provided or arranged for by the State.

Similarly, a group of MR/DD commenters claimed that at times we said that the two determinations with respect to specialized services and NF needs must be made together (§§483.128(d) and 483.126) but at other times we made it seem as though the two determinations are separable (§§483.130(p) (1 and 3) and 483.116(b)). They were concerned that many States have broad criteria for determining need for NF level of care. The question should be not whether NF care is appropriate but in what type of residential setting can the individual's documented service needs be best met. They believed that this involves a summary judgment based on careful weighing of evidence from both assessments (the need for NF care and for specialized services).

Some developmental disabilities advocates also objected that §3.126 offers States no specific criteria for determining when placement or continued residence in NF is appropriate. Viewing this task as the *raison d'etre* of Congress' requirement that HCFA produce criteria, these commenters recommended that the final rule contain statements concerning explicit circumstances under which NF placement is or is not appropriate. For example, they wanted a statement that indefinite placements in NFs are inappropriate if the individual requires specialized services except in narrowly defined circumstances (e.g., where an individual has extensive ongoing medical care needs that largely define the types of specialized services he/she requires). Quoting our statement from the preamble that we believe specialized services can be delivered in a NF only with great difficulty, these commenters asked that the rules reflect this belief.

They also asked that we make this rule consistent with the State Medicaid Manual section 4395 on appropriate placement for individuals with MR (which was most recently revised in September 1986). This would preclude a NF from admitting such an individual found to need specialized services, unless he or she has a serious, potentially life-threatening medical condition and requires inpatient skilled medical care and supervision.

In that instance, the NF must be capable of meeting both the physical care and developmental needs of the individual, with or without supplementary State services. (These commenters would except those subject to advance group determinations under §483.130 (c) and (d) and individuals of advanced years who freely elect not to receive specialized services under §483.130(j)).

Response: Many of the commenters supported their assertions with discussion of specific sympathetic cases; however, their comments as well as our own experience demonstrate that the level of care concept, which entails labeling for practical convenience areas on a continuum of care, is not susceptible to distinct definitions. Individuals whose needs are at the margins of the continuum, either on the high or low end, must be judged both on their specific needs and upon the capability of the facility to which admission (or for which continued stay) is proposed.

We noted in the preamble to the proposed rule that we believe it is difficult to provide specialized services in the NF setting, and we reiterate that belief here. However, in response to the comments suggesting that we prohibit admission or continued stay of individuals who need specialized services, we note that the language in the law does not provide a basis for such a prohibition. The law simply requires that determinations be made about the need for NF care and the need for specialized services. We therefore do not believe we have the authority to require that States deny admission to individuals who need specialized services.

The difficulty of providing specialized services (formerly known as active treatment) in a NF setting was raised historically in the context of comments on our existing manual instructions regarding the placement of persons with mental retardation in the NF setting. The instruction asserts that such placements are seldom appropriate and asserts the strong need for concomitant medical diagnoses to support such an admission. We published that instruction in 1986, before the enactment of OBRA '87, and we believe we will now need to revise it to take account of the PASARR provisions in that law. For the same reason we were advised by legal counsel to revise our earlier views as to the PASARR criteria, which were based in the same conceptual framework as the earlier instruction.

We do not believe that the Congress sent a mixed message by permitting some individuals who need only specialized services to remain in NFs. It is clear from the law that this provision extends only to individuals who have resided in the NF for 30 months or more and was intended to assure that longstanding arrangements that predated the legislation not be disrupted by it. For both longstanding and new residents, the law permits admission and continued stay for individuals who require both NF care and specialized services.

It is impossible to distinguish individuals suitable for NF admission from those who are unsuitable simply on the basis of a diagnosis of one particular mental disorder or another. This is partially why, in developing our definition of serious MI (as required in OBRA '90), we looked at other factors such as severity or impairment in addition to diagnosis. Having MI, as it is currently defined, does not necessarily preclude NF admission although, given the narrow scope the term MI now has

(i.e., serious mental illness), a larger proportion of the individuals subject to PASARR may be found unsuitable for NF residence. Having MI also does not automatically mean that the individual needs specialized services, although the likelihood that specialized services will be needed is greater for persons found to have a serious mental illness than for persons found to have a mental illness under the OBRA '87 definition. As with the previous term "active treatment," a need for specialized services does not necessarily exclude an individual from NF placement. Specialized services may be provided in an NF or in other settings, albeit with some difficulty. Determinations about appropriate placement need to be made on an individualized basis, taking into account the needs of the individual and the capability of the facility to which admission is proposed.

By the same token, it would be difficult to develop general Federal criteria with respect to the need for specialized services. We recognize the commenters' concern that the lack of uniform criteria could lead to different decisions in different cases but we do not believe that this is a problem that we can solve by writing specific guidelines because of the need for individual determinations in the many cases where individuals may be near the upper or lower ranges of a particular level of care or where individual functional abilities may lead to a different conclusion than, for example, a consideration of the diagnosis.

We strongly agree with the commenters who indicated that determinations as to the need for NF care and determinations as to the need for specialized services should not be made independently. We believe that such determinations must often be made on an individual basis, taking into account the condition of the resident and the capability of the facility to which admission is proposed to furnish the care needed. While we have provided for categorical determinations in some cases, we believe that other situations clearly call for integrated determinations. We have not attempted to specify the manner in which States should accomplish this result because we believe that the state of the art for making these determinations is now in a dynamic state and its development should not be hampered by mandated procedures which cannot reflect the variety of current practice.

Comment: Commenters also frequently asked whether mental health needs alone can qualify an individual for an NF level of care, given the statutory definition of an NF at section 1919(a)(1) of the Act. This definition would appear to cover almost anything from just above the level of room and board on up. One commenter extrapolated from the preamble discussion that if a person who only needs specialized services can be downgraded to an NF level of care when his or her intensity of need drops below the specialized services treatment level, then mental health needs alone must qualify an individual for admission to or continued residence in an NF.

Several other commenters echoed this same view by asking us to clarify whether it is physical and mental needs or physical or mental needs that qualify for NF placement. These commenters believed that the preamble discussion at several points appeared contradictory. Moreover, they felt that allowing individuals to qualify for NF level of care solely on basis of mental needs would appear to violate the intent of these PASARR provisions which is to get individuals who only need specialized services

out of NFs. They argued that earlier the draft of the criteria which prohibited anyone who needs specialized services from being in an NF with only limited exceptions is closer to the spirit of OBRA. They strongly urged that the regulations be revised to clarify that physical needs alone are what gets an individual into the NF or allows him or her to stay there, not just needing some degree of supervision.

Response: In response to the comments on whether NF care can be approved for an individual whose needs flow primarily from their mental condition, we would note that the law defining a nursing facility indicates that they are (in part), facilities that provide-

"On a regular basis, health-related care and services to individuals who because of their mental or physical condition require care and services (above the level of room and board) * * *." (Section 1919(a)(1)(C) of the Act, emphasis added.)

We believe that there are a number of individuals whose frailty due to age, when combined with, for example, mild depression and dementia, suit them for residence in a NF, especially if there are no other supports that would enable them to live safely and successfully outside a NF.

Sections 483.128 and 483.130 General Comments on PASARR Evaluation and Determination Process

Comment: A general criticism was that the data requirements are too extensive, although almost no commenters really singled out any particular items which they thought were excessive. Instead, the critics appeared to be addressing a more fundamental question: What is the purpose and role of PASARR? Several commenters indicated that they felt the collection of all the data we specified might be appropriate for developing a plan of care but they thought it was excessive for making a simple yes/no determination about placement.

Other commenters who objected to the data requirements as overly burdensome expressed the view that we were asking for too much in too little time. Some felt that because of the excessive data requirements, the entire process was also confusing to clients. While they acknowledged that we advocate the use of existing data, they noted that the data requirements are so extensive that there are almost always gaps which must be filled by additional assessments. Some commenters professed that the States should rightly establish the content of screenings.

Response: We had hoped that commenters would focus on the specific requirements we proposed and offer suggestions as to additions or deletions. Only one such suggestion was received from one commenter. (See discussion of functional assessments under the PASARR/MI at §483.134.) We did not find a basis in the comments to make such changes and we have not done so.

As to the issue of the scope and complexity of the assessments, we disagree with the commenters. As we have noted repeatedly in this preamble, decisions about admission and retention of individuals must be made with a knowledge of the individual's condition and functional status. Even though PASARR determinations are not made with the purpose of care planning, they must be

made with sufficient knowledge of the needs of the individual being screened so that they can reflect the ability of the individual to receive needed treatment in the NF or in another setting. We do not believe that such determinations can be made in the absence of an effective assessment, and we interpret the lack of substantive comments on our proposed requirements as evidence that the commenters were primarily concerned about the need to make the assessment and not the appropriateness of the data-elements we required to be used as the basis for it.

By the same token, we do not wish these requirements to impose any unnecessary burdens on States and we will continue to monitor the process to determine if future changes in the requirements are needed.

Comment: A number of commenters offered general criticisms on the requirements for the PASARR evaluation process in proposed §483.128. Several commenters pointed out a number of omissions in the requirements. First, they noted that the rules should require involvement of the resident or applicant, his or her legal representative (if applicable), and the family in the screening process.

Secondly, some commenters felt that we had ignored the need for coordination at various stages of the PASARR process. They urged us to require interdisciplinary coordination during the conduct of the evaluation(s). Also, they believed that the rules should require coordination between the Level II evaluators and the personnel at the State mental health or mental retardation authorities (or their delegates) who make the determinations. Several commenters complained that the roles of each are not distinguished adequately in the regulations.

Response: We agree with the commenters that involvement of the resident and any legally designated representative is necessary. We believe that the laws establishing such representatives already clearly require that such representatives, rather than the persons they legally represent, should be the ones consulted (although the resident, even though incompetent or incapacitated, should still be informed of what is happening to him or her).

We also believe that family involvement is often desirable. However, consistent with the resident's rights section of the February 2, 1989 rule, particularly §483.10(a) which deals with the exercise of rights of adjudicated and non-adjudicated residents in NFs, we believe that participation by family members in the screening process should be with the consent of the individual being screened or his or her legal representative. Thus, if a competent individual does not want family involvement, he may bar its participation. We are therefore amending §483.128 by adding a new paragraph (c) to require involvement of the individual; his or her legal representative, if one has been designated under State law; and, with the consent of the individual or legal representative, of the family, if available.

We are also adding a new paragraph (d) to §483.128 to provide that when multiple evaluators are used to perform different portions of a PASARR evaluation (for instance, in order to utilize different professional expertise), the State must ensure that there is interdisciplinary coordination.

We do not agree with the comment that we have not adequately spelled out the roles of individuals who make evaluations and those who make determinations in the PASARR process or that

we need to require further coordination between the evaluation and determination functions. In the case of evaluations for individuals with MI, the determinations must be based on independent evaluations. All that needs to be required is that the evaluators submit their evaluation reports to the individuals who make determinations in such a way as to allow the determinations to be made timely. (See new requirement added at §483.128(1), which is discussed under other changes to §483.128.)

Section 483.128-PASARR Evaluation Criteria

Comment: Basic questions concerning the nature and purpose of Level I screens were at the heart of a number of comments on §483.128(a), which requires the State to have a mechanism for performing Level I identifications of individuals with MI or MR. For instance, a few commenters questioned our authority to require the State to have a Level I process. They noted that the statute does not require, or even mention, a Level I screen or any other process to rule out MI or MR. It simply requires NFs not to admit such people. These commenters believed that a fair interpretation of the law would be that if there is a known diagnosis of MI or MR, a PAS must be required. They alleged that the proposed rule and the previous instructions had gone beyond the statute in requiring States and NFs to actively rule out the possibility of MI or MR.

By contrast, another commenter, who apparently believed that the screening process should more actively seek to identify individuals with MI or MR, was concerned that the Level I process was not designed to rule out MI or MR. Instead, the commenter asserted, it assumes that a person does not have MI or MR unless information in the individual's medical history indicates otherwise.

Still another commenter, an organization which actually performs PASARR evaluations in one State, requested that the Level I screen include a validation of MR (IQ of less than 70). This organization complained that it was receiving a large number of referrals of individuals that physicians have suspected having MR because, the commenter alleged, a majority of physicians are not aware of the criteria for developmental disabilities and refer cognitively impaired individuals regardless of etiology.

Response: We do not agree with the commenters who suggest that requiring Level I screens is not within the scope of our authority. We have elsewhere noted, and courts have accepted, the fact that the requirement in section 1919(e)(7) of the Act for screening presupposes the existence of a mechanism for identifying persons for whom a screening is necessary. We also believe that it is within the authority of States implementing these regulations to require that this review be done by NFs.

We have already responded in several places in this preamble to the suggestion that "known diagnosis" be the basis for the screen. It is clear to us that reliance on known diagnosis would cause the process to miss individuals whose mental illness or mental retardation had not been specifically identified either through lack of physician care (when the individual is proposed for admission by his or her family without prior consultation with a physician or mental health professional) or when a physician has avoided articulating the diagnosis out of consideration for the individual or the family.

It is also clear to us that some commenters misunderstood the purpose of the Level I screening step. Its purpose is to identify for further screening those individuals for whom it appears that a diagnosis of mental illness or mental retardation is likely. Thus, we would respond to the commenter who complained of Level II referral of individuals whose physicians had incorrectly suspected mental retardation in cases where cognitive impairment is present that such referrals are appropriate. It is the purpose of Level II screening to make the appropriate finding based on an expert evaluation. Of course, we do not dispute the need for increased awareness of general practitioners as to the proper diagnosis of these impairments, but that is an issue outside the purpose of these regulations.

Comment: Commenters reacted both favorably and unfavorably to the degree of flexibility we had given States in designating their Level I systems. On the one hand, a number of States expressed appreciation for being given so much flexibility in deciding how it would accomplish the identification function. On the other hand, a few States asked for more specific instructions concerning how to design or operate their Level I systems.

One hospital-based commenter, writing from a large metropolitan center located in a multi-State area, objected to allowing each State to implement Level I as it sees fit. Asking for a greater degree of interstate consistency, the commenter claimed that allowing States so much flexibility results in so much variation from State to State that it is difficult for a hospital in a multi-State area to refer patients to NFs in surrounding States. The commenter noted that in his area some of the States are not screening patients who are in a private pay status while other States are and that each State is using a different form.

Response: We believe that the flexibility permitted in this regulation is appropriate, given the state-of-the-art in operating PASARR systems. We would note that the law requires that these systems be established and operated by the States and does not require either reciprocity among States or a central Federal management. In our view, States operating PASARR systems should have the flexibility to individualize them to fit with the operations of their mental health and mental retardation service systems. While we recognize that placements from one State to another may present a greater challenge than intrastate placements, we do not believe there is an appropriate regulatory solution for this challenge. States that routinely do not apply their PASARR process to all applicants and residents with MI or MR, regardless of their method of payment for care, invite compliance actions.

Comment: A number of commenters also reacted both favorably and unfavorably toward allowing States to use hospital discharge planners to perform Level I screens. Several hospitals or hospital associations strongly supported the proposal to utilize hospital discharge planners. However, they voiced concern over the usage of general terminology of "discharge planner". They wanted us to specify qualifications for those performing this function (i.e., licensed social worker with BS or MS or RN providing discharge planning services on a regular basis).

Another group of hospital-based commenters felt that we had not gone far enough. While we permitted States to utilize hospital discharge planners, we did not require them to do so. These

commenters wanted us to require States to permit hospitals to do Level I screens if the hospital so desires.

A few NFs, however, objected to having hospital discharge planners perform Level I evaluations. They stated that hospital discharge planners are more motivated by the need to move people out of hospitals than by a desire to thoroughly review patients for mental health needs. They asserted that they have found a basis for questioning the status of a large number of people being referred to them by hospitals as not needing Level II screens. Consequently, the NF found it necessary to rescreen the individuals to assure accurate Level I determinations and appropriate referrals.

Response: As we have stated in previous responses, we believe that States should have the latitude to involve hospitals in the Level I screening process. We have not specified who should perform these screens in any setting and do not believe it is necessary to do so in the hospital setting. If a State's system results in incorrect Level I findings, we believe it is the State's responsibility to remedy any shortcomings in the process. States have an incentive to do so because they share in the funding of the process and ultimately pay for its inefficiencies. NFs that screen prospective admissions to assure that they are appropriate for NF care, including whether they may have mental illness or mental retardation, are acting appropriately and we encourage this behavior, which is a key behavior in assuring that only appropriate admissions are made.

Comment: Several nursing facilities objected to having to stigmatize applicants or residents in their performance of Level I screens. They note that the suggestion of MI or MR is embarrassing for the resident or family. It can lead to anger at the NF for being the government's vehicle for wasting taxpayers' money by sending someone to suggest that they need help with their mental problems. Moreover, the cost and effort of screening may well be wasted if the resident or family refuses any treatment that is recommended.

Response: We recognize that mental illness and mental retardation can be sensitive family issues and that objections by family members and others may arise in the course of PASARR reviews at both Level I and Level II. Moreover, although commenters have suggested that great tact is needed in handling the screening, section 1919(e)(7)(F) of the Act requires that individuals be given appropriate notices of the findings, which may be appealed. We believe that section 1919(e)(7) of the Act is clear and that these final regulations correctly interpret the Act.

We note that OBRA '90 contained two provisions which may be perceived to impact on the Level I process. We, therefore, offer our thoughts on these topics here by way of guidance to the States in operating their PASARR programs. First, OBRA '90 prohibited States from delegating any of their PASARR responsibilities to NFs. We do not believe that this provision in any way hinders States from using NFs to perform Level I identifications. The actual PASARR is accomplished through Level II. Second, the change in the definition of MI for PASARR purposes may alleviate some of the States' and NFs' concerns about missing individuals with MI on whom documentation of their mental condition may be scanty or nonexistent. Serious mental illness, such as we have defined MI to be, is not so likely to have gone unnoticed

and undocumented. Large numbers of individuals with only minor mental disorders will not risk possible embarrassment by being referred for Level II screening.

Section 483.128(a) Level I Notices

Comment: On the one hand, commenters raised a variety of technical concerns relating to the requirement that the State's performance of Level I function must provide for issuance of written notice of referral for Level II. These technical questions may be summarized as follows:

- How often do Level I notices have to be sent;
- Who must receive them;
- Is it a resident right to receive a notice or a State responsibility to issue it;
- Who has responsibility for developing and issuing the notice, the NF or the State;
- What form or style should the notices have and in what manner should they be delivered to applicants or residents;
- Should informed consent be required or could it substitute for Level I notice.

On the other hand, commenters also addressed the issue of Level I notices in relation to Level I appeals, questioning whether formal written Level I notices would be needed if Level I appeals are eliminated. As discussed later under the appeals section, commenters were overwhelmingly opposed to having Level I determinations subject to appeals. In response to our specific request for comment on negative Level I notices, commenters indicated strongly that negative Level I notices are unneeded and would constitute an enormous burden if required. The question remains, then, whether formal Level I notices are needed if positive Level I determinations are not subject to appeal.

Response: To a degree, the need for a Level I notice was linked to the position that we took in the proposed rule that Level I determinations were appealable and that formal notice would have to be given, advising the person being referred for a screening of his or her appeal rights. (See our discussion on Level I appeals in the appeals section). Since we are persuaded by commenters that Level I determinations should not be subject to appeal, there is now no need for a negative Level I notice. When an applicant or resident is referred to the State for Level II evaluation, however, he or she (and his or her legal representative) still needs to be advised of what is happening to him or her even though the Level I determination is not appealable. Under the resident rights section of the February 2, 1989 rule (§483.10(b)), a resident has a right to be informed of treatments to which he or she is to be subjected. However, applicants to a NF would not be protected by these provisions until after admission, if admission is determined to be appropriate. Therefore, we believe that our requirement that the State's exercise of the Level I function must provide for issuance of written notice to individuals being referred for Level II screening, at least for the first time, is appropriate.

Having determined that positive Level I notices are needed, we must address the many technical questions raised by commenters. These are addressed in separate comments and responses below.

Comment: Concerning the frequency of Level I notices, one

State reported that its current process allows for Level I to be performed only once, at intake to the NF, unless illness occurs or information is uncovered which would alter the original Level I determination. Due to the notice of appeal rights and interfacility transfer requirements presented in the proposed rule, the State noted that each time an individual is referred for a Level II screening a new notice would have to be sent. For example, any time a resident with MI or MR sought a transfer, which would have required a new PAS as proposed in the NPRM, and any subsequent year that the NF's routine annual resident assessment triggered a Level II ARR (as required by the requirement for coordination of resident assessments and PASARR), the resident would have to be sent a new Level I notice. The State claimed that this process would be cumbersome, unwieldy, and unnecessarily bureaucratic. Moreover, the State would have to increase its staff to handle the notice function.

Response: We direct readers to our discussion of coordination of PASARR with the NF's resident assessment at §483.108. In this section we described the way in which the RA may function as a Level I to identify new individuals with MI or MR who need to be included in the State's tracking system. We do not believe that individuals who are already in the tracking system would have to be issued a Level I notice every year when it comes time for their next ARR. They already know that they are in the system. Only when an individual is being referred for the first time to the State authorities should a Level I notice be required. We also call readers' attention to the fact that we have eliminated the need for a PAS in the case of interfacility transfers (See discussion of §483.106(b)). We are amending the regulation by inserting the phrase, "at least in the case of first time identifications," into the requirement for written Level I notices. States which choose to give individuals more frequent notices may do so.

Comment: Some commenters asked that the regulation specify that the legal representative, if one has been appointed, must receive a copy.

Response: We are adding a reference to the individual's or resident's legal representative in §483.128(a).

Comment: Another commenter, noting that Level I as proposed in the NPRM carried with it appeal rights, wanted the regulation text to state this requirement in another way: that persons subject to Level I must receive written notice rather than that the State's Level I function must provide for notices to be given. Apparently the commenter felt that the notice requirement should be considered a resident's right rather than a State responsibility and wanted the regulations text to be structured to reflect this reality.

Response: Since appeal rights are no longer involved, we do not believe it is critical whether the right to notice is couched in the regulation as an individual right or a State responsibility. The effect is the same. We, therefore, are not restructuring the requirement at §483.128(a).

Comment: Concerning whether the State or the NF is responsible for developing and issuing the Level I notice, most commenters believed that whomever the State has designated as the Level I evaluators should actually issue the written notice but that the State should develop a model statement for NFs, hospital

discharge planners, or other Level I evaluators to use so that there would be uniformity to the notices issued in the State. Others noted that the State Medicaid agency should periodically monitor this process.

Response: We agree with commenters that, since the State has responsibility for overseeing the Level I process in the State, it should take a leadership role in the development of a model statement even though the Level I evaluator would issue the notice. A common notice form would ensure consistency throughout the State and facilitate monitoring. However, to permit States flexibility in operating their Level I mechanisms, we are not requiring this.

Comment: With respect to the form and style of the notice, some commenters suggested that the notice should be in large print and simple English. Another commenter, noting that communication disorders are a prevalent problem among individuals with MI and MR, proposed that the regulation take into account the individual's language and means of communication.

Response: We believe that the concerns raised by some commenters over style of the notice and recognition of the communication needs of the audience to which the notice is directed are relevant concerns in designing these Level I notices which States may wish to incorporate into the notices they adopt.

Comment: One State expressed the view that there is no need for a separate notice for Level I. To go on to Level II, their State requires informed consent. They claimed that the informed consent papers serve as the notice and any other notice would be redundant.

As a related issue, a few commenters expressed the belief that we should require informed consent prior to evaluation. Since the screening includes functional, neurological and psychiatric assessments, these commenters felt that the invasiveness of the testing and the need for cooperation by the individual warrant the client's documented understanding of what is happening.

Response: We do not believe that an informed consent requirement is needed for Level II screens because the law requires that screening be accomplished by the State in all cases where a person with mental illness or mental retardation is proposed for admission to an NF, and the law prohibits an NF from admitting any individual with mental illness or mental retardation who has not been screened and found to need NF care. Thus, the individual who desires to be admitted to an NF has no choice as to whether to undergo a screen except to forego admission. To introduce an apparent choice for such an individual would not increase his or her actual choices with respect to the issue.

We believe that States may choose to require informed consent, but we are not requiring States to do so. Since we are not specifying the form of the Level I notice, States which require informed consent may, we believe, substitute their consent forms for positive Level I notices.

Section 483.128(b)-Language and Cultural Background

Comment: Concerning the requirement that PASARR evaluations must be adapted to the cultural background, language, ethnic origin and means of communication used by the individual being evaluated, several States asked for clarification of how far

the State and the NF must go. They recommended that we add language requiring the State to "make reasonable efforts" to adapt PASARR evaluations and notices to individual differences. They noted that some States have very small minority groups such as Southeast Asian immigrants for whom it would be very difficult to obtain interpreters with comprehensive enough technical language skills. Since the information that must be gathered for PASARR is often very technical, the commenters believed that they could not rely on interpreters such as other family members with only rudimentary English language skills. One State asked how the State could meet the timeliness standard if it has to look for an interpreter.

Response: We recognize that this requirement may present challenges to a State. We note that similar questions were addressed in the February 2, 1989 rule concerning the resident's right to be informed of his or her rights in language that the resident understands (See the discussion of §483.10(b)(1) at 55 FR 5320). In that instance, we held that the facility should have copies of the rights statement in foreign languages commonly encountered in its area and make the services of an interpreter available. For foreign languages that are seldom encountered in the area, the assistance of a representative of the individual could explain the rights and sign for the individual. We also required the facility to accommodate the needs of hearing and sight-impaired individuals in advising them of their rights.

We would expect that, in adapting PASARR evaluations and notices to individual differences, the State should make similar efforts to see that interpreters are used where necessary and that the screening instruments used do not contain recognizable cultural biases. Also, communication deficits noted in the physical examination and medical history should be taken into account by the evaluator in conducting the other elements of the screening.

Section 483.128(d)-Relationship Between NF and Specialized Services Determinations

Comment: A number of commenters applauded the holistic approach taken in §483.128(d). In that section we required that the two determinations concerning the need for a NF level of care and for specialized services be interrelated and based upon a comprehensive analysis of all data, gathered throughout all applicable portions of the PASARR evaluation (i.e., PASARR/NF, PASARR/MI and PASARR/MR).

As indicated in our discussion of appropriate placement at §483.126, other commenters believed we were giving mixed messages. They claimed that, on the one hand, we were saying that the two determinations must be made together while, on the other hand, we were making it seem as though the two determinations are separable.

Response: Because the comments on the interrelatedness of the two determinations are part of the larger question of appropriate placement, we have discussed these issues under that section at 483.126.

Section 483.128(g)(4)-Report Must Identify NF Needs and Specialized Services Needs

Comment: Several States advocated that we delete the requirement

that the PASARR evaluation report identify the NF level mental health services which the person being screened needs. They believed that it is the NF's job to assess these needs. Having to go into such depth of needs analysis, the States claimed, makes meeting the timeliness standard impossible.

Response: We refer readers to the discussions of the purpose of PASARR under general comments on PASARR evaluations and determinations at §483.128 and of the need for two assessment processes under coordination of PASARR with resident assessments at §483.108. Congress intended that there be two systems of assessment for the mentally ill and the mentally retarded populations. We believe Congress gave the State mental health and mental retardation authorities responsibility for PASARR determinations presumably in order to call in the appropriate specialists for something akin to a second opinion on the needs of individuals in these two populations. We do not perceive of the PASARR process as merely serving a directive purpose. It must perform a classifying function; and, thus, there must be reasons presented for why an individual should go one direction or another and the overall process should result in appropriate care in whatever setting the individual is directed toward. Therefore, we believe the evaluation report must contain enough detailed information about the individual's mental health or mental retardation needs to be able to explain why NF placement is or is not appropriate and, if it is determined that the individual may enter or remain in this setting, to enrich the care planning process in the NF.

On this point, we would note that coordination between the NF's resident assessment process and the State's PASARR process is required at §483.106(a). We believe that, for ARR's, it would be thoroughly appropriate for the PASARR evaluator(s) to review the NF's plan of care on the resident, which flows from the RA, and comment on it in the evaluation report, ratifying the care plan or suggesting changes or additions. For PAS's, the evaluator could make recommendations which could serve as a basis for the NF's plan of care until the NF has had the opportunity to conduct its first assessment on the resident (which it must do within the first 14 days of admission). Likewise, the NF may use data developed under PAS in conducting its first RA on the new resident.

Section 483.128(h)-Abbreviated Written Report for Categorical Determinations

Comment: A couple of States expressed the opinion that the requirements for issuing an abbreviated written evaluative report in cases where categorical determinations are made were much too detailed. They claimed that these requirements would create a paperwork burden for the States. These States also noted that tracking categorically determined individuals will be difficult because these determinations are made at the NF level.

Response: Categorical determinations are not exemptions from PASARR. They are determinations by the State even though they are applied locally and at the Level I stage. We believe that the requirements listed are the minimum elements necessary to complete the PASARR process in those easy-to-identify cases for which a categorical determination is possible. We do not

believe these requirements are overly burdensome. It is the State's responsibility to keep track of the individuals for whom categorical determinations are made and to monitor the manner in which the State's designated Level I evaluators are making these determinations. We note that categorical determinations, like individualized Level II determinations, are appealable. Therefore, the action by the State (and its agent, the NF or other Level I evaluator in applying the categorical determination) must provide the basis for such action. The evaluation report does this.

Section 483.128(i)-Findings Must Be Interpreted to Individual or Legal Representative and the Individual or Legal Representative Must Receive a Copy of the Report

Comment: A few commenters felt that the requirement that the findings of the evaluation be interpreted to the individual or his or her legal representative was too burdensome and time consuming. They thought the evaluator should only be required to deliver a copy of the written report to the individual or his or her legal representative. One commenter felt that requiring delivery of the full evaluative report to the individual or legal representative was excessive and that provision of the findings should be enough. Other commenters believed it was inappropriate to have the evaluator tell the person being screened what the results of the screening were before the determiner had made a decision. They thought it would make better sense to have a face-to-face discussion after the determination is known.

Response: We are not specifying how or when or by whom the State must provide an interpretation and explanation of the findings of the evaluation to the individual being screened or his or her legal representative. States vary considerably in the way they have their screening systems organized. Also, the individuals being screened present several different types of situations, depending upon whether they can be dealt with categorically or not and whether they are competent to understand an explanation or whether the explanation must be given to a legal representative.

Since categorical determinations are applied at the Level I stage, the evaluator will likely be different from the evaluator who performs the individualized Level II evaluation. For individualized evaluations, some States may use standardized forms which the evaluator fills out during the course of the evaluation. In such a case, the evaluator could provide an explanation during or at the conclusion of the screening and could provide the individual with a photocopy of the report. Under other State processes, the evaluation report may not be written up until a day or two after the screening has been completed. Some States may use evaluation teams who move from one facility or locality to another on a routine basis. In such a case, the evaluator may not be available to provide a face to face interpretation after the screening is completed. Telephone calls might be a possible alternative means of communication. We also agree that in some cases, especially the more complex ones, it may make sense to have the explanation given after the determination of the SMHMRA is known.

While we are not specifying how, when or by whom the explanation must be given and the copy of the report provided, we believe it is essential that the person being screened or his or her legal representative receive a layman's explanation and a copy of the full evaluation report for several reasons. These are sensitive issues for the person being screened and the results of the screening may have great impact on the individual's options for future care. These are disabled populations for whom extra care must be given to allow them to exercise their rights. Since PASARR Level II determinations are appealable, they must understand the basis on which the determinations were made in order to assess whether they should submit an appeal. If they seek the advice of an advocate, the first thing an advocate would want to see would be the evaluation report. Therefore, we believe the individual or legal representative must be informed both orally and in writing and that the full evaluation report must be provided.

Because we are identifying other recipients of the evaluative report at §483.128(l) (i.e., the SMHMRA; the NF; the individual's attending physician; and the discharging hospital, in cases in which NF admission is being sought from a hospital), we are relocating the language at §483.128(k) that requires that the individual or legal representative must receive a copy of the report to a new §483.128(l) so that States and evaluators will readily understand exactly to whom copies of the report must be sent and under what circumstances. (See also discussion of §483.134 personnel requirements.) Because the attending physician and the discharging hospital (in non-exempt cases) also need to know the outcome of the PASARR process for their patient, we are also adding a corresponding requirement at §483.130(n) that a copy of the determination made by the SMHMRA be sent to them.

Other Changes to §483.128

In response to comments we received on the timeliness standard at §483.112(c) that we not establish a separate timeframe for evaluations under PAS, but rather leave it to the States to establish whatever timeframes they need to meet the overall timeframe required by §483.112(c) for making a determination once referral to the State authorities is received, we are removing specific timeframes for evaluations in proposed §483.128(j).

We are also adding a new provision in paragraph (l) that the evaluator must submit the evaluation report to the State authorities in sufficient time for the State authorities to meet the timeframe for PASs established in §483.112(c) and for ARRs in §483.114(c). These additions are consistent with our discussions elsewhere in this preamble.

Section 483.130-PASARR Determination Criteria Categorical Determinations

Comment: A number of State agencies and other commenters supported the use of categorical determinations and reacted favorably to the degree of latitude the proposed regulation gave States in devising categorical determinations. Most of these commenters expressed appreciation for this opportunity to restrict the broad statutory definition of MI, which existed

at the time, to serious MI and thereby reduce PASARR costs and avoid unnecessary inconvenience to clients who are not likely to need specialized services. To assure national uniformity in how PASARR is applied, however, other commenters urged us to dictate the categories States may use or even must use.

Response: Originally we devised the system of categorical determinations primarily as a means of allowing States to reduce the number of extensive, individualized screenings they would have to perform on individuals who fit the OBRA '87 definition of MI by making presumptions about individuals with certain diagnoses. This definition encompassed all individuals who have a primary or secondary diagnosis of a mental disorder described in the Diagnostic and Statistical Manual of Mental Disorders, 3rd edition, revised (DSM-III-R) and do not have a primary diagnosis of dementia (including Alzheimer's disease or a related disorder). Because DSM-III-R catalogs virtually every known mental affliction, whether or not severe or disabling, the net cast by this definition was very broad indeed. In making determinations about individuals with MI, States could speedily deal with clear-cut cases in a cost efficient manner by using presumptions. They could then focus their resources on the more seriously mentally ill for whom active treatment (now known as specialized services) or an alternative placement might be needed. We also allowed States to create categories of physical need which would enable them to deal quickly with individuals whose need for NF care was readily apparent (i.e., convalescent care following an acute hospital stay; terminal illness; severe chronic and debilitating illnesses).

As noted elsewhere in this preamble, OBRA '90 restricted the definition of MI for PASARR purposes to serious mental illnesses as defined by the Secretary in consultation with the National Institute of Mental Health. It also excluded non-primary dementias from the definition of MI. In addition, OBRA '90 allowed for certain admissions from hospitals for convalescent purposes. All of these statutory changes had an impact upon our system of categorical determinations, rendering several of them superfluous and requiring others to be altered. These changes are discussed below under each separate heading.

We disagree with those commenters who wanted us to impose a uniform national system of categorical determinations. States vary in how their mental health and mental retardation systems are structured and how they approach service delivery to these populations. We believe that States should have some degree of flexibility in determining how the categories are designed. We have indicated certain types of categories which may or may not be used or placed limitation on their use. We believe these strictures are sufficient.

Comment: One commenter asked that the regulation clarify that categorical determinations should be done as part of Level I and that any errors can be picked up in NF's resident assessment.

Response: We believe that the preamble discussions in the proposed rule presented sufficient explanation that categorical determinations are State determinations applied at the Level I stage in clear-cut cases and have not amended the regulation.

Comment: The statements of some commenters appear to indicate that some States continue to view categorical determinations as exemptions to PASARR screenings rather than as determinations

by the State. For instance, one commenter stated that the rules appear to allow temporary placements (for respite or provisional placement) yet state that if an individual is admitted without PASARR, FFP will be denied. We also heard allegations that the convalescent care category has been used to admit people to NFs while it takes the State up to 120 days to do evaluations. Another State explained that it is using the respite category to avoid individual screenings for admissions that are expected to last less than 30 days. The State did not mention any other criteria such as proof that there is a caregiver who needs temporary relief and to whom the individual being admitted to the NF will return. It only stated that if a stay exceeds 30 days, the State screens the individual. Moreover, the State recommended this strategy to reduce paperwork.

Response: As we noted above under §483.128(h), categorical determinations are determinations by the State and not exemptions from screening. Therefore, FFP is available for NF care provided in accordance with these determinations. We note, however, that we recognize the potential for abuse by States in creating and applying a system of categorical determinations. In doing future reviews of State PASARR programs, we will evaluate the reasonableness of the categories a State has established and the manner in which they have been applied. When categorical determinations are being used inappropriately, for example, to avoid the need for screenings, the State would be subject to compliance actions.

We hope that the OBRA '90 provisions which redefine MI to reduce the size of the population needing screening and which permit admission to NFs without PAS of hospital patients being discharged to NFs for short-term (less than 30 days) convalescence from a condition for which they were hospitalized will reduce the temptation for States to use categorical determinations inappropriately.

Section 483.130(d)(1) Convalescent Care and Section 483.130(d)(2) Terminal Illness

Comment: Commenters supported the use of these categories. Their main objection was that they wanted us to dispense with the requirement that an MI or MR evaluation still be performed.

Response: As discussed elsewhere in this preamble, categorical determinations are not exemptions and for those for whom a determination is required both questions must be asked and answered, either categorically or individually. By contrast, OBRA '90 now permits certain individuals being discharged from hospitals to NFs for brief convalescent care to be exempt from PAS. Because not all individuals being discharged from hospitals to NFs will be able to meet all the statutory criteria for exemption from PAS (e.g., the 30 day projected limit for such a stay), we are retaining the proposed convalescent care category and have added only the following qualifying phrase: "which does not meet all the criteria for admission as a PAS-exempt hospital discharge identified at §483.106(b)(1)(ii).

Section 483.130(d)(3)-Severe Illness

Comment: Several commenters made suggestions about conditions or diagnoses which they felt should or should not be included

under the severe illness category. For instance, one State questioned the inclusion of congestive heart failure (CHF) and the omission of cardiovascular accident (CVA) from the list. Other commenters suggested the addition of CVA with aphasia or Niemann-Pick disease. One medical society recommended inclusion of quadriplegia, advanced multiple sclerosis, muscular dystrophy, cerebellar degeneration, stroke, and stage renal disease, severe diabetic neuropathies, and refractory anemias. Also, these commenters favored retention of the "such as" language to indicate that the list is not all-inclusive.

Response: We do not wish to dictate to States which conditions they must include on a list of severe illnesses. States may wish to use these suggestions.

Section 483.130(d)(4)-Provisional Placements and (d)(5)-Respite

Comment: A number of commenters addressed specific categorical groups, either by making suggestions or asking questions. One commenter expressed appreciation for the provisional admissions category at §483.130(d)(4), noting that it would be useful for people who cannot be screened due to effects of anesthetic, medication, unfamiliar environment, severity of illness or electrolyte imbalance until these effects clear. Other commenters applauded inclusion of the respite category at §483.130(d)(5) but asked that we clarify that the individual must still meet NF level of care. Several noted that the minor mental disorders category at §483.130(f) would be very helpful.

Although we had proposed that brief admissions could be made to permit alternative arrangements for long term care in emergency situations requiring protective services, one commenter noted that, as drafted, the proposed rules would make it virtually impossible to admit children with MR who need a NF level of services on an emergency basis. The main obstacle to admitting, for example, medically fragile children brought to the commenter's NF because of abuse and neglect is the requirement that even though the NF level of care question can be dealt with categorically, the rules still require that the specialized services determination be made individually.

The commenter also noted that this requirement delays admission of children with MR for very brief stays under the respite care category, for instance, when the parents must take care of other needs, sometimes on short notice. The commenter asserted that in an emergency situation, there is no time to meet the requirements of §483.130(h), as proposed, which provide that the SMRA must make a determination based on an individualized evaluation by professional staff, including a licensed psychologist. For respite cases, where the individual will be in the NF only a few days, it is not feasible to implement a detailed specialized services program for MR. Therefore, the commenter thought, it makes little sense to hold up admission to the NF in order to obtain the detailed screening which would lay the basis for development of such a program.

The commenter noted that his State had adopted rules which allow a mentally ill or mentally retarded child under age 21 who needs NF care to be admitted pending determination of placement for longer term care. The State's rules also allow individuals who need NF care and are not a danger to themselves or others

to be admitted to a facility for respite care for up to 14 days, twice a year. In both of these cases, the commenter noted, the State rules recognize that it is not reasonable or appropriate to require a detailed individualized screening process or provision of highly specialized MR services while the individual is in the NF on an emergency basis or for only a brief respite stay.

Response: We believe that many of the concerns expressed by commenters arise from a misunderstanding of the nature of the determinations required under the PASARR process. Assessment of the need for specialized services must necessarily take account of the time and effort needed to assess the individual and implement a specialized services regimen. In the case of a mentally retarded individual living at home who is proposed for a brief respite stay in a NF, for example, the lack of time to develop and implement a plan may lead the State mental retardation authority to conclude that specialized services are not necessary for the individual. A different decision would be dictated by a longer stay. In still another example, an individual with severe behavioral symptoms may require specialized services even during a short stay because of the potential danger to the patient or others.

We do not believe that the resolution of the problems raised by the commenters lies in providing exemptions from the need to make determinations about the need for specialized services (either detailed or categorical-see the following discussion of §483.130(h)) but, rather, in viewing the need for specialized services in the context of the proposed stay. Clearly, it would not be appropriate to order an assessment and development of a treatment program when that activity would require virtually as long as the stay itself so that it would not, as a practical matter, be possible to implement the treatment program during the stay.

While we recognize that there are numerous examples of situations in which an NF admission could be appropriately made on an emergency basis without the types of screening and determinations required under these regulations, we must note that the law does not provide for any exceptions. All individuals with MI or MR must be screened, either individually or categorically. Thus, measures we suggest here are the least intrusive possible under current law.

Comment: As indicated under our discussion of the timeliness standard under §483.112(c), a sizable number of commenters asked for a provisional admissions category for cases in which record availability is a problem or the case was unusually complex yet it appears that NF care is needed. A number of commenters also asked for an emergency admissions category or an expansion of the provisional admissions or respite categories to encompass such situations.

Response: In response to comments, we are revising section 483.130(d) to provide that the State may make an advance group determination that NF services are needed in the case of provisional admissions pending further assessment in emergency situations requiring protective services with placement in an NF not to exceed 7 days. We had proposed such an idea in the proposed rule as part of the respite category, but commenters appeared not to have noticed it. It now stands on its own as a separate category at §483.130(d)(5).

Section 843.130(e)-Required Individualized Evaluations for Major Mental Illnesses and Section 483.130(f) Minor Mental Disorders.

Since OBRA '90 changed the definition of MI to "serious mental illness (as defined by the Secretary in consultation with the National Institute of Mental Health)," there is no longer a need for the minor mental disorders category originally proposed at §483.130(f). Such individuals are no longer subject to PASARR, so we have removed this provision.

We are also eliminating §483.130(e), which proposed that the State's PASARR system must assure that at least all individuals with diagnoses of schizophrenia, paranoia, mood disorders, schizoaffective disorders, and atypical psychosis receive individualized screens to determine if they require specialized services. Individuals with diagnoses of serious mental illnesses such as these are now the very group to which the definition of MI is restricted. To retain this categorical group would be superfluous, on the one hand, and, on the other hand, would require individualized screens in all cases, thus, prohibiting the use of any categorical determinations for individuals with MI.

Because of the seriousness of MI as it is now defined, we believe that as a general rule, individuals with these diagnoses should receive individualized screens. Except as noted below, the only exceptions to the performance of a complete evaluation which deals with both questions on an individualized basis should be when there is a clear physical need for NF care or a need to act quickly. In the case of a clear physical need for NF care (e.g. need for convalescent care or very severe or terminal illness), but no emergency, a categorical determination that NF services are required could be made as identified in §483.130(d)(1-3) accompanied by an individualized MI or MR specialized services evaluation as required by §483.134 or 483.136. In cases in which there is a need to act quickly, as identified in §483.130(d)(4-6) (e.g. provisional, emergency or respite placements), a categorical determination could be accompanied by either an individualized MI or MR screen or a categorical determination, as permitted in §483.130(e).

As noted earlier under the discussion of the dementia exclusion at §483.102(b)(2), the statute and the legislative history speak only of an exclusion from MI for dementias. There is no statutory exclusion from MR for dementia. Many commenters, including disabilities advocates and professionals involved in treatment of individuals with MR, asked that we permit a dementia/MR exclusion from PASARR. Some commenters proposed that we create a categorical determination which would permit such individuals to be dealt with without extensive screening. We have added such a provision at §483.130(g). Along with the provisional admission, emergency or respite situations which are available for both individuals with MI and those with MR, this dementia/MR categorical determination would permit a negative categorical finding that specialized services are not needed. Application of this categorical determination would need to be based on the same level of diagnostic certainty as the application of the dementia exclusion from MI (i.e., physician's diagnosis).

Sections 483.130 (g) and (h)-Limitations on Categorical Specialized Services Determinations

Comment: One commenter representing mental retardation professionals asserted that §§483.130(b)(1) and 483.130(g) or 483.130(h) appear to contradict each other. Paragraph (b)(1) permits 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 specialized services is or is not normally needed.

Paragraph (g) states that the State mental health or mental retardation authority must not make categorical determinations that specialized services are needed without requiring that such a determination be followed by a more individualized evaluation through a PASARR/MI or a PASARR/MR. In other words, there can be no positive specialized services determinations made categorically. Paragraph (h), as proposed, states that the State mental retardation authority must not make categorical determinations that specialized services are not needed for individuals with MR and that a negative active treatment determination must be based on a more extensive individualized PASARR/MR. Taken together these two provisions mean that only negative determinations for specialized services/MI may be made categorically and that no categorical determinations with respect to the need for specialized services, either positive or negative, can be made for individuals with MR. Yet paragraph (b)(1) indicates that both positive and negative categorical NF care and specialized services determinations are possible. Once a categorical determination on NF needs is made, it must be followed by an individualized PASARR/MR.

Response: We agree that an inconsistency exists in the rule as proposed and are revising §483.130(b)(1) to provide that determinations may be 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 is normally needed or that the provision of specialized services is not normally needed. Paragraph (g) then emphasizes that only negative categorical specialized services determinations can be made. (See the following discussion of §483.130(h).)

We have also clarified this position further by removing the phrase "without requiring that the determination be followed by a more extensive individualized evaluation * * *" because this language suggested that positive categorical determinations with respect to specialized services could initially be made so long as a more thorough screen was later performed. We have substituted instead a statement that more clearly requires all positive determinations concerning the need for specialized services to be based on the more extensive individualized evaluation.

Our reason for prohibiting positive categorical specialized services determinations is that, for individuals who need specialized services, we do not believe it is sufficient to simply say that they need them. If they need specialized services, the State must do something about this need. The screening process should, therefore, take a close look at the individual's specialized services needs for any bearing it may have on the NF level of care determination and to lay the groundwork for coordination of care between the NF and the State if NF placement is approved.

As noted elsewhere in this preamble, individualized determinations are needed to establish an individualized list of specialized

services. For each individual who is subjected to PASARR and found to need specialized services, the PASARR report holds the key for surveyors to use when surveying the NF. The NF cannot be held responsible for supplying those services identified as being within the realm of the State's responsibility. Anything else, which is not listed as a State responsibility, is a responsibility of the NF. Additionally, whether or not specialized services are needed, the PASARR report should provide information about the other mental health or mental retardation needs the individual has which are below the specialized services level of intensity.

As discussed under the definition of specialized services at §483.120, we are reluctant to establish a generic list of specialized services. We are, however, allowing States, if they so choose, to develop such a list and include it in their State plan preprint. Whether the SMHMRA has in hand a State-established list of specialized services to draw from or not, the PASARR report identifies what the list of specialized services is for this particular individual. The report should also identify, for the benefit of the NF as well as of surveyors, the types of NF services which the SMHMRA thought the individual needed. Surveyors could then look to see if the NF were providing these mental health or mental retardation NF services.

Because of the reduced need for categorical determinations as a result of the change in the definition of MI and because of the need to have the PASARR report serve as a linchpin in the care planning and surveying process, we have considerably reduced the scope of applicability for categorical determinations. We continue to believe that categorical determinations have utility in some situations as identified above, but the use of individualized screens should be the norm.

Section 483.130(h)-State MR Authority Must Not Determine Categorically That Specialized Services Are Not Needed

Comment: Several commenters objected to the requirement at §483.130(h) (as proposed) that, for individuals with MR, the State mental retardation authority must not determine categorically that specialized services are not needed. Some commenters who opposed this restriction stated that the ability to use categorical determinations for both types of determinations (specialized services and NF care) should be equal for both groups, (individuals with MI and MR). However, a few other disabilities advocates strongly supported the emphasis placed on individualized determinations for individuals with MR in all cases.

Response: We originally proposed this requirement because the definition of MR was not as broad as the definition of MI. As noted earlier, the system of categorical determinations was devised, at least in part, in an effort to assist States in reducing the numbers of individuals with MI who would have to be screened individually by eliminating from intensive evaluation all those who had only minor mental disorders which would probably never need specialized services. The definition of MR, while it does include mild retardation, did not potentially encompass a major share of the nursing home population in the way the original statutory definition of MI did. We were concerned that if we permitted use of categorical determinations for individuals with MR that active treatment is not needed, some States could

establish a category which would deprive individuals with milder levels of mental retardation from receiving an individualized screening to identify those services they might need.

We are persuaded by commenters, however, that it is not equitable to have negative active treatment categorical determinations available for individuals with MI but not for those with MR, at least in the two or three instances in which they are urgently needed, (i.e., in provisional admission, emergency and respite situations). In all other instances (except as identified in §483.130(g)), we believe that individualized screens concerning the need for specialized services for MR should be required. We have, therefore, amended the proposed §483.130(h) (now located at §483.130(e)) to convert it from a prohibition against MR categorical determinations of the need for specialized services in all circumstances to an explicit, but limited, permission to use categorical determinations in these limited situations.

Because of the change in the definition of MI and the reduced need for MI categorical determinations of the need for specialized services, we have also amended the proposed §483.130(h) to place these same limitations on categorical determinations concerning the need for specialized services for individuals with MI made by the SMHA. Both groups, thus, will be subjected to the same rules and limitations at §483.130(e).

Section 483.130(i)-Severity of Mental Illness

Comment: One commenter objected to §483.130(i) which permitted the State to establish a categorical determination that individuals with certain mental conditions or levels of severity could normally not be accommodated in a NF because their care needs would be too heavy, even with supplemental active treatment services provided by the State. The commenter thought that this category discriminated against these individuals on the basis of diagnosis.

Response: We disagree. Medicaid regulations relating to sufficiency of amount, duration, and scope of services at §440.230(c) prohibit a State from "arbitrarily" discriminating on the basis of diagnosis. The provision of this regulation explicitly authorizes categorical determinations when they are based on the medical condition of the patient and the care needs to which such conditions give rise. By using such a category, a State would not be barring such individuals from entering a NF solely on the basis of diagnosis of MI or MR. The State would simply be acknowledging that certain individuals with severe mental illness or profound retardation have needs that are so great that a service delivery system for that individual would be difficult to construct or cost prohibitive. In the best interests of the individual, he or she should be accommodated in another setting where the more intensive services the individual needs can be provided more completely and efficiently.

In the process of reconsidering all the categorical determinations in light of the OBRA '90 changes, however, we have concluded that §483.130(i), as proposed, is both unnecessary and contrary to the statute. The statute clearly indicates that if NF services are needed, the individual may be admitted to the NF; and, if specialized services are also needed, they must be provided in the NF if the individual is admitted. This provision is not consistent with the statute because it would allow States to

determine that, even though NF services are needed, some active treatment needs might dictate placement in another setting.

The key to resolution of the problem lies in the definition of appropriate placement at §483.126 and in the requirement at §483.128(f) that both determinations, because of their interrelated nature, must be made in tandem. The NF level of care is, as we discussed in the NPRM, analogous to a layer cake. If an individual's service needs are above a level which can be accommodated in a NF, with or without the specialized services which the State can effectively and efficiently bring into the NF or take the individual from the NF to, then the individual should be considered not to need a NF level of services. He or she needs a higher level of services, not NF services. In such cases, a negative finding on the question of whether NF care is needed should be used to direct the individual toward those other more appropriate settings instead of accomplishing the same end by means of this categorical determination. We are, therefore, deleting §483.130(i) as proposed.

Section 483.130(j)-Categorical Determinations Based on Advanced Years, Right To Refuse Active Treatment

Comment: We proposed that the State may make a categorical determination that certain individuals of advanced years be allowed to decline specialized services in a NF under certain circumstances.

A number of commenters strongly objected to this category on the grounds that limiting the right to refuse treatment is contrary to existing Medicaid regulations at §483.10(b)(4). These commenters felt that compelling a resident to receive specialized services just because he or she needs NF services is a fundamental violation of his or her rights. Another indicated that many court decisions have established that an individual cannot be forced to receive psychiatric treatment against his or her will unless he or she presents a danger to him or herself or others.

Those who favored use of an advanced years category suggested a number of changes in it. Whether or not there should be a fixed age for the category was a particularly contentious issue. Some commenters wanted a fixed age so that evaluators would be consistent. A number of other commenters supported the position that no set age should be used while, as indicated above, some wanted no set age, but a lower limit. Still others asked that we clarify that anyone of any age can refuse specialized services.

Describing the preamble discussion in the proposed rule as unnecessarily inflammatory, one commenter objected to the prohibition against a blanket use of advanced years category. Others agreed with the preamble's concern that an advanced years category could be easily misused, but noted that individuals with MI or MR of any age vary in their ability to benefit from specialized services. One developmental disabilities advocate, who particularly appreciated the reference in the proposed rule to the special needs of persons with Downs Syndrome, strongly supported inclusion of a limited option to decline specialized services on an individualized basis without creating rigid age ranges.

Other disabilities advocates, however, while supporting the concept of an advanced years category, found the provision,

as drafted, confusing. They asked that we specify that the State must establish specific criteria governing circumstances under which persons of advanced years may be permitted to decline specialized services. However, they urged that in no case should a State be able to offer this categorical choice to groups who are less than 60 years of age. Also, they asked that the State continue to be required to individually determine specialized services needs before offering the choice of refusing treatment and to be required to provide or arrange for specialized services for all persons falling into this category who elected to receive such services, regardless of age.

Another DD advocate noted that this provision leaves the resident potentially susceptible to highly injurious manipulation. Since FFP is not available for specialized services in the NF and frail, elderly people are afraid of being discharged or transferred, the SMHMRA's could easily pressure the resident to sign away his or her rights to specialized services. This commenter advocated that we revise this provision to state that as a person ages, the components of a specialized services program must be tailored to the individual's changing needs. Moreover, we should state that the decision to forego specialized services must be left up to the individual resident; that the State must provide sufficient information to the resident that services can be adjusted for age-related concerns; and that the choice is the resident's to make. This advocate further urged that the State should have to prove that these conditions have been met whenever a resident is said to have refused specialized services on the basis of age. To prevent abuse of the concept that older people should be allowed to retire, this commenter also advocated that in no case should the State be allowed to set the age level below 60.

Response: We are persuaded by a review of the comments to delete the "advanced years" category because we recognize that the regulations otherwise permit a resident to refuse treatment and that this category is not needed. In deleting it, we are conscious of the concerns of advocates who fear that permitting any option to refuse treatment is susceptible to abuse; however, we believe that the overall right to refuse treatment, conferred in the resident's rights language in §483.10(b)(4), cannot be limited.

In the survey guidelines which accompany the February 2, 1989 rule we indicated that,

A resident's refusal of treatment must be persistent and consistently documented in the resident's record. Refusals of treatment should also be countered by discussions with the resident of the health and safety consequences of the refusal and the availability of any therapeutic alternatives that might exist

* * *

Individual probes which are to be used by surveyors involve asking residents: Have you ever refused a medication or treatment? What happened? How did the staff react? Has the facility offered alternative treatments to the ones you've refused? (Tag No. F157, p. 32, State Operations Manual, Transmittal No. 232, September, 1989). We note that the survey guidelines for the ICF/MR regulations contain similar provisions to assure that the right to refuse

treatment is not abused. These include instructions to surveyors to question whether the facility repeatedly offered alternative treatment to the treatment refused and whether the resident's record documents this fact. While we recognize that abuse is possible, we do not believe that we can require anyone to receive treatment, including specialized services.

Section 483.130(1)-State May Not Waive Specialized Services Determination if Making Physical NF Categorical Determination

Comment: A number of commenters objected to this provision because they believe it seriously undermines the utility of categorical determinations based on physical needs such as the convalescent care, terminal illness or severity of illness groups. They also indicated that, as noted above, this requirement senselessly hampers the application of the respite category and prevents creation of an emergency placement category, especially for individuals with MR (See discussion of §483.130(h)).

One association of mental retardation professionals noted that it is wasteful to require the specialized services determination when the physical need categorical determinations are time limited and the assumption is that, because the physical need is so debilitating, the individual cannot be expected to benefit from a specialized services program. This commenter noted that most States have been exempting persons in these categories from Level II assessments, including the specialized services assessment.

Another commenter, apparently wanting the specialized services determination waived so that acutely psychotic patients with skilled care needs (e.g. ventilator dependent, CHF, terminal illness) could be accommodated in NFs, indicated that such individuals are not likely to be taken in by psychiatric facilities because of their heavy physical care needs. This commenter asserted that if these individuals cannot be admitted to NFs, they would have to stay in regular hospitals where their specialized services needs are not met any better than in an NF and their care is much more expensive.

Response: It is clear to us that the Act does not permit us to waive either of the determinations required of the State under PASARR. We have provided for categorical determinations, discussed extensively elsewhere in this preamble and in the preamble to the proposed regulation, to assist States in dealing with clear and obvious situations. Thus, we could not make the changes recommended by the commenters. In addition, despite the many compelling examples presented by commenters, we were not persuaded that there are many, if any, situations in which it can always be assumed from a resident's diagnosis whether specialized services are or are not needed. Moreover, as discussed earlier in this preamble, the specialized services determination would likely vary depending on the reason for admission and the proposed length of stay.

Comment: One commenter suggested that §483.130(1) be rephrased. As drafted, it states that if the State mental health or mental retardation authority makes a categorical determination with regard to need for NF services (which could be either positive or negative according to §483.130(b)(1)), it may not waive the specialized services determination. The commenter asserted that if NF care is determined categorically not to be needed, this

provision, as it applies to applicants, conflicts with §483.118(a) concerning applicants who do not need NF care and §483.112(b) which requires the specialized services determination for applicants only in cases in which the need for NF care has been established. The commenter suggested that we revise §483.130(l) to state that if the State mental health or mental retardation authority determines categorically that NF services are needed, it cannot waive the specialized services determination.

Response: We agree with the point made by the commenter that the specialized services determination is not required for applicants to NFs if it has been determined that there is no need for NF care. (See §483.112 as opposed to §483.114). However, the technical revision proposed by the commenter would not be appropriate for cases involving residents of NFs for whom both questions must be asked, regardless of the response to the NF level of care question. A requirement can only be waived if it is indeed applicable to a given situation. For applicants to NFs who are determined not to need NF care, the requirement for a specialized services determination is not applicable.

Section 483.130(m)-Determination Must Be Entered in Individual's Record

Comment: A few commenters asked us to clarify what records must be included in an individual's record: the Level I determination, the Level II evaluation report, or the Level II determination notice?

Response: We believe that the record of the individual, if admitted to or residing in an NF, should contain as many of these documents as apply to him or her. As we indicated under the earlier discussions of the need for integrated care planning to result from the two assessment processes which are required for individuals with MI or MR, the NF must receive a copy of the evaluation and the determination. These documents are needed for care planning in the facility and also to demonstrate the status of these residents to surveyors. For individuals who are not admitted to an NF or are discharged as a result of PASARR, other treatment settings to which they go will likely wish to have these documents on file as part of their client records. Our primary concern here, however, is that the NF have copies of all PASARR records pertaining to the resident with MI or MR on file (see §483.128(l)).

Sections 483.130 (n); (o); and 483.204(a)(2)-Content Requirements for Written Level II Notices

Comment: One State objected to written notices because it believed that face-to-face explanations were in order.

Response: We refer readers to the discussion of the need to provide an interpretation and explanation of the evaluation report to the person being screened or his or her legal representative at §483.128(i). We believe that the State could meet these two requirements in either a one-step or two-step process and have accordingly provided States considerable latitude for working out what they believe to be the most sensible procedure for informing persons being screened both orally and in writing of the findings of the evaluation and of the determinations

that have been made concerning them. Because the Level II determinations carry with them appeal rights, the individual must be notified in writing and advised of how and to whom he or she may appeal (See the appeals discussion). Since the notice of determinations made by the State mental health or mental retardation authority must present placement options (see following discussion of §483.130(p)), the State will certainly need to engage in face-to-face encounters with individuals who fall into the long or short term group who need only specialized services if the State has an ADP in effect.

Comment: Some commenters asked who is responsible for the transfer and discharge notices that may be required in conjunction with these Level II notices in cases in which residents must be transferred or discharged.

Response: We believe that establishing procedures for giving notices is part of the State's responsibility under its PASARR program. That is, a State may establish procedures under which it gives notices or under which NFs give the notices on behalf of the State. In either case, the State is responsible for assuring that alternative arrangements for care are actually available before discharge from the NF. As noted at §483.128(e), we added a conforming amendment to §483.130(n) to ensure that the attending physician and the discharging hospital (in non-exempt cases) receive copies of the SMHMRA's determination.

Section 483.130(p)-Inclusion of Placement Options

Comment: One commenter noted that when some of these options that must be presented are community placement options which are covered under an ADP and have not yet been developed, it is difficult to list or describe them. This commenter urged that the regulation take this problem into account.

Response: We agree that it is difficult for a resident or his or her representative to choose among options when one of them has not been created at the time the choice is made. States that have ADPs under which non-institutional alternatives to NF care are being established may also receive FFP for NF services pending the establishment of the alternatives. We would anticipate that States would offer residents choices of actual alternatives available at the time the choice is made, so that an individual for whom continued residence in an NF is permissible would be able to exercise the choice to remain there or accept an alternative placement at the time the alternative has been created. We are not specifying in the regulation the time at which the choice must be made because we believe that is a decision that should be left to the State, based on its actual ability to offer choices consistent with these regulations and its ADP.

Comment: One commenter asserted that the regulation fails to deal with situations in which a person is dangerous. Such individuals, the commenter thought, should not be allowed to remain in the facility.

Response: The law and regulations permit the facility to discharge a resident immediately (see 42 CFR 483.12) if the safety of individuals in the facility is endangered. We believe that this authority overrides the statutory requirement that long-term residents be allowed the choice to remain in the facility. Thus, we agree with the commenter and believe that regulations

already are responsive to the comment.

Section 483.130(q) Specialized Services Needed in an NF

We proposed that if a determination is made to admit or allow to remain in an NF an individual who requires specialized services, the determination must be supported by assurances that the needed specialized services can and will be provided or arranged for by the State while the individual is in the NF.

Comment: One State recommended that States rely on their survey and certification procedures or state licensure process in order to determine that facilities generically are appropriate for arranging specialized services.

Response: The regulatory requirement does not specify how a State must meet this need and the expedient suggested by the commenter is one way it could do so. We would note, however, that we would expect that a State would support any assurance with a discussion of how the requirement will be met.

Section 483.130(r)-Record Retention and Section 483.130(s)-Tracking Systems

Comment: A few States asked for guidelines about record retention: what should be retained, by whom, and for how long? Two other States were of the opinion that the record keeping and tracking requirements are more extensive than they should be. These commenters thought the Level I decision records and supporting documentation should be filed at the NF and not be made part of the State's PASARR records. They also felt that the records on categorical determinations should be kept locally at the NF since these decisions are made there. Another commenter noted that the State's tracking system should include records on the provision of services that are identified as needed.

Response: Regulations for retention of records under State Medicaid programs may be found at 45 CFR part 74. States have considerable latitude in deciding on the physical location of the records they must retain and, of course, may retain them for longer periods than required under the regulations.

Section 483.132 Evaluating the Need for NF Services and NF Level of Care

In §483.132(a)(1), we proposed that the evaluator must assess whether an individual's needs can be met on an institutional basis and that the NF is the appropriate institutional setting.

Comment: The few comments which we received on the PASARR/NF portion of the evaluation were closely related to those we addressed under the discussion of appropriate placement at §483.126 and of the definitions of specialized services for MR and MI at §483.120. Commenters who objected in general to what they perceived to be an institutional bias in the regulations expressed the view that in §483.132(a)(1) we offered no justification nor provided any standards for making the determination called for in this section regarding whether an individual's needs can only be met on an institutional basis. These commenters were concerned that, in addressing (a)(1), States would foreclose further inquiry about appropriate community placements. Commenters

also felt that a similar institutional bias was revealed by raising the question of the viability of community care while making no corresponding reference to viability of institutional care. They are concerned that institutional placements will continue to be considered more viable. These commenters, therefore, want strong incentives built into the regulation to ensure that community placements will not only be considered, but created. They also agreed that the institutional versus community placement is appealable.

Response: Quite to the contrary of these commenters' views, we intended that §483.132 (a) and (b), taken together, should result in a consideration of community versus institutional placement for an individual and that the NF placement would be selected only after less restrictive settings had been rejected because the individual's care needs are so extensive that the individual requires institutional care. Then, if institutional care is the option of choice, the PASARR/NF evaluations should also explore further whether the NF setting is appropriate or whether another more intensive type of care such as would be provided by an ICF/MR (or waiver program), a psychiatric hospital, or an IMD is needed.

The essential question which must be answered by the PASARR/NF is whether the individual being evaluated needs a NF level of services. Section 1919(a)(1)(C) makes consideration of whether the individual's needs can only be met on an institutional basis an inherent part of the definition of what a NF is-

"An institution * * * which is primarily engaged in providing to residents skilled nursing care * * * rehabilitation services * * * or on a regular basis health-related care and services to individuals who because of their mental or physical condition require care and services (above the level of room and board) which can be made available to them only through institutional facilities * * *." (Emphasis added.)

In enacting OBRA '87, Congress moved this language verbatim into the new NF requirements from section 1905(c) of the law, where it had previously defined ICF services. Moreover, section 1905(f) defines nursing facility services, in part, as services which "* * * as a practical matter can only be provided in a nursing facility on an inpatient basis." (Emphasis added.)

Because of these statutory requirements, it is not possible to delete references to institutions or institutional care from this section of the regulation. We have, however, revised the section in an attempt to respond to commenters' concerns about an individual being "marked" as needing institutional care. These revisions require consideration of community settings first and at subsequent points in the consideration of alternative appropriate settings. For instance, placement in a home and community-based waiver is an option for individuals determined to need institutional care because, in order to be eligible for the waiver, individuals must, but for the waiver, need institutionalization (e.g., in a NF or an ICF/MR).

Section 483.134-Evaluating Whether an Individual with Mental Illness Requires Specialized Services

(b) Minimum Data Required

Comment: One professional association recommended that the minimum data measures for MI include evaluation of the individual's speech, language, and hearing. The commenter noted that studies indicate that 45-65% of adult psychiatric patients have speech and language disorders compared to 5-6% in the general adult population.

Response: We agree that a more detailed evaluation of an individual's speech, language, and hearing may well be appropriate in connection with assessment and care planning in an NF. We continue to believe, however, that the current requirements in (b)(1) relating to physical examination will generally result in data that are adequate to support the screening activity required in PASARR.

Comment: The only specific criticism we received on the data requirements for individualized screenings concerned the mandatory functional assessment of individuals with MI at §483.134(b)(5). As proposed, this assessment would examine the individual's ability to engage in the activities of daily living, the level of support that would be needed to assist the individual to perform these activities while living in the community, and whether this level of support can be provided in the community rather than in a NF. Factors to be considered are self-monitoring of health status, medication treatment and compliance, nutritional status, handling money, dressing appropriately and grooming. In line with the comments we discussed earlier concerning the purpose of PASARR evaluations, this commenter thought that the requirement was appropriate for care planning but not for supplying a simple yes or no answer with respect to admission. Noting that appropriate grooming would not likely be the threshold upon which a NF admission decision would be made, the commenter believed that the expected outcomes of such a functional assessment do not merit the cost, time and paperwork of such an effort.

Response: We believe that an assessment of how well an individual with MI functions is very important to making determinations concerning community versus institutional placement for an individual. We have therefore not altered or deleted this requirement.

Comment: Noting that the data collection requirements to determine if specialized services for MI are needed are very comprehensive, one commenter suggested that rather than having the independent evaluator rewrite a complete history and physical exam, information from the psychiatric hospital where the patient is completing treatment should be acceptable. The commenter noted that most patients requiring a Level II evaluation are being discharged from a inpatient psychiatric facility to a NF.

Response: As we indicated in redesignated §483.128(e), evaluators may use relevant evaluative data obtained prior to the initiation of PAS or ARR if the data are considered valid and accurate and reflect the current functional status of the individual.

Comment: One medical society requested that the rule explicitly state that physical examinations and drug histories performed by a physician are to be adequately reimbursed by the proper authority.

Response: As we indicated above, existing data may be used if it is still current, so a new physical examination or drug history may not be needed. We have also indicated that Federal Medicaid funding is available at the 75 percent rate for PASARR activities performed by the State and at the State's FMAP rate for PASARR activities performed by the NF. If a new physical examination and drug history are needed, the responsible State agency must arrange for (or provide) them, and reimbursement to physicians will depend on the arrangements made by the State. For example, if a State contracted with a physician, there would be a contractual payment rate.

Comment: Concerning the drug history, one commenter asked that we clarify that mere use of psychotropic drugs is not, by and of itself, an indication that MI is present or that specialized services are needed.

Response: We refer readers to our previous discussion of drug indicators.

Section 483.134-Personnel Requirements

We proposed that a board-eligible or board-certified psychiatrist must review and concur with conclusion of psychiatric evaluation if it is not performed by a physician. Based on the data compiled, a board-certified or board-eligible psychiatrist must validate the diagnosis of MI and determine whether a program of psychiatric specialized services is needed.

Comment: Virtually all States responded to the issue of credentials as it relates to the use of psychiatrists in reviewing PASARR/MI evaluations performed by non-physicians and in validating a diagnosis of MI and determining if specialized services are needed. We also heard from over 60 psychologists or psychological associations and some members of Congress on the role of psychologists.

Only a small minority of States and the other commenters favored the requirement as proposed. Psychiatrists were among this group. Because the data being collected is comprehensive—including a complete medical history, physical examination, neurological evaluation, psychosocial evaluation, drug history, functional assessment and a comprehensive psychiatric evaluation—psychiatrists believe that non-physicians do not have the necessary skills to conduct a comprehensive psychiatric evaluation much less interpret and evaluate such medical data to validate the diagnosis of MI and determine whether a program of psychiatric specialized services is needed. In their view, only physicians have the education, training and experience to make or confirm a medical diagnosis. Therefore, they believe that the confirmation of a psychiatric diagnosis and determination of specialized services should remain within medicine and specifically within the expertise of psychiatry. They also noted that there are over 29,000 board-eligible psychiatrists. This, they believe, forms a sufficient core of psychiatrists nationwide to provide the confirmation of diagnosis and specialized services determinations required under the proposed rule.

The vast majority of commenters requested that we allow any registered, accredited or certified (as the case may be in the State) mental health professional, as designated by the State, to perform the psychiatric evaluation, validate the diagnosis of MI, and determine whether a program of specialized services

is needed. The many psychologists and their associations also requested that they be allowed to supervise a program of specialized services without the oversight of a psychiatrist or physician. (This comment was dealt with under the discussion of the definition of specialized services for MI at §483.120(a)(2).)

Those who favored allowing non-physician mental health professionals, and particularly doctoral-level psychologists, to conduct the evaluations, validate a diagnosis of MI, and determine the need for specialized services presented a variety of reasons for allowing this change. Their arguments included:

- Manpower considerations (62 percent of counties nationwide have no psychiatrists);
- Documentation of the specialized training and qualifications of doctoral-level licensed psychologists to perform these evaluations;
- Recognition by a number of other Federal programs of licensed psychologists' competence to practice independently; and
- Practical considerations such as budgetary constraints and the desirability of avoiding paper reviews.

Commenters advocating an independent role for psychologists under PASARR indicated that a large number of Federal programs afford psychologists the status of independent mental health professionals. For example, psychologists' mental evaluations and expert testimony are accepted to the same degree as psychiatrists' in determining eligibility for disability benefits based on mental impairment under SSI and SSDI. Similarly, the Vocational Rehabilitation Act permits assessments to be made by a licensed psychologist in accordance with State laws and regulations. Psychologists are recognized in both the Federal Rules of Criminal and Civil Procedure to perform mental examinations and provide expert testimony on issues such as competency to stand trial and in civil commitment proceedings and to perform court-ordered mental examinations.

Also, under CHAMPUS, Veterans Administration programs, and the Federal Employees Health Benefits Program (FEHBP), psychologists may independently diagnose and treat patients, both in hospital and outpatient settings. The Federal Employees Compensation Act includes clinical psychologists within its definition of "medical, surgical, and hospital services." In OBRA '89 Congress recently granted elderly Medicare beneficiaries direct access to qualified psychologists' services "as would otherwise be covered if furnished by a physician," limited, of course, by State licensure laws. Psychologists are thus eligible to treat Medicare beneficiaries in all settings (including inpatient psychiatric hospitals where the psychologist may supervise the active treatment plan of care) for all Medicare covered services that they are eligible to perform under State licensure laws, as long as they notify the beneficiary's attending physician about the fact of treatment. These services include diagnosis and treatment of the full range of mental disorders, including serious mental illnesses.

For all the above-stated reasons, the vast majority of commenters proposed that we permit Level II screens to be performed by qualified mental health professionals recognized by State law. To ensure interdisciplinary coordination, many commenters also suggested that we consider requiring that the results of the screen, whether performed by a psychologist, psychiatrist, or other mental health professional, be sent to the resident's

primary care physician.

Response: We are persuaded by commenters who presented convincing arguments that other mental health professionals, and particularly doctoral level psychologists, are capable of performing PASARR/MI evaluations, validating diagnoses of MI, and determining whether specialized services are needed. Also, due to the expansion of the scope of practice accorded licensed psychologists in other Federal programs, we believe that we should allow States the flexibility of specifying which mental health professionals it wishes to allow to perform the PASARR/MI and under what conditions. Some States may wish to continue requiring the oversight of a psychiatrist while others may choose to allow licensed psychologists or other mental health professionals to perform the evaluations independently.

To clarify all the credential requirements for PASARR/MI evaluators we have grouped all requirements in a new §483.134(c) and redesignated proposed paragraph (c), data interpretation, as paragraph (d). We are retaining the requirement that if the medical history and physical examination is not performed by a physician, a physician must review and concur with the conclusions, formerly located at §483.134(b)(1), now in new paragraph (c)(1). In paragraph (c)(2), we are providing that the State may designate the mental health professionals that are qualified to perform the evaluations required under the data elements in paragraph (b)(2)-(6), which include the comprehensive drug history, the psychosocial evaluation, the comprehensive psychiatric evaluation and the functional assessment. We are deleting the credential requirements formerly proposed at paragraph (b) (3) and (4) that required the review and concurrence of a social worker on the conclusions of the psychosocial evaluation and of a board-certified or board-eligible psychiatrist on the conclusions of the comprehensive psychiatric evaluation.

We also agree with the suggestion that the regulations should specify that the results of the screen, whether performed by a psychologist, psychiatrist, or other mental health professional, be sent to the resident's primary care physician. Accordingly, we have added a new requirement at §483.128(1) requiring that a copy of the evaluation report be sent to the individual's attending physician. This means that copies of the evaluation report must be sent to:

- The individual being screened or his or her legal representative so that he or she will know what is happening to him or her and will have this information in hand should he or she wish to appeal the subsequent determination by the State mental health or mental retardation authority;

- The State mental health or mental retardation authority or its subcontractor so that it can make the determination required at §483.134(d) in a timely fashion as required at §483.112(c) or 483.114(c);

- The NF so that it can incorporate recommendations from the evaluation into its care planning process and coordinate the individual's care with the State if specialized services are determined to be needed;

- The individual's attending physician so that the physician will be apprised of the mental health professional's (s') assessment of the patient's needs.

- The discharging hospital, if admission is being sought

from this setting so that it will be advised of whether NF admission is likely or whether it must make other discharge arrangements.

Comment: We also received a few comments from social workers and nurses who believed that they should be accorded a larger role. Social workers asserted that licensed clinical social workers with two years of post-graduate experience should be allowed to do the comprehensive psychiatric evaluation required at proposed §483.134(b)(4) without the review of a psychiatrist. Nursing organizations also felt that nurses with clinical specialization in psychiatric/mental health practice should be allowed to perform the psychosocial evaluation at §483.134(b)(3), the comprehensive psychiatric evaluation at paragraph (b)(4), and the functional assessment at (b)(5).

Response: As indicated above, States may include qualified mental health professionals to perform all or parts of the evaluations.

Comment: We also received a small number of comments on the requirement at §483.134(b)(3) that, if the psychosocial evaluation is not conducted by a licensed social worker, than a licensed social worker must review and concur with the conclusions. Psychologists felt that this requirement is clinically unnecessary, redundant, and unnecessarily costly. They contended that psychologists are specifically trained and qualified to perform the psychosocial evaluation as well as the other components of the PASARR/MI. We also heard from psychiatric nurses who believed that they are as competent as social workers to perform the psychosocial evaluation and should not have to be supervised by them.

Some States noted that they do not license social workers, but rather have a registration or certification process. They recommended that the language be changed to cover different types of credentials. Other commenters representing social workers noted that a licensed or certified social worker cannot ethically review and support conclusions of a psychosocial evaluation which is conducted by someone else, unless the social worker is familiar with that person's work. If the person completing the evaluation does not have the appropriate training, he or she must receive necessary supervision.

Response: Because we agree with commenters that, in general, the State should be allowed to designate which mental health professionals it wishes to employ for each of the components of the PASARR/MI, we are removing the requirement that the psychosocial evaluation must be either performed or reviewed by a social worker. We will defer to the State's judgment as to who is competent to perform these evaluations.

Section 483.136-Evaluating Whether an Individual With Mental Retardation Requires Specialized Services

We proposed that a licensed psychologist who meets the requirements of a qualified mental retardation professional, as defined in §483.430(a), identifies the individual's intellectual functioning measurement and validates that the individual has MR or is a person with a related condition.

Comment: Several States asked that we delete the word "licensed" from "licensed psychologist" in §483.136(c)(1) because in a number of States a licensed psychologist means a psychologist who holds a Ph.D. degree. They claimed that doctoral level psychologists are unlikely to also fit the qualifications of a qualified mental

retardation professional since a qualified mental retardation professional must have at least one year's experience working directly with individuals with MR or other developmental disabilities. Hence, they asserted that the word "licensed" unnecessarily restricts the number of available screeners by excluding most qualified mental retardation professional psychologists who are available in the State to do the data interpretation and validation of the diagnosis of MR.

Response: We have verified with the psychologists' professional association that in all but a very few States, a doctoral-level degree is a prerequisite for licensure. Three States allow persons with Master's degrees in psychology to be licensed as psychologists. In all States, a person cannot call him or herself a psychologist without being licensed by the State. Additionally, some States have a limited license for individuals with a Master's degree with titles such as psychometrist or psychological assistant. In most States these individuals with limited licenses could administer examinations to determine the level of intellectual functioning but probably could not legally interpret the results or validate a diagnosis of MR. In almost all States, only a doctoral-level licensed psychologist may make these determinations.

We believe that the coupling of the licensed psychologist requirement with the QMRP requirement rather than the "licensed" qualification alone appears to restrict the supply of available manpower. In view of the expert information cited above, we believe that rather than eliminating the word "licensed," we should remove the requirement that the person making the intellectual functioning determination on persons with MR or a related condition also meet the qualifications of a QMRP. While a year or more's experience working specifically with persons with MR/DD or related conditions would certainly be desirable, we are not requiring it.

We are moving the requirement concerning validation of a diagnosis of MR or a related condition from (c)(1) to (c)(2) in order to restrict the exclusive role of licensed psychologists to measurement of intellectual functioning. Licensed psychologists may certainly be used in validating a diagnosis of MR or developmental disability, but they are usually not the only professionals who are permitted under State law to establish these diagnoses. For instance, a physician may also make these determinations. A licensed psychologist may be permitted to, and in fact regularly do, make diagnoses of developmental disabilities, but a more precise diagnosis of a specific related condition such as cerebral palsy or epilepsy, under most State licensure laws, could only be made by a physician. However, a physician, and even a psychiatrist, is usually not competent or authorized under State law to administer, score, and interpret an IQ test. This function, alone, is in the exclusive domain of licensed psychologists, as indicated in (c)(1). As with the credentialing issues for individuals with MI, we are allowing States in (c)(2) to specify which personnel should be used to validate a diagnosis of MR or a related condition and determine whether specialized services are needed.

Comment: As noted under the delegation issue, one commenter believed that if the State mental retardation authority delegates MR evaluations to a subcontractor, the regulation should contain safeguards to ensure that properly trained screeners are used. The commenter also noted that for MR evaluations, the proposed

rule only included one credential requirement, that a psychologist who is a Qualified Mental Retardation Professional identifies the level of intellectual functioning and validates the diagnosis of MR.

Response: During the early stages of development of these criteria in the Spring and Summer of 1988 we consulted extensively with a wide variety of outside groups. At that time, the existing credential requirement was the only one proposed for MR evaluators. During further consultations with all interested groups over the next two years, no one has ever proposed any change in these MR requirements, with the exception of the previous comment which asked for less stringent rather than more stringent standards. While the MI credential issue elicited a large response, this commenter was the only one to suggest that more credential requirements should be imposed for MR evaluations. We assume that this lack of response by other commenters continues to indicate general satisfaction with the requirements (or lack of them) as proposed.

Comment: Several commenters found the data interpretation requirement at §483.136(c)(2) confusing. They asserted that requiring comparison of data against a list of characteristics is imprecise. They asked how the presence of any or some of these characteristics is to be treated. Are they to serve as a guideline or a prescription? Moreover, what if not all indicators are present? At what point are specialized services needed?

Response: We agree with these commenters that the language of this section is imprecise. We are revising it accordingly. In the course of revising this section, we also noted that the PASARR/NF regulations text at proposed §483.132 did not contain a determination requirement similar to §§483.134(d) and 483.136(c)(2). We are, therefore, amending section 483.132 by adding a new paragraph (c), which states that, based on the data compiled in §483.132 and, as appropriate, in §§483.134 and 483.136, the State mental health or mental retardation authority must determine whether a NF level of services is needed. Thus, the requirements for all three evaluation processes (PASARR/NF, PASARR/MI, and PASARR/MR) end with parallel statements concerning the determination process that is to be based on the data compiled. The statement in §483.132(c) also further stresses the interrelatedness of all parts of the evaluation process in making determinations concerning appropriate placement. (See earlier discussion of §483.126.)

Use of Medicaid Fair Hearing Process

Comment: Commenters were almost unanimous in their support for the use of the Medicaid fair hearings process set forth at 42 CFR part 431, subpart E, for appeals of discharges, transfers and PASARR determinations. While a few commenters suggested that an entirely separate process be established, the majority, including commenters from both the States and advocacy groups, concurred that the statutory provisions at sections 1819(e)(3), 1819(f)(3), 1919(e)(3) and 1919(f)(3) of the Act and the legislative history of section 1919(e)(7)(F) contemplate the use of the Medicaid fair hearing process. Although the majority of commenters enthusiastically supported the use of the Medicaid fair hearing process, some did note that modifications should be made in the hearing process to accommodate what they believe are the

special needs of nursing facility residents and the mentally ill and mentally retarded.

Response: We believe that the requirements set forth in the Medicaid fair hearing regulations meet both the statutory requirements for the appeals process required by the Medicaid and Medicare statutes, as well as the requirements of due process. While the Medicare and Medicaid statutes require the Secretary to establish minimum standards that States must meet, sections 1819(e)(3), 1919(e)(3) and 1919(e)(7)(F) of the Act require the State to provide the required appeals process. We believe it is the State that must determine how best to implement the fair hearing process so long as it meets the requirements for fair hearings at 42 CFR part 431, subpart E. Thus, to the extent that there are concerns as to whether additional provisions should be included to meet the needs of special patient populations they should be addressed to the States.

Comment: Many of the commenters sought to have requirements added that are already provided in the fair hearing regulations. For example, many requested that the notice provisions be modified to include elements that are already required such as a statement of the action to be taken, the reasons for the action, the basis in law or regulation for the action, the right to request a hearing, how to obtain a hearing, the right to representation, and the circumstances under which Medicaid is available pending the appeal (42 CFR 431.206, 431.210).

Response: In response to concerns that individuals will not be adequately informed, §483.128 requires that PASARR determinations be issued in the form of a written evaluation report that must be interpreted and explained to the individual.

With regard to the conduct of the hearing itself, the fair hearing regulations already require the elements listed above as well as other elements sought by the commenters such as an independent evidentiary hearing, conducted at a reasonable time, date and place, access to the record and opportunity to present witnesses and conduct cross-examination (42 CFR 431.205, 431.233, 431.240, 431.242, and 431.244).

Comment: Advocacy groups sought to have the notice include a statement concerning the ombudsman and protection and advocacy agencies and how an individual can contact those agencies.

Response: The statutory requirement for such notice by nursing facilities in the case of transfers and discharges is already provided in 42 CFR 483.12(a)(5)(iii). The statute does not require that such notices be provided in the case of PASARR determinations. While the State may wish to provide patients with information concerning the services of such agencies, the statute does not require them to do so.

Comment: Commenters also requested that individuals have access to an independent medical assessment paid for by the State agency.

Response: This is already provided for in §431.240(b). Such an evaluation is performed at the discretion of the hearing officer. We do not believe it is appropriate, as one commenter asked, to require that every appeal contain such an evaluation if requested by the individual who has brought the appeal. However, the States are certainly free to provide such evaluations if they wish to do so.

Comment: An organization representing hospitals throughout

the country requested that appeals be expedited for individuals currently in hospitals and awaiting nursing facility placement.

Response: While we encourage States to provide for expedited appeals for such individuals, we believe that the individual States must determine how best to implement this element of the appeals process based on their experience and that of providers in their area.

Comment: Comments were received concerning a variety of other issues such as methods for compelling medical experts to testify and the payment of attorneys' fees when a resident prevails in a PASARR appeal.

Response: We believe that these are issues which are properly left to the State to determine as they establish the details of the appeals processes.

Elimination of Level I Appeals

Comment: A majority of commenters, particularly State representatives, were adamantly opposed to the proposal to permit a separate appeal from the Level I identification of those individuals who are mentally ill or mentally retarded. They objected on the basis that such appeals are not required by statute, would pose difficult notice problems, result in unnecessary delays in the screening process, and impose enormous financial and administrative burdens on the State agencies responsible for PASARR and the appeals from PASARR determinations.

Response: We have reexamined the PASARR statute and legislative history and have determined that because such appeals are not required by the Medicaid statute and because consideration of such determinations can be provided as part of the Level II appeals, we are deleting this requirement.

Section 1919(e)(7)(F) of the Act requires that each State "must have in effect an appeals process for individuals adversely affected by determinations under subparagraph (A) or (B)." The phrase "determinations under subparagraph (A) or (B)" refers to section 1919(e)(7)(A) and (B) of the Act. Section 1919(e)(7)(A) requires States to have in effect a preadmission screening program for making determinations under section 1919(b)(3)(F). The specific determinations made under section 1919(b)(3)(F) are whether "the individual requires the level of services provided by a nursing facility," and if so, "whether the individual requires * * * [specialized services] for mental illness" or for "mental retardation."

Similarly, section 1919(e)(7)(B) requires that the State specifically "determine * * * whether or not the resident * * * requires the level of services provided by a nursing facility" and "whether or not the resident requires * * * [specialized services] for mental illness." Thus, the determinations referred to in the appeals requirements of section 1919(e)(7)(F) are those limited to whether the individual needs nursing facility services and whether he needs specialized services. This interpretation is reaffirmed in the legislative history of the appeals provision which describes the adverse actions subject to appeal: "[i]ndividuals 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 * * * [specialized services]." H.R. Rep. No. 100-391, 100th Cong., 1st Sess. 462-

463 (1987).

The Level I identification of the mentally ill and mentally retarded clearly is not included in the statement of adverse determinations subject to appeal. Because such a separate appeal is not required or even contemplated by the statute, we believe there is no basis for imposing this additional requirement.

Furthermore, as several commenters indicated, the only actions that could result in adverse determinations under the statute are those taken as a result of the Level II screening. The only possible consequence of a positive Level I determination is that the individual would be referred to the State for the additional Level II determination. A Level I screening alone could never result in the individual being wrongly discharged, transferred or refused admission to the nursing facility.

As we discuss below, the deletion of provisions for a separate Level I appeal does not mean, however, that an individual would be precluded from challenging a Level I determination that they are mentally ill or mentally retarded and thus subject to the PASARR requirements. What it means, simply, is that such a challenge could be raised only in the appeal of the final PASARR (Level II) determination.

Comment: Several commenters suggested that if a Level II review results in an adverse determination then an appeal from the Level II determination by the affected individual could include consideration of any allegations that the individual was not mentally ill or mentally retarded or that the individual had a diagnosis of dementia. Moreover, they contend, because the Level II determination requires a comprehensive psychiatric evaluation to determine whether an individual needs specialized services, the appeal of the Level II determination is a logical and efficient method for challenging the Level I identification of MI or MR.

Response: We agree and are clarifying that a Level II appeal may also include consideration of whether the Level I determination was correct. Because we are eliminating the requirement for a separate Level I appeal, we do not address the specific comments made with regard to how the Level I appeals should be implemented.

Comment: Commenters also noted that permitting a separate appeal of Level I determinations will result in delay in nursing facility placement. If an individual requests a hearing, he or she may have to wait up to 90 days for a decision under the Medicaid fair hearing regulations. However, under the 7-day time frame required for preadmission screening, the entire Level II determination process could easily take less time than the Level I appeal. Requiring States to hold Level I hearings would also impose significant administrative burdens on the State Medicaid agencies as they would be required to provide two separate hearings—one for Level I and then another for Level II, when all issues could easily and efficiently be heard at the Level II appeal.

Several beneficiary advocacy groups supported the provisions for notice and appeals of negative Level I determinations, although the majority of commenters opposed them. A negative Level I determination is described as a finding that the individual is not mentally ill or mentally retarded or is suffering from dementia and is thus not subject to Level II screening. While allegations concerning incorrect positive Level I determinations

could be heard during a Level II appeal, negative Level I determinations will not be considered because there would be no Level II determination.

While permitting appeal of a negative Level I determination would provide no additional benefit to the individual, numerous commenters detailed the substantial burden placed on the State and nursing facilities if they are required to notify hundreds of thousands of individuals, in effect the entire nursing facility population, that they are not mentally ill or mentally retarded. As several commenters indicated, such a requirement is contrary to common sense and good practice as notification is not required to be given to individuals who will not be subject to the actions for which notification is given.

Response: We agree that there should be no separate appeals of negative Level I determinations. First, as indicated above, the only adverse determinations contemplated by the statute and legislative history are those related to the Level II determinations, determinations which would never even be made if a person is not first identified as subject to PASARR. Secondly, as several commenters noted, a negative determination would not deny the individual anything since, if the individual is not required to submit to PASARR, he will be admitted immediately, or if he is already in a nursing facility, he will be allowed to stay. To the extent an individual might conceivably have some additional rights to continued placement if he or she had been found mentally ill or mentally ill, these are issues that can be raised in the individual's appeal of any adverse determinations such as a decision that the individual must be transferred or discharged. Thus, to the extent there is even a remote possibility of an impact on an individual as a result of a negative Level I screen, the remedies available would fully meet the requirements of due process.

Application of the Appeals Process to Non-Medicaid Patients

Comment: Several commenters objected to and others sought clarification of the requirement that the appeals process be applied to non-Medicaid patients as well as Medicaid recipients.

Response: As indicated above, the statute and legislative history clearly indicate that the provisions governing transfers and discharges, as well as PASARR, apply to both groups. This is true as well of the appeals provisions which make no distinction between the Medicaid and the non-Medicaid patient as they apply to "any resident" and "any individual" and are not restricted to Medicaid applicants and recipients. These final regulations likewise reflect the fact that both groups are included (§§431.206 (c)(3) and (c)(4); and 431.220 (a)(3) and (a)(4)).

Furthermore, we are also revising the Medicare regulations to specifically exempt these determinations from the appeals provided for under the hospital insurance program (§405.705 (e) and (f)). Thus, as many of the commenters requested, all individuals seeking such appeals will have the same rights, regardless of source of payment. However, contrary to the request of several commenters, payment through the period of appeal is specifically provided for only for Medicaid recipients. In the absence of additional statutory authority, payment is available only as otherwise provided by the Medicare statute for Medicare patients and through the privately paying patient's own insurance

arrangements.

Definition of Transfers and Discharges

Comment: Several advocacy groups objected to the fact that the definition of transfers and discharges subject to the appeals provisions does not include relocation within a facility (which is defined at §483.5 as a certified entity, not as a physical plant). Movement from a certified bed to a noncertified bed or movement from a certified bed to a bed in an entity that is certified as a different provider is a transfer even though the different entities may be housed within the same physical plant. Movement from one certified bed to another bed within the same certified entity is not a transfer and is not appealable. Commenters objected that these movements caused just as much trauma for residents as transfers, as they are defined. Additionally, these advocates claimed that residents are confused when some movements within the same physical plant are appealable and others are not.

Response: As many commenters noted, and we agree, sections 1819(c)(2)(A) and 1919(c)(2)(A) of the Act and the pertinent legislative history both refer to transfer and discharge * * * from the facility. The "facility," under the law, always means the certified entity. Thus, we believe there is no authority for extending the appeal rights to movements within the same certified entity.

Definition of Adverse Determination

Comment: Several States suggested that we clarify the term adverse determination.

Response: In response to comments, in order to further clarify the type of determination that can be appealed, we are adding a definition of the term "adverse determination" in §431.201 as follows:

"Adverse determination" means a determination made in accordance with sections 1919(b)(3)(F) or 1919(e)(7)(B) of the Act that the individual does not require the level of services provided by a nursing facility or that the individual does or does not require specialized services.

Conduct of Hearing By Medicaid State Agency

Comment: Several commenters noted that it is not clear whether the State Medicaid agency itself is required to conduct the hearing. One State indicated that regulations at §483.12(a)(5) suggest that the States have discretion regarding which State agency they wish to designate to hear appeals. A protection and advocacy group asserted that the Medicaid State agency, rather than the State mental health or mental retardation authorities, should hold the hearings in order to guard against potential abuses by these other agencies.

Response: The hearing is to be conducted by the State Medicaid agency as described in the fair hearing regulations in §431.205. These regulations permit the conduct of a local evidentiary hearing by an agency other than the State Medicaid so long as

there is a right to appeal the decision to the State Medicaid agency. Included is the right to a de novo hearing by the State Medicaid agency and a prohibition against participation by any person who participated in the local decision. Thus, although the State may designate another agency to provide the local hearing, such as the State mental health or mental retardation authorities, appeal of an adverse decision must be provided to and an independent judgment made by the State Medicaid agency.

We are also amending §483.12(a)(5) in a separate regulation to delete the reference to the "agency designated by the State" for such appeals. Instead, we are specifying that the transfer or discharge notice must explain that the individual may appeal the determination to the State.

FFP for Appeals

Comment: Several States and the association of State Medicaid directors requested confirmation that FFP at the rate of 75 percent is available for the conduct of the appeals described in these regulations.

Response: FFP for the administrative costs of providing these appeals processes is available at the 75 percent rate, including the costs of appeals provided for individuals who are not Medicaid recipients, and we are revising §§431.250(g) and 433.15 to clarify this.

Outside Scope of Regulations

Comment: One protection and advocacy group objected to the appeals process because it did not provide for the right to appeal additional State actions taken in response to the PASARR determination such as any alleged failures to inform residents of alternative institutional or non-institutional settings and failure to provide specialized services to residents following transfers or discharges.

Response: While we appreciate receiving these statements of concern, they are outside the scope of the appeals required by the statutory provisions implemented by these regulations and are therefore not addressed here.

Clarification of Advance Notice Requirement

Comment: One association of providers requested clarification with regard to §431.213(h), which establishes an exception from advance notice requirements for cases in which the date of action will occur in less than 10 days. The organization believed the provision did not address cases in which the date of action will occur in more than 10 days, but less than 30 days specified in §483.12.

Response: In such cases the 10-day notice requirement of §431.211 would apply because it would then be possible to give such notice and no exemption would be necessary.

Appeals Concerning Alternative Disposition Plans

Comment: Commenters requested clarification of appeals by individuals subject to alternative disposition plans. In particular,

they asked whether an individual has a right to appeal an adverse determination made in the course of an annual resident review as well as a decision made later to transfer or discharge him or her.

Response: We believe that the individual can appeal both decisions. First, they are separate decisions that may, in fact, be made at very different times and be based on different factors. Secondly, the reversal of an adverse determination made during the annual resident review would mean that the individual would not need to be transferred or discharged and thus the alternative disposition plan would be unnecessary for him or her.

Alternative Disposition Plan (ADP) Issues

Comment: Several States wanted the regulation to allow revision of alternative disposition plans (ADPs).

Response: Originally OBRA '87 did not provide for any additions to or revisions of a State's ADP after it was agreed to with the Secretary. In OBRA '90, Congress permitted States with approved alternative disposition plans (ADPs) to revise those plans, subject to the approval of the Secretary, by October 1, 1991. Under any such amendments, dispositions of inappropriately placed residents must be made no later than April 1, 1994. We are preparing a separate program instruction informing States with approved ADPs of the procedures to be followed in submitting revisions to their ADPs should they wish to make alterations.

Comment: Some States requested clarification as to who is in the ADP population, specifically whether it includes people outside of the NF who need specialized services but have already been discharged.

Response: According to our analysis of sections 1919 (e)(7)(C) and (e)(7)(E) of the Act, an ADP could potentially cover any resident found through the initial ARR process not to need NF care but to need specialized services. This includes both long-term residents who have the choice of remaining in the NF or leaving and short-term residents who must be discharged to appropriate alternative settings. Within the scope of potential coverage, who is actually covered by a particular State's ADP depends on who the ADP identified as its target population.

Comment: States also asked about the effect of an ADP on the appeals process and the required notices.

Response: Questions concerning the impact of an ADP on the appeals process are dealt with under appeals.

Comment: Another set of commenters, largely advocates for individuals with MI or MR, expressed concern over our discussion of ADPs in the preamble to the NPRM. Some suggested that we had opened up what they called "an ADP loophole" in the law. They objected to any delay in providing specialized services (formerly called active treatment) to residents who are awaiting relocation under an ADP. Believing our interpretation of the law to be overly broad, they asked that the scope and meaning of the ADP language in the law be specifically addressed in the regulation. In their view, Congress never intended that section 1919(e)(7)(E) of the Act permit delays of up to 4 or 5 years, in some instances, in the provision of specialized services to residents whose conditions require this level of service.

Response: Section 1919(e)(7)(C)(i)(IV) of the Act indicates that the State has an affirmative obligation, regardless of the long term resident's choice of placement, to provide or arrange for the provision of specialized services. Similarly, section 1919(e)(7)(C)(ii)(III) of the Act requires the State to provide or arrange for the provision of specialized services to short term residents who are discharged from the NF. An ADP allows States to provide for "the disposition" of these residents after April 1, 1990, the deadline specified in section 1919(e)(7)(C) for the completion of the initial review of all residents who entered the NF prior to the commencement of PAS on January 1, 1989.

Apparently, some commenters believe that "disposition" refers only to the physical relocation of residents and not to the provision of specialized services to them. Hence, they dispute our interpretation of the Act that through an ADP States may obtain a time extension not only for developing alternative appropriate placements but also for developing the delivery systems they need to provide specialized services to ADP-covered residents who need them wherever they are located, including in a NF. As noted above, we view this group as including both long-term residents (whether they choose to remain in the NF or go elsewhere) and short-term residents (either awaiting transfer or already transferred).

The primary basis for our interpretation of the statutory language is found in the House Budget Committee's Report on H.R. 3545 (H.R. Rep. No. 391, Part 1, 100th Cong., 1st Sess. 462 (1987)), which states:

The Committee is willing to tolerate continued inappropriate placement of mentally ill or mentally retarded individuals only in the case of long-term facility residents who elect to remain. At the same time the Committee is unwilling to see residents who are inappropriately placed in nursing facilities, but who require [specialized services], go without needed services. In the Committee's view, the responsibility for providing, or paying for the provision of, [specialized services] lies with the States. The Committee notes that these affirmative [specialized services] obligations do not take full effect against the States until April 1, 1990, over 2 1/2 years from the Committee's action; this should give States ample opportunity to prepare. In addition, the Committee amendment would expressly waive the [specialized services] requirement with respect to the residents of any facility if, before October 1, 1988, the State has entered into an agreement with the Secretary relating to the disposition of the residents in that facility and if the State is in full compliance with such agreement. [Note: The October 1, 1988 date was changed to April 1, 1989 by the Medicare Catastrophic Coverage Act of 1988 (MCCA)]. The agreement could provide for the discharge of inappropriately placed residents after April 1, 1990.

Primarily on the basis of this committee language, we instructed States through a Program Memorandum, Transmittal No. 8-88, dated September 1988, as follows:

Section 1919(e)(7)(C) of the Act, as amended by OBRA '87, specifies certain remedial steps to be taken by April 1, 1990

regarding mentally ill and mentally retarded residents of nursing facilities who have been determined not to require that level of care. If you cannot comply with the requirements of subparagraph (C) by the April 1, 1990 date, an extension can be granted if you enter into an acceptable agreement with the Secretary before April 1, 1989, relating to the disposition of mentally ill and mentally retarded residents in nursing facilities, and the State is in compliance with the agreement. This extension would only apply to meeting the requirements of subparagraph (C). An extension of the date of April 1, 1990 for complying with subparagraph (B) cannot be granted.

Among the remedial steps identified in subparagraph (C) is the requirement to provide specialized services. Therefore, at various points in the program memorandum we alluded to the provision of specialized services (formerly called active treatment). Some States incorporated into their ADPs plans, funding arrangements and time tables for initiating the provision of specialized services in various settings while other States addressed relocations only. Those States that specifically asked for time extensions to develop their specialized services delivery systems received Secretarial approval and have such extensions so long as they continue to comply with the terms of their ADPs.

Summary of Effective Dates

These regulations are effective on January 29, 1993. However, until the effective date of these regulations, only the statutory requirements governing PASARR, which appear in sections 1919(b)(3)(F) and 1919(e)(7), are effective. The statute established specific effective dates for these requirements and made them effective regardless of whether Federal PASARR criteria were available. These effective dates have already passed. The statutory requirements are, therefore, already in effect, regardless of the effective date of these regulations. These sections include-

1919(b)(3)(F), which requires that a NF not admit any new resident with MI or MR unless that person has been approved through PAS to need NF care, effective January 1, 1989.

1919(e)(7)(A), which requires the State to have a PAS process in operation, effective January 1, 1989.

1919(e)(7)(B), which requires the State to have initially reviewed all residents with MI or MR who entered NFs before the effective date of PAS by April 1, 1990 and by that same date also to have in operation in on-going ARR process for all residents with MI or MR, regardless of whether they were initially screened under PAS or ARR.

1919(e)(7)(C), which requires appropriate placement and/or initiation of appropriate treatment for residents determined not to need NF care to be accomplished by April 1, 1990 unless the State had an alternative disposition plan, pursuant to 1919(e)(7)(E) approved by the Secretary by April 1, 1989. In such cases the deadline for completing disposition of residents who need only specialized services is governed by the terms of the ADP.

1919(e)(7)(F), which requires the State to have an appeals process in effect for persons adversely affected by PAS or ARR by January 1, 1989.

Similarly, the statutory requirements governing appeals of transfers and discharges from skilled nursing facilities (SNFs) under Medicare and from NFs under Medicaid that appear in sections 1819(e)(3) and 1919(e)(3) have been in effect since October 1, 1989. These sections required States to provide a fair mechanism for hearing appeals on transfers and discharges from both types of facilities by that date regardless of whether Federal guidelines were available. These regulations, effective April 1, 1991, contain the Federal guidelines on appeals of transfer and discharges from SNFs and NFs as well as for PASARR appeals.

We note that many of the statutory changes in the PASARR provisions effected by OBRA '90 are effective as if they were part of the original OBRA '87 legislation. Others are effective as of the date of enactment of OBRA '90 (November 6, 1990). These changes are discussed in the background section at the beginning of this preamble.

Waiver of Proposed Rulemaking

We ordinarily publish notices of proposed rulemaking in the Federal Register, and offer the public an opportunity to comment on proposed rules. Such notices include a statement of the nature of the rulemaking proceeding, reference to the legal authority under which the rule is proposed, and the terms or substance of the proposed rule or a description of the subjects and issues involved. However, this requirement can be waived when we find good cause that such a notice and comment procedure is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and its reasons in the rule issued.

With regard to the provisions of OBRA '90 that are self-executing, identified earlier in the preamble, we believe that issuance of these legislative changes for notice and comment would be unnecessary and contrary to the public interest since they are being incorporated into these regulations as they appear in the statute and are given an effective date as specified in OBRA '90, unless the provisions are otherwise authorized under current law. Therefore, we find good cause to waive the proposed rulemaking procedure with respect to these provisions.

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.

Regulatory Impact Statement

A. Introduction

Executive Order (E.O.) 12291 requires us to prepare and publish a final regulatory impact analysis for any proposed regulation that meets one of the E.O. 12291 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 Medicaid certified nursing facilities 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 if a final rule will have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that has fewer than 50 beds and is located outside a Metropolitan Statistical Area.

The provisions of this rule merely 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 and sections 4008 and 4801 of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), Public Law 101-508.

The provisions of this rule set forth State requirements for preadmission 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. These provisions also set forth an appeal 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.

Approximately 40 percent (out of 736) of the comments we received requested that we provide an impact analysis in the final rule. Although we expect incremental costs as a result of this rule, we believe the majority of the costs alluded to by the commenters are the result of a misunderstanding of the regulations or a result of the statute. Most of the costs mentioned by comments are addressed in the comment and response section of this final rule.

As set forth by the statute, the effective dates of these provisions have already passed and States have taken actions to effect these requirements based on instructions issued. The costs associated with adhering to these provisions is minimized by the availability of 75 percent FFP. Although nursing facilities may incur some additional significant costs to ensure continued compliance with these provisions, we believe the benefits to individuals far outweigh those costs. Heretofore, individuals may have been admitted to nursing facilities where mental health needs have been generally under-identified and under-served in the past. We believe that these provisions will serve to identify those types of admissions and enhance the quality of life and care for these individuals through the provision of

more appropriate services in other types of facilities.

For these reasons, we have determined that the threshold criteria under E.O. 12291 are not 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. Therefore, we have not prepared a regulatory flexibility analysis or an analysis of effects on small rural hospitals.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Nursing homes, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 431

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

42 CFR Part 433

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

42 CFR Part 483

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

42 CFR Chapter IV is amended as set forth below:

A. Part 405 is amended as follows:

PART 405-FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

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

Authority: Secs. 1102, 1154, 1155, 1869(b), 1871, 1872, and 1879 of the Social Security Act (42 U.S.C. 1302, 1320c, 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).

Subpart E-Fair Hearings for Applicants and Recipients

2.-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" and adding a definition for "adverse determination" 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 residents and adverse determinations made by a State with regard to the preadmission screening and annual resident review requirements of section 1919(e)(7) of the Act.

Adverse determination means a determination made in accordance with sections 1919(b)(3)(F) or 1919(e)(7)(B) of the Act that the individual does not require the level of services provided

by a nursing facility or that the individual does or does not require specialized services.

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 new paragraphs (g) and (h) and the introductory text is republished 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 is amended by revising paragraph (a) 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 or she 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 resident; 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 the State or local agency or the skilled nursing facility or nursing facility at the hearing;

* * * * *

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. Section 431.250 is amended by revising paragraphs (f) (2) and (3), and adding a new paragraph (f)(4) to read as follows:

§431.250 Federal financial participation.

FFP is available in expenditures for-

* * * * *

(f) Administrative costs incurred by the agency for-(1) Transportation for the applicant or recipient, his representative, and witnesses to and from the hearing;

(2) Meeting other expenses of the applicant or recipient in connection with the hearing;

(3) Carrying out the hearing procedures, including expenses of obtaining the additional medical assessment specified in §431.240 of this subpart; and

(4) Hearing procedures for Medicaid and non-Medicaid individuals appealing transfers, discharges and determinations of preadmission screening and annual resident reviews under part 483, subparts C and E of this chapter.

13. 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 1919(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 §§431.112(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, except through the appeals process, 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 through 483.136 are met.

PART 433-STATE FISCAL ADMINISTRATION

C. 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), 1396k, and 1396r(e), unless otherwise noted.

2. Section 433.15 is amended by adding a new paragraph (b)(9) to read as follows:

§433.15 Rates of FFP for administration.

* * * * *

(b) Activities and rates. * * *

(9) Preadmission screening and annual resident review (PASARR) activities conducted by the State: 75 percent. (Sections 1903(a)(2)(C) and 1919(e)(7); 42 CFR part 483, subparts C and E.)

C. Part 483 is amended as follows:

PART 483-REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

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

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

2. Part 483 is amended by adding a new subpart C containing §§483.100 through 483.138, and new subpart E containing §§483.200 through 483.206 to read as follows:

Subpart C-Preadmission Screening and Annual Review of Mentally Ill and Mentally Retarded Individuals
Sec.

483.100 Basis.

483.102 Applicability and definitions.

483.104 State plan requirement.

483.106 Basic rule.

483.108 Relationship of PASARR to other Medicaid processes.

483.110 Out-of-State arrangements.

483.112 Preadmission screening of applicants for admission to NFs.

483.114 Annual review of NF residents.

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

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

483.120 Specialized services.

483.122 FFP for NF services.

483.124 FFP for specialized services.

483.126 Appropriate placement.

483.128 PASARR evaluation criteria.

483.130 PASARR determination criteria.

- 483.132 Evaluating the need for NF services and NF level of care (PASARR/NF).
- 483.134 Evaluating whether an individual with mental illness requires specialized services (PASARR/MI).
- 483.136 Evaluating whether an individual with mental retardation requires specialized services (PASARR/MR).
- 483.138 Maintenance of services and availability of FFP.

Subpart E-Appeals of Discharges, Transfers, and Preadmission Screening and Annual Resident Review (PASARR) Determinations
483.200 Basis.

483.202 Definitions.

483.204 Provision of a hearing and appeal system.

483.206 Transfers, discharges and relocations subject to appeal.

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

§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 and definitions.

(a) This subpart applies to the screening or reviewing of all individuals 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 source of payment for the NF services, and regardless of the individual's or resident's known diagnoses.

(b) Definitions. As used in this subpart-

(1) An individual is considered to have a serious mental illness (MI) if the individual meets the following requirements on diagnosis, level of impairment and duration of illness:

(i) Diagnosis. The individual has a major mental disorder diagnosable under the Diagnostic and Statistical Manual of Mental Disorders, 3rd edition, revised in 1987.

Incorporation of the 1987 edition of the Diagnostic and Statistical Manual of Mental Disorders, 3rd edition, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 that govern the use of incorporation by reference. {1}

{1} The Diagnostic and Statistical Manual of Mental Disorders is available for inspection at the Health Care Financing Administration, room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland, or at the Office of the Federal Register, suite 700, 800 North Capitol St. NW., Washington, DC. Copies may be obtained from the American Psychiatric Association, Division of Publications and Marketing, 1400 K Street, NW., Washington, DC 20005.

This mental disorder is-

(A) A schizophrenic, mood, paranoid, panic or other severe anxiety disorder; somatoform disorder; personality disorder;

other psychotic disorder; or another mental disorder that may lead to a chronic disability; but

(B) Not a primary diagnosis of dementia, including Alzheimer's disease or a related disorder, or a non-primary diagnosis of dementia unless the primary diagnosis is a major mental disorder as defined in paragraph (b)(1)(i)(A) of this section.

(ii) Level of impairment. The disorder results in functional limitations in major life activities within the past 3 to 6 months that would be appropriate for the individual's developmental stage. An individual typically has at least one of the following characteristics on a continuing or intermittent basis:

(A) Interpersonal functioning. The individual has serious difficulty interacting appropriately and communicating effectively with other persons, has a possible history of altercations, evictions, firing, fear of strangers, avoidance of interpersonal relationships and social isolation;

(B) Concentration, persistence, and pace. The individual has serious difficulty in sustaining focused attention for a long enough period to permit the completion of tasks commonly found in work settings or in work-like structured activities occurring in school or home settings, manifests difficulties in concentration, inability to complete simple tasks within an established time period, makes frequent errors, or requires assistance in the completion of these tasks; and

(C) Adaptation to change. The individual has serious difficulty in adapting to typical changes in circumstances associated with work, school, family, or social interaction, manifests agitation, exacerbated signs and symptoms associated with the illness, or withdrawal from the situation, or requires intervention by the mental health or judicial system.

(iii) Recent treatment. The treatment history indicates that the individual has experienced at least one of the following:

(A) Psychiatric treatment more intensive than outpatient care more than once in the past 2 years (e.g., partial hospitalization or inpatient hospitalization); or

(B) Within the last 2 years, due to the mental disorder, experienced an episode of significant disruption to the normal living situation, for which supportive services were required to maintain functioning at home, or in a residential treatment environment, or which resulted in intervention by housing or law enforcement officials.

(2) An individual is considered to have dementia if he or she has a primary diagnosis of dementia, as described in the Diagnostic and Statistical Manual of Mental Disorders, 3rd edition, Revised in 1987, or a non-primary diagnosis of dementia unless the primary diagnosis is a major mental disorder as defined in paragraph (b)(1)(i)(A) of this section.

(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 Retardation's Manual on Classification in Mental Retardation (1983). Incorporation by reference of the 1983 edition of the American Association on Mental Retardation's Manual on Classification in Mental Retardation was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 that govern the use of incorporations by reference; {2} or

{2} The American Association on Mental Retardation's Manual on Classification in Mental Retardation is available for inspection at the Health Care Financing Administration, Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland, or at the Office of the Federal Register Information Center, Suite 700, 800 North Capitol St. NW., Washington, DC. Copies may be obtained from the American Association on Mental Retardation, 1719 Kalorama Rd., NW., Washington, DC 20009.

(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) Requirement. 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 or mental retardation, regardless of whether they were first screened under the preadmission screening or annual resident review requirements.

(b) Admissions, readmissions and interfacility transfers.-

(1) New admission. An individual is a new admission if he or she is admitted to any NF for the first time or does not qualify as a readmission. With the exception of certain hospital discharges described in paragraph (b)(2) of this section, new admissions are subject to preadmission screening.

(2) Exempted hospital discharge. (i) An exempted hospital discharge means an individual-

(A) Who is admitted to any NF directly from a hospital after receiving acute inpatient care at the hospital;

(B) Who requires NF services for the condition for which he or she received care in the hospital; and

(C) Whose attending physician has certified before admission to the facility that the individual is likely to require less than 30 days nursing facility services.

(ii) If an individual who enters a NF as an exempted hospital discharge is later found to require more than 30 days of NF care, the State mental health or mental retardation authority must conduct an annual resident review within 40 calendar days of admission.

(3) Readmissions. An individual is a readmission if he or she was readmitted to a facility from a hospital to which he or she was transferred for the purpose of receiving care. Readmissions are subject to annual resident review rather than preadmission screening.

(4) Interfacility transfers.- (i) An interfacility transfer

occurs when an individual is transferred from one NF to another NF, with or without an intervening hospital stay. Interfacility transfers are subject to annual resident review rather than preadmission screening.

(ii) In cases of transfer of a resident with MI or MR from a NF to a hospital or to another NF, the transferring NF is responsible for ensuring that copies of the resident's most recent PASARR and resident assessment reports accompany the transferring resident.

(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 specialized services are 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 by subcontract or otherwise the evaluation and determination functions for which they are responsible 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;

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

(iii) The entity to which the delegation is made is not a NF or an entity that has a direct or indirect affiliation or relationship with a NF.

(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 MR 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. In designating an independent person or entity to perform MI evaluations, the State must not use a NF or an entity that has a direct or indirect affiliation or relationship with a NF.

§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. Only appeals determinations made through the system specified in subpart E of this part may overturn

a PASARR determination made by the State mental health or mental retardation authorities.

(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 specialized services 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) Basic rule. The State in which the individual is a State resident (or would be a State resident at the time he or she becomes eligible for Medicaid), as defined in §435.403 of this chapter, must pay for the PASARR and make the required determinations, in accordance with §431.52(b)(1).

(b) Agreements. 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) Determination of need for NF services. 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) Determination of need for specialized services. If the individual with mental illness or mental retardation is determined to require a 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 specialized services for the mental illness or mental retardation, as defined in §483.120.

(c) Timeliness-(1) Except as specified in paragraph (c)(4) of this section, a preadmission screening determination must be made in writing within an annual average of 7 to 9 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 evaluation.)

(2) The State may convey determinations verbally to nursing facilities and the individual and confirm them in writing.

(3) The State may compute separate annual averages for the mentally ill and the mentally retarded/developmentally disabled populations.

(4) The Secretary may grant an exception to the timeliness standard in paragraph (c)(1) of this section when the State-

(i) Exceeds the annual average; and

(ii) Provides justification satisfactory to the Secretary that a longer time period was necessary.

§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) Specialized services 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) Specialized services for mental retardation as defined in §483.120.

(c) Frequency of review-(1) 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.

(2) "Annually" is defined as occurring within every fourth quarter after the previous preadmission screen or annual resident review.

(d) April 1, 1990 deadline for initial reviews. 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) Individuals needing NF services. 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.

(b) Individuals needing NF services and specialized services. If the State mental health or mental retardation authority determines that a resident or applicant for admission requires both a NF level of services and specialized services 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 specialized services 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 specialized services 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 specialized services 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 specialized services 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 at least 30 months before the date of the determination, and who requires only specialized services as defined in §483.120, the State must, in consultation with the resident's family or legal representative and caregivers-

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

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

(iii) 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; and

(iv) Regardless of the resident's choice, provide for, or arrange for the provision of specialized services for the mental illness or mental retardation.

(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 specialized services, 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, specialized services for the mental illness or mental retardation.

(3) For the purpose 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 first 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 Specialized services.

(a) Definition.-(1) For mental illness, specialized services

means the services specified by the State which, combined with services provided by the NF, results in the continuous and aggressive implementation of an individualized plan of care that-

(i) Is developed and supervised by an interdisciplinary team, which includes a physician, qualified mental health professionals and, as appropriate, other professionals.

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

(iii) Is directed toward diagnosing and reducing the resident's behavioral 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 level of specialized services at the earliest possible time.

(2) For mental retardation, specialized services means the services specified by the State which, combined with services provided by the NF or other service providers, results in treatment which meets the requirements of §483.440(a)(1).

(b) Who must receive specialized services. The State must provide or arrange for the provision of specialized services, in accordance with this subpart, to all NF residents with MI or MR whose needs are such that continuous 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.

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

§483.122 FFP for NF services.

(a) Basic rule. Except as otherwise may be provided in an alternative disposition plan adopted under section 1919(e)(7)(E) of the Act, FFP is available in State expenditures 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 specialized services, meets the requirements of §483.118(c)(1), and elects to stay in the NF.

(b) FFP for late reviews. When a preadmission screening has not been performed prior to admission or an annual review is not performed timely, in accordance with §483.114(c), but either is performed at a later date, FFP is available only for services furnished after the screening or review has been performed, subject to the provisions of paragraph (a) of this section.

§483.124 FFP for specialized services.

FFP is not available for specialized services 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 specialized services provided by or arranged for by the State.

§483.128 PASARR evaluation criteria.

(a) Level I: Identification of individuals with MI or MR. 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 specialized services are needed. The State's performance of the Level I identification function must provide at least, in the case of first time identifications, for the issuance of written notice to the individual or resident and his or her legal representative that the individual or resident 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) Adaptation to culture, language, ethnic origin. Evaluations performed under PASARR and PASARR notices must be adapted to the cultural background, language, ethnic origin and means of communication used by the individual being evaluated.

(c) Participation by individual and family. PASARR evaluations must involve-

(1) The individual being evaluated;

(2) The individual's legal representative, if one has been designated under State law; and

(3) The individual's family if-

(i) Available; and

(ii) The individual or the legal representative agrees to family participation.

(d) Interdisciplinary coordination. When parts of a PASARR evaluation are performed by more than one evaluator, the State must ensure that there is interdisciplinary coordination among the evaluators.

(e) 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 MI and MR, §§483.132, 483.134 and 483.136 if a more extensive individualized evaluation is required).

(f) Data. 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 an 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 specialized services are interrelated and must be based upon a comprehensive analysis of all data concerning the individual.

(g) Preexisting data. 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.

(h) Findings. 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.

(i) Evaluation report: Individualized determinations. 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 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 specialized services are not recommended, identifies any specific mental retardation or mental health services which are of a lesser intensity than specialized services that are required to meet the evaluated individual's needs;

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

- (6) Includes the bases for the report's conclusions.

(j) Evaluation report: Categorical determinations. 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 bases for the report's conclusions.

(k) Interpretation of findings to individual. For both categorical and individualized determinations, findings of the evaluation must be interpreted and explained to the individual and, where applicable, to a legal representative designated under State law.

- (1) Evaluation report. The evaluator must send a copy of the evaluation report to the-

- (1) Individual or resident and his or her legal representative;

- (2) Appropriate State authority in sufficient time for the State authorities to meet the times identified in §483.112(c) for PASs and §483.114(c) for ARRs;

- (3) Admitting or retaining NF;

- (4) Individual's attending physician; and

(5) The discharging hospital if the individual is seeking NF admission from a hospital.

(m) 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-

(i) A primary diagnosis of dementia (including Alzheimer's Disease or a related disorder); or

(ii) A non-primary diagnosis of dementia without a primary diagnosis that is a serious mental illness, and does not have a diagnosis of MR or a related condition.

§483.130 PASARR determination criteria.

(a) Basis for determinations. Determinations made by the State mental health or mental retardation authority as to whether NF level of services and specialized services are needed must be based on an evaluation of data concerning the individual, as specified in paragraph (b) of this section.

(b) Types of determinations. Determinations may be-

(1) Advance group determinations, in accordance with this section, by category that take into account that certain diagnoses, levels of severity of illness, or need for a particular service clearly indicate that admission to or residence in a NF is normally needed, or that the provision of specialized services 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) Group determinations by category. Advance group determinations by category developed by the State mental health or mental retardation authorities may be made applicable to individuals 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. 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 which-

(i) Required hospitalization; and

(ii) Does not meet all the criteria for an exempt hospital discharge, which is not subject to preadmission screening, as specified in §483.106(b)(2).

(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) Provisional admissions pending further assessment in emergency situations requiring protective services, with placement in a nursing facility not to exceed 7 days; and

(6) 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.

(e) Time limits. The State may specify time limits for categorical determinations that NF services are needed and in the case of paragraphs (d)(4), (5) and (6) of this section, must specify a time limit which is appropriate for provisional admissions pending further assessment and for emergency situations and 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 an annual resident review before continuation of the stay may be permitted and payment made for days of NF care beyond the State's time limit.

(f) The State mental health and mental retardation authorities may make categorical determinations that specialized services are not needed in the provisional, emergency and respite admission situations identified in §483.120(d) (4)-(6). In all other cases, except for §483.130(h), a determination that specialized services are not needed must be based on a more extensive individualized evaluation under §483.134 or §483.136.

(g) Categorical determinations: No positive specialized treatment determinations. The State mental health and mental retardation authorities must not make categorical determinations that specialized services are needed. Such a determination must be based on a more extensive individualized evaluation under §483.134 or §483.136 to determine the exact nature of the specialized services that are needed.

(h) Categorical determinations: Dementia and MR. The State mental retardation authority may make categorical determinations that individuals with dementia, which exists in combination with mental retardation or a related condition, do not need specialized services.

(i) If a State mental health or mental retardation authority determines NF needs by category, it may not waive the specialized services determination. The appropriate State authority must also determine whether specialized services are needed either by category (if permitted) or by individualized evaluations, as specified in §§483.134 or 483.136.

(j) Recording determinations. 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.

(k) Notice of determination. The State mental health or mental retardation authority must notify in writing the following entities of a determination made under this subpart:

- (1) The evaluated individual and his or her legal representative;
- (2) The admitting or retaining NF;

(3) The individual or resident's attending physician; and
(4) The discharging hospital, unless the individual is exempt from preadmission screening as provided for at §483.106(b)(2).

(1) Contents of notice. 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 specialized services are needed;

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

(4) The rights of the individual to appeal the determination under subpart E of this part.

(m) Placement options. 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 specialized services are also needed, may be admitted to a NF, if the placement is appropriate, as determined in §483.126. If specialized services are also needed, the State is responsible for providing or arranging for the provision of the specialized 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 specialized services are 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 specialized services, 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 a NF but does require specialized services 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 specialized services 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 specialized services 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 specialized services. The determination notice must provide information on 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 specialized services regardless of his or her length of stay, must be discharged in accordance with §483.12(a). The determination notice must provide information on 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.

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

(o) Record retention. 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

(p) Tracking system. 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) Basic rule. For each applicant for admission to a NF and each NF resident who has MI or MR, the evaluator must assess whether-(1) The individual's total needs are such that his or her needs can be met in an appropriate community setting;

(2) The individual's total needs are such that they can be met only on an inpatient basis, which may include the option of placement in a home and community-based services waiver program, but for which the inpatient care would be required;

(3) If inpatient care is appropriate and desired, the NF is an appropriate institutional setting for meeting those needs in accordance with §483.126; or

(4) If the inpatient care is appropriate and desired but the NF is not the appropriate setting for meeting the individual's needs in accordance with §483.126, another setting such as an ICF/MR (including small, community-based facilities), an IMD providing services to individuals aged 65 or older, or a psychiatric hospital is an appropriate institutional setting for meeting those needs.

(b) Determining appropriate placement. 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) Data. 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).

(d) Based on the data compiled in §483.132 and, as appropriate, in §§483.134 and 483.136, the State mental health or mental retardation authority must determine whether an NF level of services is needed.

§483.134 Evaluating whether an individual with mental illness requires specialized services (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 a specialized services 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. 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 an 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.

(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.

(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) Personnel requirements. (1) If the history and physical examination are not performed by a physician, then a physician must review and concur with the conclusions.

(2) The State may designate the mental health professionals who are qualified-

(i) To perform the evaluations required under paragraph (b) (2)-(6) of this section including the-

(A) Comprehensive drug history;

- (B) Psychosocial evaluation;
- (C) Comprehensive psychiatric evaluation;
- (D) Functional assessment; and

(ii) To make the determination required in paragraph (d) of this section.

(d) Data interpretation. Based on the data compiled, a qualified mental health professional, as designated by the State, must validate the diagnosis of mental illness and determine whether a program of psychiatric specialized services is needed.

§483.136 Evaluating whether an individual with mental retardation requires specialized services (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 specialized services program, which is analogous to active treatment, 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-Parkinson 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 (for example, 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 identifies the intellectual functioning measurement of individuals with MR or a related condition.

(2) Based on the data compiled in paragraph (b) of this section, the State mental retardation authority, using appropriate personnel, as designated by the State, must validate that the individual has MR or is a person with a related condition and must determine whether specialized services for mental retardation are needed. In making this determination, the State mental health authority must make a qualitative judgment on the extent to which the person's status reflects, singly and collectively, the characteristics commonly associated with the need for specialized services, including-

(i) Inability to-

(A) Take care of the 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.

§483.138 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.

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 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.

(Catalog of Federal Domestic Assistance Program No. 93.714,
Medical Assistance Program.)

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William Toby,
Acting Deputy Administrator, Health Care Financing Administration.
Approved: April 30, 1992.

Louis W. Sullivan,
Secretary.

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