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Part II

Department of Health and Human Services

Health Care Financing Administration

42 CFR Part 418, et al.

Medicare and Medicaid Programs; Omnibus Nursing Home Requirements; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 418, 440, 441, 482, 483, and 488

[BPD-488-P]

RIN 0938-AD81

Medicare and Medicaid Programs; Omnibus Nursing Home Requirements

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

ACTION: Proposed rule.

SUMMARY: This rule proposes the way we would implement several provisions of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87), Public Law 100-203, that concern services to residents of nursing homes. The provisions include:

- Use of physical and chemical restraints in nursing facilities;
- Federal standards for evaluating State waivers of nursing facility nurse staffing requirements;
- Qualifications of nursing home administrators;
- Notice of Medicaid rights to be given to persons admitted to nursing facilities; and
- Other technical changes needed to include requirements of OBRA '87 in regulations.

DATES: Written comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on April 6, 1992.

ADDRESSES: Mail written comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD-488-P, P.O. Box 26676, Baltimore, Maryland 21207.

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

Room 309-G, Hubert H. Humphrey Building, 200 Independence Ave., SW., Washington, DC 20201.

Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland 21207.

Due to staffing and resource limitations, we cannot accept audio, video, or facsimile (FAX) copies of comments. In commenting, please refer to file code BPD-488-P. Written comments received timely will be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, in room 309-G of the Department's offices at 200 Independence Ave., SW., Washington, DC, on Monday though Friday of each week from 8:30 a.m. to 5 p.m. (phone: 202-245-7890).

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

SUPPLEMENTARY INFORMATION:

Background

General

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

Many of the requirements in the February 2 regulations reflected detailed, self-implementing provisions of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) (Pub. L. 100-203), which was enacted after we issued the proposed rule. Commenters were aware of the pending legislation and many commenters supported the OBRA '87 changes. An effective date of August 1, 1989 was specified for the February 2 regulations, except for those OBRA '87 provisions that relied on a statutory effective date of October 1, 1990. On July 14, 1989, the August 1 effective date was changed to January 1, 1990 (54 FR 29717) because we determined that the August 1, 1989 effective date did not give States and others adequate implementation time. On December 19, 1989, OBRA '89 was enacted. Section 6901(a) of OBRA '89 changed the January 1, 1990 effective date of the nursing home regulations to October 1, 1990. As a result, on December 29, 1989 we published in the **Federal Register** (54 FR 53611) a final rule to revise the effective date of the regulations issued in the **Federal Register** on February 2, 1989 (54 FR 5316) to October 1, 1990.

On September 26, 1991 (56 FR 48826), we published in the **Federal Register** final regulations on Requirements for Long Term Care Facilities that responded to comments on the February 2, 1989 final rule with a comment period. The provisions of this rule are effective, in general, April 1, 1992. Also on September 26, 1991, we published a related rule on Nurse Aide Competency Evaluation Programs (at 56 FR 48880) that also made changes to sections discussed in this proposed rule.

Scope of Proposed Rule

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

- Requirements imposed on SNFs that participate in Medicare and NFs that participate in Medicaid, with respect to use of physical and chemical restraints. This portion of the proposed rule would expand upon the discussion of restraints contained in the final rule published on February 2, 1989;
- Requirements imposed on States in accordance with certain provisions of sections 1819 and 1919 of the Social Security Act (the Act) (sections 4201(a) and 4211(a) of OBRA '87), which include—

—Criteria that the Secretary would use to monitor States in granting waivers of the nurse staffing requirements of the Act, and the procedures that the Secretary would use to assume and exercise the State's authority to grant such waivers if monitoring reveals that the State has established a clear pattern and practice of granting inappropriate waivers;

—Qualifications of nursing home administrators;

—Notice of Medicaid rights to be given to persons admitted to nursing facilities;

—Conforming changes to the regulations reflecting the elimination of Medicaid coverage of SNF and ICF services (except for ICFs/MR) and replacement with coverage of nursing facility services;

—Additional requirements that a hospital must meet in order to be certified as a swing-bed facility; and

—Additional requirements that a freestanding inpatient hospice must meet.

The provisions contained in these proposed regulations pertain to long term care facility requirements, which affect several parts of the Code of Federal Regulations (CFR). We will

discuss the subject matter without regard to where it appears in the CFR.

Proposed Changes to the Long Term Care Facility (SNF and NF) Requirements

Use of Restraints

Section 4201 of OBRA '87 added sections 1819(c)(1)(A)(ii) (for Medicare) and 1919(c)(1)(A)(ii) (for Medicaid) to the Act, which provide that residents of nursing facilities have the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms. Existing § 483.13(a) implements this requirement in part by restating the statutory provision. These provisions apply to skilled nursing facilities that participate in Medicare and nursing facilities that participate in Medicaid.

In these proposed regulations, we would define physical and chemical restraints, and psychopharmacologic drugs, specify when a facility may use physical and chemical restraints, how restraints are to be applied, and what documentation is required.

We would revise paragraph (a) by deleting the term "psychoactive drug" and instead use the term "chemical restraint." This term is the one used in the statute and replaces the term psychoactive drug used previously. Sections 1819(c)(1)(A)(ii) and 1919(c)(1)(A)(ii) of the Act specify that residents have the right to be free from "* * * any physical or chemical restraints imposed for purposes of discipline or convenience and not required to treat the resident's medical symptoms". Restraints may only be imposed—

- To ensure the physical safety of the resident or other residents, and
- Upon the written order of a physician that specifies the duration and circumstances under which the restraints are to be used (except in emergency circumstances specified by the Secretary) until such an order could reasonably be obtained.

Under § 483.13(a), we would define a physical restraint as any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident's body that the resident cannot remove easily, which restricts freedom of movement or access to his or her body.

We would also propose in paragraph (a), in accordance with sections 1819(c)(l)(A)(ii) (I) and (II) and 1919(c)(1)(A)(ii) (I) and (II) of the Act, to limit physical restraints to treatment of medical symptoms or when it is necessary to ensure the safety of the resident or other residents and only if imposed in accordance with a physician's order specifying the circumstances and duration under which the restraint may be used.

We are proposing under the same section that the decision to apply physical restraints would come only after assessing each resident's capabilities, evaluating less restrictive alternatives, ruling out their use for each resident, and identifying within the plan of care rehabilitative training to enable the progressive removal of restraints or the progressive use of less restrictive means. By requiring such a systematic review before applying restraints, we hope to assure that restraints would not be applied for purposes of discipline or convenience.

We are proposing to prohibit the application of physical restraints on a standing, blanket, or "as needed" basis (the phrase "as needed" is a medical term of art, and indicates use when staff, in accordance with a physician's orders, determines it is needed to treat the resident's symptoms). We believe that restraints which are ordered on a standing, blanket or as needed basis are, in essence, being applied for purposes of discipline or convenience and are therefore prohibited by law. If there is a recognition that restraints must be applied for a specific condition on a standing, blanket or as needed basis, then that condition should be dealt with in a plan of care which endeavors to reduce or eliminate the need for the restraint.

In cases of non-emergency use, we would require that the facility obtain the written consent of the resident, or if the resident has been declared incompetent or cannot understand his or her rights, the legal representative in accordance with State law. The consent given for restraints in non-emergency situations would not relieve the facility from the requirements of § 483.13(a)(1) (ii) and (iii), which require the facility to ensure that the restraint is: necessary; imposed in accordance with a physician's order; not ordered on a standing, blanket, or "as needed" basis; enabling for the resident; imposed only as a last resort; and used in accordance with the plan of care.

In cases of emergency use, we would require that the facility obtain the order to restrain the resident as soon as an order can reasonably be obtained and to limit the time the order is in effect to 12 hours. An authorization for the emergency use of restraints for up to 12 hours would apply to situations in which a resident is so unstable that the facility has determined that the continued or intermittent use of a restraint for a 12-hour period might be needed.

Also in § 483.13(a), we would specify that staff is required to be trained in the application of physical restraints. We would also require the facility to monitor the resident's condition and assist the resident as often as necessary for the resident's safety, comfort, exercise, and elimination needs. In addition, staff would be required to keep a record of the resident's condition and any assistance provided to the resident.

As proposed, the requirements governing the use of physical restraints would be applied without exceptions. However, it has been suggested that there may be a small set of residents who have demonstrated relentless self-injurious behavior for whom the application of these requirements might prove unduly burdensome on facilities. We are especially interested in receiving comments on the appropriateness of relaxing or waiving the proposed procedural limitations on the use of physical restraints with respect to these residents, as well as the types of evidence that should be solicited to support the expedited use of restraints in such instances.

We propose to define the term "psychopharmacologic drug," which appears in sections 1819 and 1919(c)(1)(D) of the Act, as any drug that is prescribed with the intent of controlling mood, mental status or behavior. By defining psychopharmacologic drugs in this way, we include not only the obvious drug classes, such as antipsychotics, antidepressants, and the anti-anxiety/hypnotic class, but any drug that is prescribed with the intent of controlling mood, mental status, or behavior, regardless of the manner in which it is marketed by the manufacturers and regardless of labeling or other approvals by FDA. By using this definition HCFA can, for example, regulate the use of antihistamines which can have a sedative side effect, in addition to merely an antihistaminic effect. This would permit HCFA to guard against the use of drugs which are not approved or marketed as "psychopharmacologic" but which can be used for that effect. This definition also allows for the regulation of drugs not currently on the market, which could be used to affect mood, mental status or behavior.

For several reasons, we believe that State agency surveyors can determine the intent of the physician in prescribing a particular drug. First, the current regulations at § 483.25(l)(i) require the facility to have adequate indications for the use of a drug. Second, the facility

must conduct an adequate assessment of the resident as required by § 483.20 and, except for acute episodic problems, drug use must conform to this assessment. Third, when drugs are used for effects not included in the official labeling, they are usually used in dosages, dosage schedules, and durations that reveal the intent of the prescriber. Finally, guidelines can be developed which assist surveyors in making these judgments by informing them of drugs that are commonly used in this manner and enumerating some situations in which they may be used. We invite comments on this definition and how we intend to apply it.

We would require that such drugs be ordered by a physician who specifies the dose, duration and reason for the use of the drug. This proposed requirement implements sections 1819(c)(1)(D) and 1919(c)(1)(D) of the Act, which require that psychopharmacologic drugs (drugs used to alter behavior, mood or mental status) may be imposed "* * * only upon the written order of a physician." We believe that it comports with the intent of Congress as provided by sections 1819(c)(1)(D) and 1919(c)(1)(D) of the Act.

We propose to require that such drugs must be used only as an integral part of the resident's comprehensive care plan that is directed specifically towards the elimination or modification of the symptoms for which the drugs are prescribed. We believe that this use of drugs which alter behavior, mood or mental status is consistent with the intent of Congress regarding use of these drugs as provided by sections 1819(c)(1)(D) and 1919(c)(1)(D) of the Act.

We propose that such drugs must not be used until the facility can justify that the beneficial effects of the drug clearly outweigh its potential harmful effects. We are proposing this requirement because we believe that it is necessary to the health and safety of residents that there be a thoughtful analysis of the relative benefits versus the potential harm of drug use in each case. Drugs that are used to alter behavior, mood or mental status may have longlasting or permanent adverse effects on the functional level of residents and should be prescribed only where the potential adverse effects are outweighed by the benefits of drug use.

Also, in § 483.13(a), we propose that the resident who is administered such a drug must be monitored closely, in conjunction with the drug regimen review requirements at § 483.60(e) for desired responses and adverse consequences by facility staff. We believe that this requirement is also essential to resident health and safety to prevent potentially serious longlasting or permanent loss of function.

We believe that there is a tendency to continue drug therapy that has been under way for a long period of time under the assumption that it continues to be necessary. This proposed rule, in § 483.13(a), would require that, unless there is a sound clinical basis for not attempting to withdraw the resident from use of a drug used to control behavior, mood or mental status, a gradual withdrawal must be undertaken at least semi-annually (e.g., every 6 months) in a carefully monitored program so that the interdisciplinary team can reevaluate whether the use of the drug continues to be necessary. We are proposing this requirement because we believe that it is necessary to protect resident health and safety by forcing the facility to determine whether long term drug therapy continues to be essential to the health and safety of the resident.

Sections 1819(c)(1)(D) and 1919(c)(1)(D) of the Act require that skilled nursing facilities and nursing facilities undergo an annual independent, external consultant review of the appropriateness of the drug plan of each resident receiving such drugs. To implement this requirement, in § 483.13(a) we propose to require that the use of drugs intended to alter behavior, mood or mental status must be reviewed annually by a physician who has training or experience in geriatrics and psychopharmacology, for the appropriateness of the drug plan for each resident receiving such drugs. We are proposing that this review be performed by these professionals because we believe their credentials will put them in the most favorable position to influence other physician prescribing behavior. Since the law specifically requires this review to be conducted by an independent, external consultant, we are proposing to require that the reviewer of psychopharmacologic drugs not have a contractual, financial, employment or familial relationship with the facility, its owner, its attending physicians, medical director, or administrator within any of the 36 consecutive months prior to the date of the review. We particularly invite comments on the appropriateness of this proposed timeframe.

We also do not want to rule out the possibility that the annual resident review by the State mental health authority under the preadmission screening and annual resident review (PASARR) requirement could be used to satisfy the annual review of psychopharmacologic drugs required by sections 1819(c)(1)(D) and 1919(c)(1)(D) of the Act. This is why we have included a provision that would allow the States the option of using the State mental health authority to satisfy this requirement. We believe that avoidance of duplication of review function would save the taxpayer money while carrying out the fundamental requirement of the statute. We realize that this may expand the review function of the State mental health authority since more residents use psychopharmacologic drugs than are determined to be mentally ill. However, we expect the expansion of the review function to be offset substantially by avoiding duplication of review functions.

To enable health professionals in the facility to determine if drugs used to alter behavior, mood or mental status are in fact achieving the desired results, we would include recordkeeping requirements in § 483.13(a). We propose to require that such drugs must be used only when a record is maintained of the administration of the drug, the dose, the route of administration, a description of the behavior, mood or mental status which the drug is intended to alter, the effect of the drug on the behavior, mood and mental status of the resident, and any other change in behavior, mood, mental status or physical condition which occurs with the administration of the drug.

We also propose to require that the drug review conducted by an independent external consultant (a physician with experience or training in geriatrics and psychopharmacology) include a review of the appropriateness of the indications for use, the dose, the duration of therapy, and the adequacy of monitoring. We would also propose that the reviewer ascertain whether valid justification exists for using a chemical restraint as permitted under paragraph (a)(8) of this section. This provision will enlist the expertise of the independent external consultant in deciding whether the use of a chemical restraint carries with it a valid justification for its use.

In § 483.13(a)(1)(v), we propose that before a psychopharmacologic drug can be used in a non-emergency situation, the facility must explain the use of the drug as required by § 483.10(d), explain the resident's right to refuse the drug, as required by § 483.10(b)(4), and obtain written consent for the use of the drug. The requirement to obtain written consent before a psychopharmacologic drug can be used in no way relieves the facility from its responsibilities under § 483.10(a)(3) (i) through (iv), and (vi) and (vii).

We would define "chemical restraint" as a psychopharmacologic drug (i.e., any drug that affects mood, mental status or behavior) which is used in excessive dose, for excessive periods of time, without adequate monitoring, without adequate indications for its use, in the presence of "adverse consequences," which indicate the dose should be reduced or discontinued, in a manner that results in a decline in the resident's functional status, or any of the reasons above. We propose that a psychopharmacologic drug becomes a "chemical restraint" when it is used under the circumstances of "excessive dose," "inadequate indicators," etc. and invite public comment on how to define these terms. We believe this is the only way to avoid the use of all psychopharmacologic drugs with the pejorative term "chemical restraint." This proposed regulation would implement sections 1819(c)(1)(ii) and 1919(c)(1)(ii) of the Act, which give the resident the right to be free of "chemical restraints imposed for the purposes of discipline or convenience and not required to treat the resident's medical symptoms." This proposal would establish a stricter standard than the statute. The statute allows the use of a chemical restraint when not used for convenience or discipline and when used to treat medical symptoms (e.g., hallucinations, delusions, paranoia). The statute exempts the facility from the above standard when it says, "Restraints may only be imposed to ensure the physical safety of the resident or other residents." In other words, the resident need not have medical symptoms for the imposition of a chemical restraint if they represent a threat to themselves or others. However, we are concerned about the indiscriminate application of this principle in situations such as those involving a resident who strikes at another resident out of self-defense or who strikes at an abusive aide. This would be normal behavior and would not be the result of a hallucination or delusion, yet a chemical restraint would be permitted. That is why this regulatory proposal would tie the use of a chemical restraint to proper indications for use (as well as other criteria, e.g., dose, duration of therapy, monitoring and excessive side effects), instead of allowing physical safety to be the sole criterion for use of a chemical restraint.

We also note that there are frequent occasions when residents' medical symptoms (hallucinations, delusions, paranoia) may result in potential harm to themselves or others. To treat these medical symptoms should not be considered use of chemical restraints. It should be considered the reasonable and necessary practice of medicine. However, when this treatment is without proper indications, the dose is excessive, treatment is for an excessive duration, monitoring is inadequate, or side effects are too great, then this constitutes a chemical restraint.

Under § 483.13(a)(8), use of a chemical restraint would be permissible (as the Act requires at 1819(c)(1)(A)(ii)(I) and 1919(c)(1)(A)(ii)(I)) only when it is imposed to ensure the safety of the resident or other residents and properly ordered.

However, to be consistent with the concept that a chemical restraint situation should only rarely occur, we are proposing that an emergency situation should exist before a chemical restraint may be used in accordance with the statutory circumstances "to ensure the physical safety of the resident or other residents." This would serve to limit the application of this provision to rare circumstances in which the resident is acting out so violently that he or she must indeed be "chemically restrained." We would require that such drugs, when used as an emergency restraint be accompanied by physician's orders (not necessarily a written order) in effect for no longer than 12 hours, and be administered to residents only if the resident is monitored continually for the first 30 minutes after administration and every 15 minutes thereafter. This particular monitoring schedule assumes that the drug will be administered parenterally since it is in an emergency situation. We believe that these proposed requirements are necessary to protect resident health and safety by ensuring that the residents are not continuously under the influence of these drugs without careful professional monitoring being given to the continued use of them, or without careful observation of the effects of the drugs on the resident. We believe that continued use of such drugs in an emergency situation should be reevaluated by a physician no later than 12 hours after the initial order to ensure that the drug continues to be appropriate. Moreover, due to the impaired physical status of most residents, we believe that continuous monitoring for the first 30 minutes after administration of the drug, and monitoring every 15 minutes thereafter for as long as the resident is under the influence of the drug are necessary to ensure that any adverse side effects that may occur would be noticed and appropriate actions would be taken as soon as possible.

We believe the proposed regulations on psychopharmacologic drugs and chemical restraints are necessary to cope with a significant public health problem in many, but not all of this nation's long-term care facilities. For many years, there have been allegations of misuse of psychoactive drugs in these facilities. In 1975, the Special Committee on Aging of the U.S. Senate held hearings on this public health problem and made reference to "chemical straight jackets" in nursing homes. In 1980, the House Select Committee on Aging held hearings on the same subject. They entitled their report, "Drug Abuse in Nursing Homes." Most recently, articles that deal with this subject have appeared in a number of medical journals. These papers generally question the extent of the use of psychopharmacologic drugs in nursing homes and question whether adequate monitoring of the use of these drugs exists.

Congress took action on this issue by enacting the chemical restraint provisions of OBRA '87. In enacting these provisions, Congress has determined that the facility, and not only the prescribing physician, can be held responsible for the inappropriate use of chemical restraints. They did this by giving the resident the right to be free of chemical restraints except under certain circumstances and held the skilled nursing facility or the nursing facility responsible for "protecting and promoting" this right for each resident (see sections 1819(c)(1)(A) and 1919(c)(1)(A)).

Although section 1801 of the Act (no such provision exists in title XIX of the Act) prohibits Federal interference in the practice of medicine, the provisions on chemical restraints in OBRA '87 do not contradict that provision. The physician is free (within the confines of facility policy) to prescribe chemical restraints if such drug use is necessary in an emergency to "ensure the physical safety of the resident or other residents," and if such drug use is not for discipline or convenience and is required to treat medical symptoms (see sections 1819(c)(1)(A)(ii)(I) and 1919(C)(1)(A)(ii)(I)). The "chemical restraint" prohibition would apply only when such drugs are prescribed for discipline or convenience and not to treat medical symptoms. Since the prescribing of "chemical restraints" for these circumstances are not to treat a medical symptom, the Federal government's regulation of nursing home practices, by prohibiting the facility's use of chemical restraints under these circumstances, are not intended, or

expected to amount to Federal interference with the practice of medicine. We believe that this interpretation reasonably balances the general limitation contained in section 1801 of the Act with the specific and explicit requirements imposed by sections 1819(c)(1)(A)(ii) and 1919(c)(1)(A)(ii) of the Act.

As proposed, the requirements governing the use of chemical restraints would be applied without exceptions. However, it has been suggested that there may be a small set of residents who have demonstrated relentless self-injurious behavior for whom the application of these requirements might prove unduly burdensome on facilities. We are especially interested in receiving comments on the appropriateness of relaxing or waiving the proposed procedural limitations on the use of chemical restraints with respect to these residents, as well as the types of evidence that should be solicited to support the expedited use of restraints in such instances.

State and Federal Waivers of Nurse Staffing Requirements

Section 4201 of OBRA '87 added section 1819(b)(4)(C)(i) to the Act, which requires that a Medicare SNF provide 24-hour licensed nursing service, and use the services of a registered professional nurse at least 8 consecutive hours a day, 7 days a week. Section 4211 of OBRA '87 added section 1919(b)(4)(C)(i) to the Act, imposing the same requirement on Medicaid NFs. Section 1819(b)(4)(C)(ii) authorizes the Secretary to waive the requirement that a SNF use a registered professional nurse for more than 40 hours a week if certain criteria specified in section 1819(b)(4)(C)(ii)(I)–(III) of the Act are met by the facility. Section 1919(b)(4)(C)(ii) authorizes a State to waive the 24-hour licensed nursing requirement or the registered professional nurse requirement in a Medicaid NF if certain criteria specified in section 1919(b)(4)(C)(ii)(I)–(III) are met.

The proposed regulations concerning nurse staffing waivers would be located in two places in the CFR. In part 483, subpart D, new § 483.165 would add requirements that must be met by States and State agencies concerning designation of nurse staffing waiver authority, nature of waivers, effective dates, renewal of waivers, and notices. In part 488, subpart B, current rules specify survey and certification procedures that are used by the State survey agency and HCFA to determine if long term care facilities meet the requirements in part 483, subpart B.

State Requirements—Nurse Staffing Waivers

In § 483.148, we describe the scope and statutory basis of the regulatory requirements that apply to States with respect to Medicaid participating long term care facilities. In § 483.165, we propose to specify the requirements that must be met by the State in deciding whether to grant nurse staffing waivers to Medicaid participating nursing facilities and distinct parts. Specifically, in § 483.165(a), we propose to require that the Medicaid agency must designate an entity within the State, including itself, that is responsible for deciding whether to grant a waiver of the nurse staffing requirements at 42 CFR 483.30 (a) and (b). Moreover, we propose that the State cannot delegate or subcontract this function to an entity outside of the State government. We believe that it is important that nurse staffing waivers not be granted unless the State has determined that resident health and safety will not be adversely affected, and therefore, we do not intend that any entity outside of the government of the State make the decision of whether to grant a waiver of the nurse staffing requirements.

In § 483.165(b), we propose that the State may grant a waiver of these requirements for a Medicaid-only participating nursing facility or a Medicaid-only distinct part nursing facility when, at the request of the nursing facility, the State finds that the conditions in § 483.30 (c) and (e) are met by the nursing facility. A facility would be deemed to have made a diligent effort to meet the nurse staffing requirements if it can demonstrate that it (1) continuously attempts to recruit registered or licensed practical nurses, or both, to fill its vacancies by advertising, solicitation at education programs, and job fairs within a radius of 100 miles of the facility, and (2) offers salaries and benefits that are competitive with the salary and benefits offered by other nursing facilities that are located within a 100 mile radius of the facility. In addition, we propose that a State could only grant a nurse staffing waiver to a facility that had been in compliance with all of the requirements of § 483.25 regarding quality of care both at the last standard or extended survey and at the time the waiver is to be effective. We propose this requirement because we believe that it is an essential measure of minimal health and safety protection for the residents in a facility. A nursing facility or distinct part that has been found out of compliance with any of the quality of care requirements of § 483.25 should not be granted a nurse staffing waiver, since nurse staffing is crucial to the patient outcomes addressed in the quality of care standard. Although this requirement is not explicit in the statute, it is consistent with the statutory requirement that the State not find any health and safety problems (see section 1919(b)(4)(C)(ii)(II) prior to granting a waiver).

The State may not grant a waiver of the nurse staffing requirements of § 483.30 (a) and (b) to Medicare-only skilled nursing facilities or Medicare-only distinct part skilled nursing facilities. Since these facilities participate in Medicare, they will only be eligible for Medicare waivers of nurse staffing requirements. This is because a waiver of nurse staffing requirements under section 1919(b)(4)(C)(ii) of the Act, and regulations at § 483.30 (c) and (e), would cause Medicare participating facilities to be out of compliance with the Medicare requirements for participation that require 24 hour nursing. These facilities and distinct parts that participate in Medicare may be granted waivers of the nurse staffing requirements of § 483.30 only by HCFA, as provided under § 488.56. Dually-participating facilities (i.e., those which participate both as a Medicare SNF and a Medicaid NF) that seek to have nurse staffing requirements waived would need to obtain two separate waivers: A Medicare waiver from HCFA, and a Medicaid waiver from the State. The Medicare waiver authority is far more limited than is the States' authority under Medicaid since a State may waive any element of the nurse staffing requirement, whereas the Secretary may waive only the registered nurse (RN) requirement to the extent that it would entail an RN being on duty more than 40 hours a week, and only then in rural facilities. Since the scope of Medicaid's nurse staffing waiver authority under the law is far broader than Medicare's, a dually-participating facility that obtains a nurse staffing waiver under Medicaid, which is broader in scope than would be allowable under Medicare, is disqualified from further participation in Medicare. We anticipate that in situations where HCFA grants a Medicare waiver to a dually-certified facility, the State might choose to grant automatically a comparable Medicaid waiver.

In § 483.165(c), we propose that the effective date of nurse staffing waivers granted by the State may not precede the date of the facility's request and expire on the earlier of:

• The anniversary of the effective date;

• The date by which the State becomes aware that the facility acquires sufficient nurse staffing to comply with the requirements without a waiver; or

• The date that the State determines that the facility has ceased to be in compliance with any of the requirements of § 483.25 or determines that the health and safety of residents has become jeopardized.

We are limiting waivers in this way because of our concern that the waivers be granted only when continued resident health and safety are ensured.

We are also proposing at § 483.165(c) that waivers may not be granted with retroactive effective dates in order to preclude skilled nursing facilities and nursing facilities from avoiding penalties for noncompliance with the nurse staffing requirements discovered during a survey by requesting and receiving a retroactive waiver. We believe that compliance with the statutory requirement for adequate nurse staffing is essential to ensuring the health and safety of residents and that the waivers of the nurse staffing requirements are not to be granted without careful consideration and a sound belief that resident health and safety will not be adversely affected. At § 483.165(d), we would provide that the State may renew a nurse staffing waiver after it has expired (or before it expires) if the State has reevaluated the facility to ensure that the criteria continue to be met and resident health and safety has not been adversely affected by the waiver.

We believe that it is appropriate to limit the duration of a nurse staffing waiver. Requiring reassessment of the waiver at least once a year forces the facility to be able to demonstrate what it has done to acquire sufficient nurse staffing so as not to need the waiver. The automatic termination of the waiver when the facility acquires sufficient staffing to meet the statutory requirements is appropriate because the acquisition of such staffing both obviates the need for the waiver and demonstrates that the facility can find sufficient staffing to meet the requirements. The automatic termination of the waiver if the State finds that the facility is out of compliance with a quality of care requirement under § 483.25 or that the health and safety of residents has been adversely affected by the waiver is only appropriate, since the statute prohibits a waiver if resident health and safety is adversely affected by it, and for consistency with § 488.56. The focus of the requirements, and in particular of the nurse staffing requirement, is to protect resident health and safety.

In § 483.165(d), we propose that waivers of nurse staffing requirements may be renewed for a subsequent period of 12 months if the State, after full development and review of a facility's request for renewal, finds that the criteria of § 483.30(c) and (e) or (d), as applicable, continue to be met and resident health and safety are not endangered by the waiver.

In § 483.165(e), we propose that copies of each notice to a facility that allows a nurse staffing waiver and the information on which the State based its waiver must be provided to the Secretary within 30 days of the date of notice to the nursing facility. This requirement is proposed to implement section 1919(f)(9) of the Act, which requires the Secretary to monitor State grants of nurse staffing waivers under section 1919(b)(4)(C)(ii) of the Act. It is essential that we be advised of the waivers granted by the State and provided the information on which the waiver is based so that we can adequately perform our monitoring function. We believe that the 30 day timeframe will impose no hardship on States as they grant nurse staffing waivers.

In § 483.165(f), we also propose to require that when the State grants a nurse staffing waiver, it must notify the Long Term Care Ombudsman and the protection and advocacy system in the State for the mentally ill and the mentally retarded as well as the resident's immediate family within 30 days of the notice of approval of the waiver. We propose this requirement in accordance with the provisions of section 4801(e)(5)(D)(iv) of OBRA '90 and because we recognize the important role these individuals play in advocacy for residents of these facilities. We also recognize that if they are aware of waivers of nurse staffing, they can serve as onsite watchdogs of facilities that have been granted nurse staffing waivers to ensure that the quality of care does not deteriorate as a result of the waiver.

We propose this requirement, in part, as a result of the concerns expressed by consumer groups with these waivers. In particular, they are concerned that individuals who are concerned with the quality of care provided by nursing facilities be aware of such waivers when they are granted. In addition to this requirement for notification of the ombudsman, we also propose to require at § 483.30(c) that the facility post a notice of its waiver in a public place and that all current residents and new admissions be advised when a waiver is granted. We believe that these requirements sufficiently attend to the concerns of consumer representatives.

In § 483.30(c), we propose that the facility must, within 30 days of the notice of approval of a nurse staffing waiver, post in a prominent public location a notice of the services for which a nurse staffing waiver has been granted; the date of expiration of the waiver; and the name, address and phone number of the entity in the State to which complaints about the facility should be directed. We believe that it is important that individuals who have an interest in a facility be advised that the facility has been granted a waiver of the Federal nurse staffing requirements, so that if there are concerns with the absence of adequate nurse staffing they can make the appropriate entity in the State immediately aware of those concerns.

We believe that each resident of a facility that has been granted a waiver of the Federal requirements for nurse staffing has the right to know that the facility has been granted such a waiver, and as such does not meet the specific Federal requirements for nurse staffing in certified facilities. Therefore, in § 483.30(c) we propose that the facility must notify each new admission and each current resident in accordance with notification requirements under "Residents Rights" section (§ 483.10(b)) of the services for which a nurse staffing waiver has been granted within 30 days of the notice of approval of the waiver.

Some groups also want us to require that the State not be permitted to grant a nurse staffing waiver until after the State has published a proposed notice and considered public comments on the proposed nurse staffing waiver as a means of preventing waivers that might adversely affect resident health and safety. We have chosen not to impose such requirements because we believe that the result would be an unnecessary delay of the decision-making process. Moreover, we believe that the safeguards we propose to install in the Federal monitoring process, and revocation of improperly granted waivers will ensure that resident health and safety is protected when waivers of nurse staffing are granted.

In § 483.30(b) we propose to require that when a waiver under paragraph (c) of that section results in a facility not having a registered nurse on staff, the facility must—

• Designate a licensed practical nurse to supervise nursing staff;

• Contract with a registered nurse to conduct or coordinate resident assessments and sign and certify the

completion of the assessment as required by section 1919(b)(3)(B)(i) of the Act; and

• Designate a licensed practical nurse with responsibility for the resident to participate in the development of a comprehensive care plan as required by section 1919(b)(2)(B) of the Act.

When a waiver under paragraph (d) results in the facility having a registered nurse on staff less than 7 days a week, the facility must designate a licensed practical nurse to serve as the health services supervisor in the absence of the registered nurse.

We propose to include these requirements to address who may supervise health services when a nurse staffing waiver is granted by the State. We believe that they offer a reasonable solution to the questions that have arisen regarding who can supervise health services, conduct or coordinate resident assessments, and participate in the development of plans of care when there is a nurse staffing waiver in the facility.

Section 1919(b)(4)(C) of the Act requires that a facility demonstrate to the satisfaction of the State that the facility has been unable, despite diligent efforts (including offering wages at the community prevailing rate for nursing facilities), to recruit appropriate personnel. In § 483.30(c)(6), we propose to adopt the "diligent effort" criteria used in § 488.57(b)(2), as discussed below, for consistency and conformity.

We propose in § 488.56(a) the conditions under Medicare for waiving of nurse staffing requirements, the duration of such waivers and the nature of the effective date(s) of such waivers. Specifically, § 488.56(a) would provide that upon the request of a State, we will decide whether to waive the requirement to provide services of a registered nurse for more than 40 hours a week as specified in § 483.30(d). It would also provide that any waiver we grant must meet the requirements specified in this section.

We would only grant such a waiver if the skilled nursing facility has made and continues to make a diligent effort to comply with the requirement to have a registered nurse on duty more than 40 hours a week, but such compliance is impeded by the unavailability of registered nurses in the area (§ 483.30(d)). We would provide that a facility has made a diligent effort to meet the requirements when it continuously attempts to recruit registered nurses to fill its vacancies by advertising, soliciting at educational programs and participating in job fairs within a radius of 100 miles of the facility, and when it offers salaries and benefits that are competitive with other skilled nursing facilities within a 100 mile radius of the facility. We propose this requirement to ensure that the facility continues to try to meet the nurse staffing requirements notwithstanding the granting of the waiver. In § 488.56(a)(2), we describe what demonstrable actions we expect the SNF to take in attempting to recruit registered nurses. This reflects a longstanding policy for nurse staffing waivers in skilled nursing facilities and we continue to believe that it is appropriate. We are especially interested in receiving comments on possible ways to improve the effectiveness of these requirements.

We believe it is appropriate to grant such a waiver only if the facility has been in compliance with all of the requirements of § 483.25 both at the last standard or extended survey and at the time the waiver is to be effective. We propose this requirement because we believe that a facility that has or has recently had a deficiency in the quality of care requirements demonstrates a problem in quality of care and that these problems would likely be exacerbated by the absence of registered nurse staffing. We invite public comments on our use of this standard of compliance with quality of care requirements in this context.

Section 1819(b)(4)(C) of the Act requires that such waivers shall be subject to annual review. We believe that nurse staffing is sufficiently important to the quality of care of residents that the waiver should only be continued after one year where there has been another request by the State, review by HCFA and specific approval for another one year period. Consequently, we propose in § 488.56(a)(4) that we would permit waivers of nurse staffing to extend for a period of no more than 12 months from the date the waiver goes into effect.

We propose to specify that a waiver can only be effective on or after the date of the facility's request for the waiver (but not earlier than that date), to ensure that facilities that are cited for being out of compliance with the nurse staffing requirements are not sheltered from sanctions by seeking and receiving retroactive waivers.

Also in § 488.56(a), we propose that HCFA would revoke the waiver effective on the date the facility is found to be out of compliance with any requirement of § 483.25. We believe that lack of compliance with a requirement under § 483.25 demonstrates the presence of a problem in the quality of nursing care in particular, and that it would not be appropriate to continue a waiver in such a facility.

We propose in § 488.57 to address how HCFA will monitor nurse staffing waivers granted by States and the circumstances under which HCFA would revoke the State's authority to grant nurse staffing waivers. Section 1919(b)(4)(C)(ii) of the Act states that a waiver granted by the State "* * * shall be accepted by the Secretary for purposes of this title to the same extent as is the State's certification of the facility." Moreover, section 1919(b)(4)(C)(iii) requires that "if the Secretary determines that a State has shown a clear pattern and practice of allowing waivers in the absence of diligent efforts by facilities to meet the staffing requirements, the Secretary shall assume and exercise the authority of the State to grant waivers." Therefore, we propose to establish requirements for HCFA's monitoring of State nurse staffing waivers and procedures that will govern HCFA's assumption and exercise of the State's authority to grant waivers.

We propose in § 488.57(a) that HCFA will monitor each nurse staffing waiver granted by each State under § 483.30(c) to determine if the waiver meets the criteria specified in paragraph (b) of this section. In proposing to monitor every waiver that is granted, we assumed that there would be relatively few waivers granted and that the potential for quality of care problems when such a waiver is granted is sufficient to justify individualized Federal oversight. However, we would be interested in receiving comments on whether the number of waivers granted may be too great to support our assumption and whether monitoring of a sample of the waivers would be sufficient to ensure adequate Federal oversight. In determining if a waiver meets the criteria of paragraph (b) of this paragraph, HCFA will evaluate the information used by the State to grant the waiver and the information available from any survey of the facility.

We believe that not only should the State not grant a waiver if the statutory requirements are not met, but that no waiver should be granted to a facility that has a recent history of noncompliance with the quality of care requirements, and that waivers should be revoked from facilities that are found out of compliance with quality of care requirements. These requirements are almost totally based on the quality of nursing and nursing related services, and where deficiencies exist in any of them, we believe that a State reasonably could conclude that health and safety of

residents would be adversely affected by a nurse staffing waiver. Therefore, we propose that HCFA will find that a waiver was inappropriate if HCFA determines that the statutory requirements for a waiver as found in § 483.30(d) were not met when the waiver was granted or if the State granted a waiver to a facility that had one or more deficiencies under § 483.25 (the quality of care requirements for facilities) at the last standard or extended survey prior to the waiver or at the time the waiver became effective.

When we find that the State has granted a waiver that is inappropriate as defined in paragraph (b) of § 488.57, we propose to notify the State of these findings, and HCFA may perform a survey to determine if resident health and safety is in jeopardy. In providing for the performance of a survey in this context, we considered specifying in the regulations that such a survey must be a standard rather than an abbreviated one. However, we anticipate that our survey requirements will be adaptable in such a manner as to allow a survey to be upgraded in thoroughness as evidence is uncovered to warrant such an action. Therefore, rather than prescribing at the outset the type of survey that must be conducted, we believe it is preferable to let the surveyor determine this as the survey progresses.

If we determine that resident health and safety is in jeopardy, we may subject the facility to adverse action notwithstanding the State's granting of a waiver of the nurse staffing requirements. We also propose that when we determine that the State has granted an inappropriate waiver, we will consider whether to revoke the State's authority to grant nurse staffing waivers. We want to place the emphasis in our process upon HCFA's monitoring of State waivers to minimize the likelihood that we will need to revoke a State's authority to grant waivers.

However, we propose procedures for revocation of a State's waiver authority in § 488.57(b) because the law, at section 1919(b)(4)(C)(iii) of the Act, requires us to revoke a State's authority to grant waivers if the Secretary determines that a State has shown a clear pattern and practice of allowing waivers in the absence of diligent efforts by the facility to meet nurse staffing requirements.

In § 488.57(b) we propose that our review of each nurse staffing waiver granted by the State will include an evaluation of whether the nursing facility has made a diligent effort to meet the nurse staffing requirements. We would provide that a facility has made a diligent effort to meet these requirements if it continuously attempts to recruit registered and/or licensed practical nurses to fill its vacancies by advertising, solicitation at educational programs and participating in job fairs within a radius of 100 miles of the facility, and when it offers salaries and benefits that are competitive with other nursing facilities within a 100 mile radius of the facility. We believe that these actions indicate a diligent effort.

We would assume and exercise the authority of the State to grant waivers if the State has demonstrated a clear pattern and practice of allowing waivers in the absence of diligent efforts to meet the nurse staffing requirements as specified in § 483.30 of this part. Our authority to do so is based on the requirements of section 1919(b)(4)(C)(iii) of the Act.

In § 488.57(b)(4), we propose to find that the State has demonstrated a "clear practice" of granting inappropriate waivers when HCFA's review, based upon the subsequent year's survey information or any other available information, shows that the State has a continuing practice over time of allowing waivers in the absence of diligent efforts by facilities to meet the nurse staffing requirements.

We propose to find that the State has demonstrated a "clear pattern" of allowing waivers in the absence of diligent efforts by facilities to meet the nurse staffing requirements when we determine that the State has granted waivers to more than five facilities or 5 percent of all facilities (whichever is greater) in the absence of diligent efforts by the facilities to comply with the nurse staffing requirements. We chose five or 5 percent of all facilities (whichever is greater) for this definition of a clear pattern because we thought that it was a number that was large enough so that it could reasonably be used to define a pattern, yet small enough to limit the scope of the review to reasonable levels. We request public comment on this definition for this purpose, and are particularly interested in data that would reflect the prevalence of facilities meeting the quality of care requirements in the absence of mandated nurse staffing.

When we find that the State has demonstrated a clear pattern and practice of allowing waivers in the absence of diligent efforts by facilities to meet the nurse staffing requirements, we would advise the State that HCFA intends to revoke the State's waiver authority. HCFA would allow the State to retain its authority to grant waivers only if, within 30 days of receiving this notification, the State submits evidence satisfactory to HCFA's Administrator which demonstrates diligent efforts by the facilities in question to meet the staffing requirements. We are interested in receiving comments on whether 30 days is a reasonable period of time to demonstrate that the State's waiver process is acceptable. We would publish a notice of the revocation of the State's authority in a Statewide periodical or the major newspapers of the State. The notice would include the effective date of the revocation, a statement that waivers granted by the State remain in effect until their expiration date or until the date that HCFA specifically revokes them (whichever comes first) and the procedures by which a facility may apply to HCFA for a waiver of the nurse staffing requirements. We believe that this public notice process is necessary to enable facilities and the public to know the status of facilities' waivers after revocation of the State's authority.

We considered whether to include a mechanism for States to regain lost waiver authority. Although the statute does not address returning lost waiver authority, we assume Congress did not intend to cause a permanent loss. Because we do not anticipate that many States will lose their authority, we decided to reserve rulemaking until the need arises. In the event that we do revoke waiver authority from a State, we plan to revoke it for at least one full cycle of waivers, which will allow sufficient time for rulemaking.

Qualifications of Nursing Home Administrators

Sections 1819(f)(4) and 1919(f)(4) of the Act, added by section 4201 of OBRA '87, require that the Secretary establish standards to assure the quality of nursing home administrators. Section 1819(f)(4) of the Act applies to skilled nursing facilities (Medicare), and section 1919(f)(4) applies to nursing facilities (Medicaid).

In developing these requirements, we consulted a variety of groups with programs that impose or evaluate nursing home administrator standards. We have tried to develop standards that are stringent enough to assure quality administration yet flexible enough to accommodate the current system. We invite public comment on all aspects of this proposal, and particularly on whether the use of a competency evaluation (see discussion of § 483.85(d) below) would, in itself, be sufficient to ensure high quality administration.

We propose that a skilled nursing facility or nursing facility may not employ any person as a nursing home administrator unless that person meets the following requirements. In

§ 483.85(a), we propose that the individual meet the license requirements imposed by the State in which the facility is located.

We would require, in § 483.85(b), that a nursing home administrator have at least a baccalaureate degree. In developing this requirement, we considered several options. We considered requiring only a high school education. We decided, however, that the administrator of a nursing home must be able to understand the basics of nursing practice, Federal and State laws and regulations governing the operation of nursing facilities, licensing and payment programs, and general business practices. We do not believe that a high school education provides sufficient background to enable an individual to function adequately in this respect. We also considered requiring that administrators have a graduate degree in health care administration or the health sciences. We decided, however, that such a high level of training is not characteristic of nursing home administrators and is not necessary for the effective administration of a nursing facility. (While we have not required administrators to have advanced degrees, we note that States could make such a requirement if desired.) We, therefore, came to the conclusion that a bachelor's degree is a necessary, basic requirement for administrators of nursing homes. However, we invite public comment on whether the combination of a high school education and experience would be sufficient to enable an individual to be a competent administrator.

In § 483.85(c), we propose that individuals must complete to the State's satisfaction an internship program of at least 12 weeks duration. The internship will include practical training in daily facility operation and instruction in those areas determined by the State, but at least applicable standards of environmental health and safety; applicable Federal, State and local health and safety laws and regulations; State personnel licensing and/or registration requirements; general administration of an institution, including departmental organization and management; psychology of patient care; personal care and social services; therapeutic and supportive long term care and services; and community resources and interrelationships. We believe that these areas comprise the basic level of knowledge a nursing home administrator must have. We recognize that for those individuals who have managed a nursing home for at least 1 year such an internship program may be redundant, and we will not require that they complete the internship. We emphasize that the internship program may be taken while the individual is working towards his or her degree.

We believe that a standardized examination is necessary to determine the competency of potential administrators.

Therefore, in § 483.85(d), we propose to require that individuals pass with a score of at least 75 percent a State-selected standardized examination tailored to the State, a State-developed examination, or a national standardized examination.

Because we believe that continuing education is necessary to ensure that administrators remain effective, we would require, in § 483.85(e), that administrators satisfactorily complete 20 clock hours of continuing education for any calendar year in which an individual serves as an administrator.

We believe that most long-term care facility administrators are competent and capable; therefore, in § 483.85(f), we would provide that any individual who has been continuously employed as a long-term care facility administrator by the same facility for at least one year on the date of publication of the final rule is deemed to meet the requirements of § 483.85 with the following exceptions. (This 12-month timeframe is consistent with that proposed in § 483.85(c)(2), which would waive the internship requirement for an administrator with at least one year's management experience in a long-term care facility.) We would not deem long-term care facility administrators to meet State licensure requirements and continuing education requirements. The continuing education and licensure requirements indicate ongoing activities in which all administrators should participate, while the other requirements specify initial qualifications. We request public comment both on the overall acceptability of deeming current administrators to meet the requirements and on whether provisions in addition to licensure and continuing education should be excluded from such deeming.

Finally, in § 483.85(g) we propose that hospital administrators administering hospital-based nursing facilities may meet the current State requirements for hospital administrators in lieu of these requirements to the extent permitted under State law. Some States allow hospital administrators to run hospital-based nursing facilities. To require such individuals to meet these requirements could force hospital-based nursing facilities to hire separate administrators for the nursing facilities, which would impose an undue expense on these entities.

Notice of Medicaid Rights

Section 4211 of OBRA '87 added section 1919(e)(6) to the Act, which requires, as a condition of approval of its Medicaid State plan, that each State develop and periodically update a written notice of the rights and obligations of residents of nursing facilities (and spouses of such residents) under Medicaid. We would implement this statutory requirement in § 483.167. We would propose that the State must develop a written notice that contains the resident rights that are provided for under §§ 483.10, 483.12, 483.13, and 483.15 and must include any other right or obligation that is granted or imposed by the State under title XIX. These sections of the requirements governing nursing facilities that participate in Medicaid address the rights and obligations of residents with which facilities must comply to participate in Medicaid. We believe that these rights and obligations are those intended by the Congress to be included in the notice to be provided by the State under the law.

In § 483.167(b), we propose to require that the notice be updated as necessary to keep the applicants and residents and their spouses notified of Medicaid rights and obligations, and published in a Statewide periodical or the major newspapers of the State at least once every 12 months.

We would also propose that printed copies must be made available to the public upon request. We propose these requirements because we believe that Congress included this provision in the law to ensure that the public would be made aware of the rights and obligations of nursing facility residents. A requirement that the State publish the notice in a Statewide periodical and make copies available to the public is essential to fulfill this intent.

Notice of Transfer or Discharge

Existing § 483.12(a)(3) requires that before a facility transfers or discharges a resident, the facility must notify the resident and, if known, a family member or legal representative of the transfer or discharge and the reasons. Section 483.12(a)(5) specifies the contents of the written notice, including the resident's right to appeal the action to the State agency designated to handle these appeals. We believe that current regulations do not go far enough to spell out sufficiently to whom and how a resident can appeal such an action. For this reason, we would require that the

facility also include the following information in the notice.

In § 483.12(a)(6)(iv) we propose to add a new paragraph (D) to require that the facility include in its notice of discharge or transfer, the name, address and phone number of the State entity to which the resident or his or her legal representative can appeal the decision to discharge or transfer the resident from the facility, the hours of operation of that entity and the date and means by which the appeal must be filed.

Requirements Applicable to Coverage of Nursing Facility Services Under the Medicaid Program

Part 431 of our regulations, in subpart C, contain administrative and provider relations requirements that States must meet under the Medicaid program. Parts 440 and 441 of the regulations identify covered services and limits in those services. We propose to revise §§ 440.40, 440.140, 440.150, 440.250, 440.170, 440.220, and 441.100 to implement section 4211(f) of OBRA 87. That section makes changes, effective for services provided on or after October 1, 1990, to specific sections of title XIX which eliminate Medicaid coverage of "skilled nursing facility services" and "intermediate care facility services" (except for "intermediate care facilities for the mentally retarded or persons with related conditions"), and replace them with coverage of "nursing facility services." The changes in these sections of the regulations are proposed to conform the Federal regulations to the law.

The effect of these changes is to make "nursing facility services" a mandatory service for any population for which "skilled nursing facility services" have heretofore been mandatory. Therefore, the full range of nursing facility services, as we propose to define them in this proposed rule, would now have to be provided to categorically needy individuals age 21 and over. Further, in § 440.220(c), the State would now be required to provide coverage of home health services under Medicaid for any population for which it is required, or chooses, to provide coverage of "nursing facility" services.

In order to conform our regulations to the statute as revised by section 4211(b) of OBRA 87, we propose to revise § 440.40(a) to address "Nursing facility services for individuals age 21 or older (other than services in an institution for mental diseases)." We propose to eliminate the word "skilled" wherever it appears, to reflect that, after October 1, 1990, coverage of "skilled nursing facility care" is replaced by coverage of "nursing facility care." We propose the following changes to § 440.40(a) in addition to the change of the title.

We propose that "nursing facility services" include "skilled nursing care," "rehabilitation services," and "health related services above the level of room and board." The requirement that nursing facility services be "above the level of room and board" is a fundamental element of "intermediate care facility services" at current § 440.150(a)(1)(i). We indicate that the services must be "health related" to clarify that they must be related to a health problem caused by the resident's physical or mental condition.

We propose to revise § 440.40(a) to indicate that the level of care requirements of §§ 409.31 through 409.35 do not need to be met for nursing facility services to be covered. Those sections of the regulations defined "skilled nursing facility care" under Medicare and were used in this regulation to define "skilled nursing facility care" for Medicaid also. The inclusion of "health related services above the level of room and board" as "nursing facility services" would encompass services formerly defined as "skilled nursing facility services" since services that meet the requirements of §§ 409.31 through 409.35 clearly are "health related services above the level of room and board."

In § 440.40(a), we would provide that a distinct part of a facility that meets the requirements of our proposed § 440.40(a)(2) or § 440.40(a)(1)(C) could also provide nursing facility services.

We propose to permit, at § 440.40(a), that nursing facility services may be provided in a distinct part of a facility other than a nursing facility, only if the distinct part—

- Meets all requirements for a nursing facility under subpart B of part 483;
- Is an identifiable unit, such as an entire ward, wing, floor, or building;
- Consists of all beds and related facilities in the unit;
- Houses all recipients for whom payment is being made for nursing facility services; and
- Is approved in writing by the State survey agency.

These requirements are comparable to those currently applicable to intermediate care facility services in distinct parts at § 440.150(d) and we believe that they are as applicable to "nursing facility services" as they were to "intermediate care facility services."

In § 440.40(a) (3), we would permit services provided in Christian Science sanatoria to be considered "nursing facility services." This adopts the current provision at § 440.150(b) (1) under which such services are considered "intermediate care facility services." We would also permit services provided on Indian reservations by facilities that furnish on a regular basis, health related services and are certified to meet the standards in subpart B of part 483 to be considered "nursing facility services." This adopts the current provision at § 440.150(b) under which such services are considered "intermediate care facility services."

In § 440.70(c), which defines a recipient's place of residence for Medicaid home health services, we propose to delete the existing references to home health services in intermediate care facilities, and to add nursing facilities to the list of facilities that cannot be considered a recipient's place of residence for home health coverage purposes.

We propose at § 440.140 to eliminate the discussion of "intermediate care facility services" in institutions for mental diseases, and to delete the word "skilled" from "skilled nursing facility services", to comply with the changes to the statute. Specifically, we propose to delete § 440.140(c), which discusses coverage of "intermediate care facilities for individuals age 65 or over in institutions for mental diseases", and to delete the word "skilled" from § 440.140.(b) to comply with the statute.

In § 440.140(a), we propose to revise the definition of an "institution for mental diseases" to comply with the changes made by section 411(k) of the Medicare Catastrophic Coverage Act of 1988 (Pub. L. 100–360). Specifically, we propose that an institution for mental diseases would mean a hospital, nursing facility or other institution of more than 16 beds that is primarily engaged in providing diagnosis, treatment, or care of persons with mental diseases, including medical attention, nursing care and related services. This definition mirrors the statute.

We propose to revise the title and content of § 440.150 to discuss only "intermediate care facility services for the mentally retarded or persons with related conditions" (ICF/MR services). The current section discusses "intermediate care facility services", which, except for ICF/MR services, cease to exist as a benefit on October 1, 1990. Specifically, we propose to change the title of § 440.150 to "Intermediate care facilities services for the mentally retarded or persons with related conditions." Moreover, we propose to delete § 440.150(a), (b), and (f). The content of these sections has been moved to our new definition of "nursing facility services" at § 440.40 as we previously indicated.

We propose to define ICF/MR services as they are currently defined. The only changes we have made are organizational, and to indicate that the requirements apply only to ICFs/MR.

We propose to delete the word "skilled" from the discussion of "skilled nursing facility services" in §§ 440.170, 440.220, 440.250, and 441.100 to conform the current regulations with the statute.

The changes we propose in this NPRM do not encompass all of the changes to the Federal regulations that must be made to conform the regulations to the statute. There will be other changes made to other sections as appropriate.

"Swing-Bed" Hospital Requirements

Current regulations at § 482.66 contain special requirements that hospital providers must meet in order to be approved to provide extended care services (i.e., to be approved as "swing-bed" facilities). These regulations provide that to participate in the swing-bed program, facilities must have fewer than 100 beds, excluding beds for newborns and beds in intensive care type inpatient units or distinct parts. Facilities of from 50 to 99 beds must meet additional requirements. They must have availability agreements with SNFs in the same geographic area. Once notified of the date a SNF bed becomes available, the extended care patient must be transferred within 5 days of the date unless the patient's physician certifies that the transfer is not medically appropriate.

OBRA '87 enacted additional requirements that long term care facilities must meet in order to participate in Medicare or Medicaid, or both, as a skilled nursing facility. On February 2, 1989, we published regulations that implemented many of these additional statutory requirements at 42 CFR part 483. We have now considered which of the additional requirements or the new requirements for skilled nursing facilities at 42 CFR part 483 should be added to the requirements to be met for a hospital to be approved as a swing-bed facility.

In § 482.66(b), we propose to require that in order to receive HCFA approval to provide skilled nursing facility services, hospitals providing long term care services ("swing-bed hospitals") must meet the following requirements for skilled nursing facilities that participate in Medicare:

- Resident rights (§ 483.10(b) (3)–(6), (d), (e), (h), (i), (j), (l), and (m));
- Admissions, transfer and discharge rights (§ 483.12(a) (1)–(4) and (6)–(7));
- Resident behavior and facility practices (§ 483.13);
- Resident activities (§ 483.15(f));
- Social services (§ 483.15(g));
- Discharge planning (§ 483.20(e));
- Specialized rehabilitative services (§ 483.45);
- Dental Services (§ 483.55).

Essentially, these are the same requirements that are specified in the current § 482.66(b), with the citations updated to reflect the recodification of the long-term care facility requirements.

We propose to require that a swing-bed hospital meet these SNF requirements because we believe that they are necessary to ensure that the care provided by these hospitals to patients who are receiving skilled nursing facility services meets the statutory requirements that apply to care that would otherwise be provided in a skilled nursing facility. We did not require that other SNF requirements be met because we did not consider them necessary in light of the fact that the swing-beds are located in hospitals that meet Medicare requirements; however, we are interested in receiving comments on whether the requirements we propose to use or another set of requirements would be the most appropriate for ensuring quality of care.

We are specifically requesting comment on whether to require that swing-bed hospitals meet the nurse aide training and competency evaluation requirements and preadmission screening and annual resident review (PASARR) requirements that were imposed by OBRA '87 on nursing facilities or any other SNF requirement. Section 1883(f) of the Act permits us to exclude swing-bed hospitals from nursing facility requirements that "* * * the Secretary determines are inappropriate in the case of these services being furnished by a hospital under this section."

We believe that the nurse aide training and competency evaluation requirements and the PASARR requirements may be inappropriate for patients of swing-bed hospitals. These providers are certified to participate as hospitals, and as such provide a higher level of care than do nursing facilities and are less reliant upon nurse aides to provide care to patients. Moreover, we are not aware of any problems that have been cited by Congress or other sources with regard to the quality of nurse aide care or the improper placement of mentally ill or mentally retarded individuals in swing-bed facilities. However, if we are convinced by commenters that these requirements are appropriate for swing-bed hospitals, we will impose them in the final rule.

We are also soliciting comments on whether or not explicitly to include the quality of care requirements found at § 483.25 in the swing-bed requirements. The requirements at § 483.25 are the result of the Institute of Medicine recommendations which called for both positive and negative outcome measure of quality long-term care services. Specifically, they give the Secretary and the States authority to sanction the facility when negative outcomes result in poor resident care (e.g., pressure sores, inappropriate use of psychoactive drugs, urinary catheters, naso-gastric tubes, etc.) or when positive outcomes do not occur. We are not including these requirements in the proposed rule because we believe there is no evidence that the health care problems these outcome measures are directed toward are significant problems in small rural hospitals. We have reached this conclusion because the outcome standards found at § 483.25 are primarily directed toward long-term health care issues and swing bed residents tend to receive more medically oriented care for a shorter time than residents of SNFs and NFs.

Response to Comments

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

Revisions to the Regulations

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

1. In part 418, § 418.98, we would change "ICF" to "NF" to reflect OBRA '87 terminology.

2. In part 440, we would revise §§ 440.40, 440.70, 440.140, 440.150, 440.170, and 440.250 to reflect the OBRA'87 elimination of Medicaid coverage of skilled nursing facility and intermediate care facility services and the replacement with coverage of "nursing facility services."

3. In part 441, we would revise § 441.100 to reflect use of the same OBRA '87 term, "nursing facility services" described above.

4. In part 482, we would revise § 482.66(b) by adding requirements that hospitals providing long term care services ("swing-bed hospitals") must meet to be approved by HCFA to provide skilled nursing facility services.

5. In part 483, we would revise § 483.12 by adding additional items to be included in the discharge notice.

6. In § 483.13, we would specify requirements for the use of physical and chemical restraints in nursing facilities.

7. In § 483.30, we would include the nurse waiver requirements of OBRA '87.

8. We would add new § 483.85 to subpart B to include qualifications of nursing home administrators as required by OBRA '87.

9. In subpart D of part 483, we would add §§ 483.148, 483.165 and 483.167 to include State and State agency requirements concerning waivers of nurse staffing requirements and notice of Medicaid rights.

10. In § 488.56, we would revise the text to include OBRA '87 requirements concerning nurse staffing waivers.

11. In part 488, we would add new § 488.57 to specify when we will revoke a State's authority to grant nurse staffing waivers.

Regulatory Impact Statement

Executive Order 12291 (E.O. 12291) requires us to prepare and publish a 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 regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), unless the Secretary certifies that a regulation will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we consider all SNFs and NFs to be small entities. Individuals and States are not included in the definition of a small entity.

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

This rule would conform the regulations to certain 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. Although we believe that no significant costs would be associated with these provisions, we have identified the following provisions as being the more controversial sections of the law/regulations which may also possibly result in incremental costs:

- Use of physical and chemical restraints and psychopharmacologic drugs for nursing facility.

Sections 1819(c)(1)(A)(ii) (Medicare) and 1919(c)(1)(A)(ii) (Medicaid) of the Act specify that residents of nursing facilities have the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms. Among other things we have proposed the following requirements:

+ To permit use of restraints if they are absolutely necessary to protect the resident or others from injury in an emergency.
+ Require that restraints be used no longer than 12 consecutive hours in an emergency situation.
+ Require the use of physical restraints that are designed and used so as not to cause physical injury to the resident and so as to cause the least possible discomfort.
+ Require that the drug review be conducted by an independent, external consultant (who is a physician with training or experience in geriatrics or psychopharmacology). We estimate these reviews will cost approximately $35 million per year. We base this estimate on 1.5 million Medicare and Medicaid residents in long term care facilities. We estimate that 50 percent of these residents are receiving psychoactive drugs. We estimate that the reviews will take an average of one-half hour and that they will cost approximately $100 per hour.
+ Require that continued use of drugs in an emergency situation be reevaluated by a physician no later than 12 hours after the initial order to ensure that the drug continues to be appropriate.

- State and Federal waivers of nurse staffing requirements.

Section 1819(b)(4)(C)(ii) authorizes the Secretary to waive the requirement that a Medicare SNF use a registered professional nurse for more than 40 hours a week if certain conditions in section 1819(b)(4)(C)(ii) of the Act (implemented by regulations at § 483.30(d)) are met by the facility. Section 1919(b)(4)(C)(ii) gives the State the authority (with oversight by the Secretary) to waive the 24-hour licensed nursing requirement or the registered professional nurse requirement in a Medicaid NF if certain criteria specified in section 1919(b)(4)(C)(ii)(I)–(III) (implemented by regulations at § 483.30(c)) are met. We are proposing the following requirements that we believe may result in incremental costs in this provision:

+ Require a waiver to be granted only when a facility has been in compliance with all of the requirements of § 483.25 both at the last standard or extended survey and at the time the waiver is to be effective.
+ Require a facility to attempt continuously to recruit registered and/or licensed practical nurses to fill its vacancies by advertising, soliciting at educational programs and participating in job fairs within a radius of 100 miles of the facility, and where it offers salaries and benefits that are competitive with other facilities of the same type within a 100 mile radius of the facility.
+ Require the above-mentioned procedures to be followed by States when HCFA reviews each nurse staffing waiver granted by the State. If these criteria are not followed and there is a clear pattern (the greater of five or 5 percent of all facilities) and practice of allowing waivers in the absence of diligent efforts, HCFA may revoke the State's authority.
+ Require a Medicaid agency to designate an entity within the State to grant waivers of the 24 hour nurse staffing requirements.
+ Require a facility receiving a waiver for not having a registered nurse on staff to designate a licensed practical nurse to serve as the health services supervisor.
+ Require a facility receiving a waiver for not having a registered nurse on staff to contract with a registered nurse to conduct or coordinate resident assessments.

While we are unable to make a precise estimate at this time of the costs of the combined provisions, we note that these provisions do not serve to introduce the waiver process itself, but merely define in greater detail a few specific operational aspects of that process. The waiver process itself has already been established in regulations by the February 2 interim final rule, which included a general discussion of the regulatory impact of the nurse staffing requirements (54 FR 5355–56).

- Qualifications of nursing home administrators.

Sections 1819(f)(4) and 1919(f)(4) of the Act specify that the Secretary establish standards to ensure the quality of nursing home administrators. We have proposed the following requirements to fulfill the requirements of the above-mentioned statute:

+ Require administrators to complete an internship program of at least 12 weeks duration.

+ Require administrators to be licensed in accordance with State law.

+ Require administrators to have at least a baccalaureate degree.

We believe that many States require qualifications equal to or higher than these proposed requirements for licensing administrators. Therefore we do not expect any incremental costs as a result of these provisions. However, we are interested in receiving public comments on whether additional costs would occur due to these nursing home administrator standards.

• Notice of Medicaid rights.

Section 1919(e)(6) of the Act requires each State to develop and periodically update a written notice of the rights and obligations of residents of nursing facilities (and spouses of such residents) under Medicaid. We do not believe facilities will incur significant costs as a result of providing residents with a copy of their rights. However, there may be minor incremental costs annually as a result of the requirement that facilities provide and publish annually a copy of these rights in a Statewide periodical or the major newspapers of the State.

Although we believe that these provisions would result in some costs, we believe that the costs would be insignificant in light of the expected increase in the quality of health care to Medicare and Medicaid beneficiaries. In that this discussion of costs and benefits is not conclusive, we encourage comments and any applicable data concerning any provisions if there is a perception that they may result in significant increased costs.

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

Information Collection Requirements

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

List of Subjects

42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 440

Grant programs-health, Medicaid.

42 CFR Part 441

Family planning, Grant programs-health, Infants and children, Medicaid, Penalties, Prescription drugs, Reporting and recordkeeping requirements.

42 CFR Part 482

Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 483

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

42 CFR Part 488

Health facilities, Survey and certification, Forms and guidelines.

42 CFR chapter IV would be amended as follows:

PART 418—HOSPICE CARE

Part 418 is amended as follows:

1. The authority citation for part 418 continues to read as follows:

Authority: Secs. 1102, 1811–1814, 1861–1866, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395c–1–953, 1395xf1395cc and 1395hh).

2. Section 418.98 is amended by revising paragraph (b) as follows:

§ 418.98 Condition of participation—Short term inpatient care.

* * * * *

(b) *Standard: Inpatient care for respite purposes.* Inpatient care for respite purposes must be provided by one of the following:

(1) A provider specified in paragraph (a) of this section.

(2) A NF that also meets the standards specified in § 418.100 (a) and (f) regarding 24-hour nursing service and patient areas.

* * * * *

PART 440—SERVICES: GENERAL PROVISIONS

Part 440 is amended as follows:

1. The authority citation for part 440 continues to read as follows.

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

2. The table of contents for part 440 is amended by revising §§ 440.40, 440.140, and 440.150 to read as follows:

Subpart A—Definitions

Sec.

* * * * *

440.40 Nursing facility services for individuals age 21 or older (other than services in an institution for mental diseases) and EPSDT.

* * * * *

440.140 Inpatient hospital services and nursing facility services for individuals age 65 or older in institutions for mental diseases.

* * * * *

440.15 Intermediate care facility services, for the mentally retarded or persons with related conditions.

3. Section 440.40 is amended by revising the title and paragraph (a) as follows:

§ 440.40 Nursing facility services for individuals age 21 or older (other than services in an institution for mental diseases) and EPSDT.

(a) *Nursing facility services.* (1) *Nursing facility services for individuals age 21 or older, other than services in an institution for mental diseases,* means services that are—

(i)

(A) Skilled nursing care and related services;

(B) Rehabilitation services; or

(C) Health related services above the level of room and board;

(ii) Needed on a daily basis and required to be provided on an impatient basis;

(iii) Provided by (A) a facility or distinct part of a facility that is certified to meet the requirements for participation under subpart B of part 483 of this chapter, as evidenced by a valid agreement between the Medicaid agency and the facility for providing skilled nursing facility services and making payments for services under the plan;

(B) A distinct part of a facility that meets the requirements of § 440.40(a)(2); or

(C) If specified in the State plan, a swing-bed hospital that has an approval from HCFA to furnish skilled nursing

facility services in the Medicare program; and

(iv) Ordered by and provided under the direction of a physician.

(2) Nursing facility services may only be provided in a distinct part of a facility other than a nursing facility if the distinct part—

(i) Meets all requirements for a nursing facility under subpart B of part 483 of this subchapter;

(ii) Is an identifiable unit, such as an entire ward, wing, floor or building;

(iii) Consists of all beds and related facilities in the unit;

(iv) Houses all receipts for whom payment is being made for nursing facility services; and

(v) Is approved in writing by the survey agency.

(3) Nursing facility services include services—

(i) Considered appropriate by the State and provided by a Christian Science sanatorium operated, or listed and certified, by the First Church of Christ, Scientist, Boston, Mass.; or

(ii) Provided by a facility located on an Indian reservation that—

(A) Furnishes, on a regular basis, health-related services; and

(B) Is certified by the Secretary to meet the standards in subpart B of part 483.

* * * * *

4. Section 440.70 is amended by revising paragraph (c) to read as follows:

§ 440.70 Home health services.

* * * * *

(c) A recipient's place of residence, for home health services, does not include a hospital, skilled nursing facility, or nursing facility.

5. Section 440.140 is revised as follows:

§ 440.140 Inpatient hospital services and nursing facility services for individuals age 65 or older in institutions for mental diseases.

(a) *Inpatient hospital services.* (1) *Inpatient hospital services for individuals age 65 or older in institutions for mental diseases* means services provided under the direction of a physician for the care and treatment of recipients in an institution for mental diseases that meets the requirements specified in § 482.60 (b), (c), and (e) of this chapter and—

(i) Meets the requirements for utilization review in § 482.30 (a), (b), (d), and (e) of this chapter; or

(ii) Has been granted a waiver of those utilization review requirements under section 1903(i)(4) and subpart H of part 456 of this subchapter.

(2) *Institution for mental diseases* means a hospital, nursing facility or other institution of more than 16 beds that is primarily engaged in providing diagnosis, treatment, or care of individuals with mental diseases, including medical attention, nursing care, and related services.

(b) *Nursing facility services. Nursing facility services for individuals age 65 or older in institutions for mental diseases* means nursing facility services as defined in § 440.40 that are provided in institutions for mental diseases, as defined in paragraph (a) of this section.

6. Section 440.150 is revised as follows:

§ 440.150 Intermediate care facility services for the mentally retarded or persons with related conditions.

(a) "Intermediate care facility services" include services in an institution for the mentally retarded or persons with related conditions if—

(1) The primary purpose of the institution is to provide health or rehabilitative services for mentally retarded individuals or persons with related conditions;

(2) The institution meets the standards in subpart D of part 483 of this chapter; and

(3) The mentally retarded recipient for whom payment is requested is receiving active treatment as specified in § 483.440.

(b) "Intermediate care facility services for the mentally retarded or persons with related conditions" may include services provided in a distinct part of a facility other than an intermediate care facility if the distinct part—

(1) Meets all requirements for an intermediate care facility for the mentally retarded or persons with related conditions;

(2) Is an identifiable unit, such as an entire ward, wing, floor, or building;

(3) Consists of all beds and related facilities in the unit;

(4) Houses all recipients for whom payment is being made for intermediate care facility services, except as provided in paragraph (c) of this section;

(5) Is clearly identified; and

(6) Is approved in writing by the survey agency.

(c) If a State includes as intermediate care facility services for the mentally retarded or persons with related conditions those services provided by a distinct part of a facility other than an intermediate care facility for the mentally retarded or persons with related conditions, it may not require transfer of a recipient within or between facilities if, in the opinion of the attending physician, it might be harmful to the physical or mental health of the recipient.

§ 440.170 [Amended]

7. In § 440.170(d), the term "skilled" is removed each place it appears.

§ 440.250 [Amended]

8–9. In § 440.250 (a), the term "skilled" is removed.

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

Part 441 is amended as follows:

1. The authority citation for part 441 continues to read as follows

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

Supart C—Medicaid for Individuals Age 65 or Over in Institutions for Mental Diseases

2. In subpart C, § 441.100 is revised to read as follows:

§ 441.100 Basis and purpose.

This subpart implements section 1905(a)(14) of the Act, which authorizes State plans to provide for inpatient hospital services and nursing facility services for individuals age 65 or older in an institution for mental diseases, and sections 1902(a)(20) (B) and (C) and 1902(a)(21), which prescribe the conditions a State must meet to offer these services. (See § 431.620 of this subchapter for regulations implementing section 1902(a)(20)(A), which prescribe interagency requirements related to these services.)

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

Part 482 is amended as follows:

1. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102, 1138, 1814(a)(6), 1861 (e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1864, 1871, 1883, 1886, 1902(a)(30), and 1905(a) of the Social Security Act (42 U.S.C. 1302, 1338, 1395f(a)(6), 1395x (e), (f), (k), (r), (v)(1)(g), (z) and (ee), 1395aa, 1395hh, 1395tt, 1395ww, 1396a(a)(30), and 1396(a)).

2. Section 482.66 is amended by revising paragraph (b) to read as follows:

§ 482.66 Condition of participation—Special requirements for hospital providers of long-term care services ("swingbeds").

* * * * *

(b) Standard: Skilled nursing facility services. The facility is substantially in compliance with the following skilled nursing facility requirements, contained

in subpart B of part 483 of this subchapter:

(1) Resident rights (§ 483.10(b)(3)–(6), (d), (e), (h), (i), (j), (l), and (m));

(2) Admissions, transfer and discharge rights (§ 483.12(a) (1)–(4) and (6)–(7));

(3) Resident behavior and facility practices (§ 483.13);

(4) Resident activities (§ 483.15(f));

(5) Social services (§ 483.15(g));

(6) Discharge planning (§ 483.20(e));

(7) Specialized rehabilitative services (§ 483.45); and

(8) Dental Services (§ 483.55).

PART 483—CONDITIONS OF PARTICIPATION AND REQUIREMENTS FOR LONG TERM CARE FACILITIES

Part 483 in effect as of April 1, 1992 (See 56 FR 48826, Sept. 26, 1991)

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

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

2. The table of contents for part 483 is amended by adding a new § 483.85 to subpart B, and adding new §§ 483.148, 483.165 and 483.167 to subpart D to read as follows:

* * * * *

Subpart B—Requirements for Long Term Care Facilities

Sec.

483.85 Qualifications of nursing home administrators.

* * * * *

Subpart D—Requirements That Must Be Met by States and State Agencies

483.148 Scope and basis.

* * * * *

483.165 State waivers of nurse staffing requirements for Medicaid-only nursing facilities and distinct parts.

483.167 Notice of Medicaid rights.

3. In subpart B, the introductory text of § 483.12(a)(6) and paragraph (a)(6)(iv) are revised to read as follows:

§ 483.12 Admission, transfer and discharge rights.

(a) Transfer and discharge—

* * * * *

(6) *Contents of the notice.* For nursing facilities, the written notice specified in paragraph (a)(3) of this section must include the following:

* * * * *

(iv) The name, address and phone number of the State entity to which the resident can appeal the decision to discharge or transfer the resident from the facility, the hours of operation of that entity and the date and means by which the appeal must be filed.

* * * * *

4. In subpart B, § 483.13 is amended by revising paragraph (a) to read as follows:

§ 483.13 Resident behavior and facility practices.

(a) *Restraints*—(1) *Physical restraints*—(i) Definition: A physical restraint is any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident's body that the resident cannot remove easily, which restricts freedom of movement or access to his or her body.

(ii) Limitations on use. The facility may only impose physical restraints to treat the resident's medical symptoms, which include but are not limited to physical, emotional, and behavioral problems, if the restraint is—

(A) Necessary to ensure the safety of the resident or of other residents;

(B) Imposed in accordance with a physician's written order specifying the circumstances and duration under which the restraint is to be used; and

(C) Not ordered on a standing, blanket, or "as needed" basis.

(iii) Nonemergency use. Restraints may not be ordered in nonemergency circumstances unless the restraints are applied so as to cause no physical injury and the least possible discomfort. Except when necessary to allow the conduct of a medical or surgical procedure, restraints may not be ordered in nonemergency circumstances unless the restraints—

(A) Enable the resident to reach his or her highest practicable physical, mental, and psychosocial well-being;

(B) Are used only as a last resort if the facility, after completing, implementing, and evaluating the resident's comprehensive assessment and plan of care determines that less restrictive means have failed; and

(C) Are used in accordance with the plan of care on the comprehensive assessment, which allows for their progressive removal or the progressive use of less restrictive means.

(iv) Emergency use.

(A) Restraints may not be ordered in emergency circumstances unless they are necessary to alleviate an unanticipated immediate and serious danger to the resident or other individuals in the facility.

(B) Emergency orders for restraints may not be in effect for longer than 12 hours and must be confirmed in writing as soon as possible.

(v) Notice for non-emergency use. If a restraint is used in a non-emergency, the facility must—

(A) Explain the use of the restraint to the resident, or, if the resident has been declared to be legally incompetent or cannot understand his or her rights, to the resident's legal representative, in accordance with § 483.10(d) and State law;

(B) Explain the resident's right to refuse the restraint in accordance with § 483.10(b)(4); and

(C) Obtain the written consent of the resident or the resident's legal representative.

(vi) Restraints may be applied only—

(A) By staff who are trained in their use; and

(B) If the facility assures that the resident's condition will be closely monitored.

(vii) At a minimum, for a resident placed in a restraint, the factility must—

(A) Check the resident at least every 30 minutes;

(B) Assist the resident as often as is necessary for the resident's safety, comfort, exercises and elimination needs;

(C) Provide an opportunity for motion, exercise and elimination for not less than 10 minutes during each two hour period in which a restraint is employed;

(D) Release the resident from the restraint as quickly as possible; and

(E) Keep a record of restraint usage and checks.

(2) Definition of psychopharmacologic drug. In these regulations *psychopharmacologic Drug* means any drug prescribed with the intent of controlling mood, mental status or behavior.

(3) Any psychopharmacologic drug administered to a resident must—

(i) Be ordered by a physician who specifies the dose, duration and reason for the use of the drug;

(ii) Be used only as an integral part of the resident's comprehensive care plan that is directed specifically towards the elimination or modification of the symptoms for which the drugs are prescribed;

(iii) Not be used unless it can be justified in the clinical record that the potential beneficial effects of the drug clearly outweigh its potential harmful effects.

(iv) Be monitored closely, in conjunction with the drug regimen review requirements at § 483.60(e) for desired responses and adverse consequences by facility staff;

(v) Be gradually withdrawn at least semi-annually in a carefully monitored program conducted in conjunction with

the interdisciplinary team, unless clinical evidence demonstrates that this is contraindicated;

(vi) Be reviewed at least annually by a physician who has training or experience in geriatrics and psychopharmacology and who must not serve a facility with which he or she has had a contractual, financial, employment or familial relationship with the facility, its owner, its attending physicians, medical director, or administrator within any of the 36 consecutive months prior to the date of the review (This review may be conducted as part of the annual review and determination of residents for mental illness conducted in accordance with § 4833.114 of this part provided it is conducted by a physician with the above qualifications.);

(vii) Be used only when a record is maintained of the administration of the drug, the dose, the route of administration, side effect monitoring, a description of the behavior, mood or mental status which the drug is intended to alter, the effect of the drug on the behavior, mood and mental status of the resident, and any other change in behavior, mood, mental status or adverse drug reaction which occurs with the administration of the drug.

(4) Before a psychopharmacologic drug is used in a non-emergency situation, the facility must—

(i) Explain the use of the drug to the resident, or, if the resident has been declared to be legally incompetent or cannot understand his or her rights, to the resident's legal representative, in accordance with § 483.10(d) and State law;

(ii) Explain the resident's right to refuse the drug in accordance with § 483.10(b)(4); and

(iii) Obtain the written consent of the resident or the resident's legal representative.

(5) The drug review specified in paragraph (a) (3) (vi) of this section must—

(i) Determine whether—

(A) The drug has an appropriate indication for use;

(B) The dose is appropriate;

(C) The duration of therapy is appropriate;

(D) Valid justification exists for the use of chemical restraints as permitted under paragraph (a) (7) of this section;

(F) The benefits of using the drug outweigh the risk to the resident; and

(G) Non-drug therapy approaches have failed.

(ii) Be sent to the attending physician; and

(iii) Become a permanent part of the resident's clinical record;

(6) Chemical restraints. Except as provided in paragraph (a)(8) of this section, a facility may not use a chemical restraint.

(7) In these regulations *chemical restraint* means a psychopharmacologic drug, as defined under paragraph (a)(2) of this section, that is used for the purpose of discipline or convenience and not required to treat the resident's medical symptoms, including when the drug is used in one or more of the following ways:

(i) In excessive dose (including duplicate drug therapy);

(ii) For excessive duration;

(iii) Without adequate monitoring;

(iv) Without adequate indications for its use;

(v) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; and

(vi) In a manner that results in a decline in the resident's functional status.

(8) A chemical restraint may only be ordered in an emergency situation when necessary to ensure the physical safety of the resident or other residents.

(i) The orders must be in writing, signed by a physician who specifies the duration and circumstances under which the chemical restraint is to be used.

(ii) The orders may be oral when an emergency necessitates parenteral administration of the chemical restraint but only until a written order can reasonably be obtained.

(iii) Emergency orders for chemical restraints may—

(a) Not be in effect for more than 12 hours; and

(B) Be administered only if the resident is monitored continually for the first 30 minutes after administration and every 15 minutes thereafter and for as long as the resident is under the influence of the drug to ensure that any adverse side effects would be noticed and appropriate action taken as soon as possible.

* * * * *

5. In § 483.30, new paragraphs (b) (4) and (5) are added, paragraphs (c)(1) and (c)(7) are revised, and new paragraphs (c)(8), (c)(9), and (e) are added to read as follows:

§ 483.30 Nursing services.

* * * * *

(b) *Registered nurse.*

* * * * *

(4) When a waiver under paragraph (c) of this section results in a facility not having a registered nurse on staff, the facility must—

(i) Designate a licensed practical nurse to supervise nursing personnel;

(ii) Contract with a registered nurse to conduct or coordinate resident assessments and sign and certify the completion of the assessment as required by § 483.20(c)(1)(ii); and

(iii) Designate a licensed practical nurse with responsibility for the resident to participate in the development of a comprehensive care plan as required by § 483.20(d)(2))(ii).

(5) When a waiver under paragraph (d) results in the facility having a registered nurse on staff less than 7 days a week the facility must designate a licensed practical nurse to supervise nursing personnel in the absence of the registered nurse.

(c) *Nursing facilities: Waiver of requirement to provide licensed nurses on a 24-hour basis.* To the extent that a facility is unable to meet the requirements of paragraphs (a)(2) and (b)(1) of this section, a State may waive such requirements with respect to the facility if—

(1) The facility demonstrates to the satisfaction of the State that the facility has been unable to recruit appropriate personnel to meet the nurse staffing requirements for nursing facilities despite diligent efforts, as defined in paragraph (e) of this section.

* * * * *

(7) The facility, within 30 days of the notice of approval, posts in a prominent public location in the facility a notice of the services for which a nurse staffing waiver has been granted, the date of the expiration of the waiver and the name, address and phone number of the entity in the State to which complaints about the facility should be directed;

(8) Within 30 days of the notice of approval of the waiver, the facility notifies in writing each—

(i) New admission on legal representative that the facility has been granted a nurse staffing waiver; and

(ii) Current resident or legal representative of the services for which a nurse staffing waiver has been granted; and

(9) The facility maintains documentation of its continuing diligent effects to meet the nurse staffing requirements, and makes this documentation available to the State upon request.

* * * * *

(e) *Definition of diligent effort.* Diligent effort means that the facility can demonstrate that—

(1) It continuously attempts to recruit registered or licensed practical nurses, or both, to fill its vacancies by local and out-of-area advertising, solicitation at educational programs, and participation

in job fairs within a 100 mile radius of the facility; and

(2) It offers salaries and benefits that are competitive with the salaries and benefits offered by other nursing facilities that are located within a 100 mile radius of the facility.

6. A new § 483.85 is added to subpart B to read as follows:

§ 483.85 Qualifications of nursing home administrators.

A facility may not employ an individual as a nursing home administrator unless that individual and facility meet the requirements of this section.

(a) *State licensure.* The individual must be licensed to serve in a nursing home as an administrator in accordance with State law.

(b) *Education.* The individual must possess at least a baccalaureate degree.

(c) *Internship.* (1) The individual must complete to the State's satisfaction an internship of at least 12 weeks.

(2) The internship requirement is waived if the individual has at least one year of management experience in a nursing facility.

(3) The internship may be completed while the individual is working towards his or her degree.

(4) The internship will consist of practical training in daily facility operation and instruction in the following areas:

(i) Applicable standards of environmental health and safety;

(ii) Applicable Federal, State and local health and safety laws and regulations;

(iii) State personnel licensing and/or registration requirements;

(iv) General administration of an institution, including departmental organization and management;

(v) Psychology of patient care;

(vi) Personal care and social services;

(vii) Therapeutic and supportive long-term care and services;

(viii) Community resources and interrelationships; and

(ix) Any other areas determined by the State.

(d) *Examinations.* The individual must pass with a score of at least 75 percent one of the following:

(1) A State-selected standardized examination tailored to the State;

(2) A State-developed examination; or

(3) A national standardized examination.

(e) *Continuing education.* The individual must complete at least 20 clock hours of continuing education for any calendar year in which the individual serves as an administrator.

(f) *Individuals deemed to meet requirements.* Except for those requirements in paragraphs (a), (e), and (f) of this section, any individual continuously employed as a nursing home administrator by the same facility for at least one year on [date of publication of the final rule] is deemed to meet the requirements of this section.

(g) *Administrators of hospital-based nursing facilities.* To the extent permitted by State law, a licensed hospital administrator may serve as administrator of a hospital-based nursing facility without meeting the requirements of this section.

Subpart D—Requirements That Must Be Met by States and State Agencies

7. In part 483 the title of subpart D is revised to read as set forth above and a new § 483.148 is added to read as follows:

§ 483.148 Scope and basis.

(a) *Scope.* This subpart applies to the obligations and responsibilities of State survey agencies and Medicaid State agencies with respect to long term care facilities that participate in Medicare as skilled nursing facilities or in Medicaid as nursing facilities, or both. These obligations and responsibilities include licensure activities, survey activities, nurse aide training and competency evaluation programs, and any other activities relating to ensuring the quality of nursing facility care in Medicare or Medicaid participating facilities. Agencies that are responsible within a State for a particular function may delegate specified functions for which they are responsible to other entities as long as they fulfill their responsibility as defined in the law and maintain overall responsibility for the activity.

(b) *Basis.* (1) The requirements governing State waivers of the nurse staffing requirements of section 483.165 with respect to nursing facilities that participate in Medicaid are based upon section 1919(b)(4)(C)(ii) of the Act.

(2) The requirements of section 483.167 regarding the State's obligation to develop (and periodically update) a written notice of the Medicaid rights and obligations of residents of nursing facilities (and spouses of such residents) are based upon section 1919(e)(6) of the Act.

(3) The requirements concerning nurse aide training and competency evaluation in §§ 483.150 through 483.158 are based on sections 1819(e) (1) and (2) and 1919(e) (1) and (2) of the Act.

8. In subpart D, new §§ 483.165 and 483.167 are added to read as follows:

§ 483.165 State waivers of the nurse staffing requirements for Medicaid-only nursing facilities and distinct parts.

(a) *Designation of waiver authority.* The Medicaid agency must designate an entity within the State, including itself, responsible for granting waivers of the requirements of § 483.30 (a) and (b). The State may not delegate or subcontract the authority to grant nurse staffing waivers to an entity outside of the State government.

(b) *Nature of waivers that may be granted by States.* The State may grant a waiver of the requirement in § 483.30 (a) and (b) for nursing facility (or distinct part) that participates in Medicaid but does not participate in Medicare when, at the request of the nursing facility—

(1) The State finds that the nursing facility meets the criteria of § 483.30(c); and

(2) The facility has been in compliance with all requirements of § 483.25 during the 24 consecutive months prior to the effective date of the waiver.

(c) *Effective date.* The effective date of a waiver granted under this authority may not precede the date of the facility's request and expires on the earlier of:

(1) The 1 year anniversary of the effective date;

(2) The date by which the State becomes aware that the facility acquires sufficient nurse staffing to comply with the requirements without a waiver; or

(3) The date that the State determines, based on a routine or other survey, or other information, that the facility is out of compliance with any requirement of § 483.25 or determines by any other means that the health and safety of residents has become jeopardized by the continuance of the waiver.

(d) *Renewal of waivers.* A waiver granted under this authority may be renewed for a subsequent period of 12 months if the State, after full development and review of a facility's request for renewal, finds that—

(1) The facility continues to meet the criteria of § 483.30(c);

(2) The facility has not been out of compliance with an requirements of § 483.25 within the past waiver period; and

(3) Resident health and safety has not been adversely affected by the waiver.

(e) *Notice to HCFA.* The agency must provide HCFA within 30 days of the date of notice to the nursing facility with a copy of—

(1) Any notice to a facility granting a waiver of the requirements of § 483.30; and

(2) The information on which the State based its waiver of nurse staffing requirements.

(f) *Notice of nurse staffing waiver.* The State must notify the Long Term Care Ombudsman and the protection and advocacy system in the State for the mentally ill and the mentally retarded as well as the resident's immediate family of the granting of any nurse staffing waiver within 30 days of the date of notice of the waiver.

(g) For each nursing facility with an approved waiver in effect, the State must inspect the documenation maintained under § 483.30(c)(9) at least once during the year, at a time of the State's choosing.

§ 483.167 Notice of Medicaid rights.

The State must develop and update a written notice of the rights and obligations of residents of nursing facilities and spouses of such residents which meets the requirements of this section.

(a) *Content.* (1) The State must develop a written notice of the rights and obligations of residents of nursing facilities that receive payment under Medicaid.

(2) The notice must include the resident rights that are provided under §§ 483.10, 483.12, 483.13, and 483.15.

(3) The notice must include any other right granted or obligation imposed by the State.

(b) *Update and publication.* The State must—

(1) Update the notice as necessary to keep the residents and spouses notified of their Medicaid rights and obligations;

(2) Publish the notice in a Statewide periodical or the major newspapers of the State at least once every 12 months;

(3) Provide the notice to residents and their spouses and to applicants to nursing facilities and their spouses; and

(4) Make available to the public upon request printed copies of the notice.

PART 488—SURVEY AND CERTIFICATION PROCEDURES

Part 488 in effect as of April 1, 1992 (see 56 FR 48826, Sept. 26, 1992) is amended as follows:

1. The authority citation for part 488 continues to read as follows:

Authority: Sec. 1102, 1814, 1819, 1961, 1865, 1866, 1871, 1880, 1881, 1883, 1902(a) (28) and 1919 of the Social Security Act (42 U.S.C. 1302, 1395f, 1395i-3, 1396r, 1395x, 1395bb, 1395cc, 1395hh, 1395qq, 1395rr, 1395tt, and 1396a(a)).

2. The table of contents for part 488, subpart B, is amended by revising the title of § 488.56 and adding a new § 488.57 to read as follows:

Sec.

* * * * *

488.56 Special waivers of nursing requirements in skilled nursing facilities.

488.57 Medicaid nursing facilities: HCFA monitoring of State waivers of nurse staffing requirements and revocation of State waiver authority.

* * * * *

3. In subpart B, § 488.56 is revised as follows:

§ 488.56 Special waivers of nursing requirements in skilled nursing facilities.

(a) *Medicare skilled nursing facility waivers: requirements, duration and effective date.* Upon the request of a State, HCFA will decide whether to waive the requirement to have a registered nurse on duty more than 40 hours per week, as specified in § 483.30(d) of this chapter, in skilled nursing facilities. Any waiver granted by HCFA will—

(1) Be granted only if HCFA determines that the skilled nursing facility meets the requirements of § 483.30(d);

(2) Be granted only if the skilled nursing facility has made and continues to make a diligent effort to comply with the requirement to have a registered nurse on duty more than 40 hours per week, but such compliance is impeded by the unavailability of registered nurses in the area. A facility has made a diligent effort when it demonstrates that it—

(i) Continuously attempts to recruit registered or licensed practical nurses, or both, to fill its vacancies by advertising, solicitation at educational programs, and participation in job fairs within a radius of 100 miles of the facility; and

(ii) Offers salaries and benefits that are competitive with the salaries and benefits offered by other skilled nursing facilities that are located within a 100 mile radius of the facility;

(3) Be granted only if the facility has been in compliance with all requirements of § 483.25 at the—

(i) Last standard or extended survey of the facility; and

(ii) Time the waiver is to be effective.

(4) Extend for a period not exceeding 12 months from the effective date;

(5) Be effective on or after the date of the facility's request for the waiver (but not earlier than that date); and

(6) Be revoked by HCFA effective on the date that the facility is found to be out of compliance with any requirement of § 483.25

4. A new § 488.57 is added to read as follows:

§ 488.57 Medicaid nursing facilities: HCFA monitoring of State waivers of nurse staffing requirements and revocation of State waiver authority.

(a) HCFA will monitor each nurse staffing waiver granted by a State under § 483.30(c) to determine if the waiver meets the criteria specified in paragraph (b) of this section.

(1) HCFA will make a determination on whether a waiver meets the criteria in paragraph (b)(2) of this section by evaluating the information—

(i) On which the State based its decision to grant the waiver; and

(ii) From any survey of the facility.

(2) HCFA will conclude that a waiver is not appropriate if:

(i) The Secretary determines that any of the statutory requirements for the granting of the waiver specified in § 483.30(c), were not met at the time the waiver was granted; or

(ii) The State granted a waiver to a facility that had one or more deficiencies under § 483.25 at the last standard or extended survey prior to the waiver or at the time the waiver became effective, or failed to revoke a waiver from a facility that is found to be out of compliance with any requirement of § 483.25 during the term of the waiver.

(3) If HCFA finds that the State has granted a waiver that was not appropriate, under paragraph (b)(2) of this section, HCFA—

(i) Will notify the State of its findings; and

(ii) May perform a survey to determine if patient health or safety is in jeopardy.

(4) If HCFA determines that patient health or safety is jeopardized, in accordance with paragraph (a)(3)(ii) of this section, HCFA may subject the facility to adverse actions notwithstanding the State's granting of a waiver of the nurse staffing requirements.

(b) Revocation of the State's authority to grant nurse staffing waivers. (1) HCFA's review of each nurse staffing waiver granted by the State includes an evaluation of whether the facility has made, and is making, a diligent effort to meet the nurse staffing requirements for nursing facilities.

(2) A facility is deemed to have made, or be making a diligent effort to meet the nurse staffing requirements for nursing facilities when it meets the requirements in § 483.30(c)(6) of this subchapter.

(3) Under the procedures specified in paragraphs (b) (6) through (8) of this section, HCFA will assume and exercise the authority of the State to grant waivers if HCFA finds that the State has demonstrated a clear pattern and

practice of allowing waivers in the absence of diligent efforts by facilities to meet the nurse staffing requirements, as specified in paragraph (b) (4) and (5) of this section.

(4) HCFA will find that the State has demonstrated a "clear practice" of granting inappropriate waivers when HCFA's review, based upon the subsequent year's survey information and any other available information on the granting of waivers, shows that the State continues to have a practice of allowing waivers in the absence of diligent efforts by facilities to meet the nurse staffing requirements.

(5) If HCFA finds that the State has granted waivers to more than 5 facilities or 5 percent of all certified facilities (whichever is greater) in the absence of diligent efforts of the facilities to meet the nurse staffing requirements, HCFA will determine that the State has demonstrated a "clear pattern" of allowing waivers in the absence of diligent efforts by facilities to meet the staffing requirements.

(6) When the HCFA finds under paragraphs (b) (4) and (5) of this section that the State has demonstratead a clear pattern and practice of allowing inapproprite waivers, HCFA will notify the State that HCFA intends to assume and exercise the State's authority to grant waivers.

(7) HCFA may allow the State to retain its authority to grant waivers only if, within 30 days of receiving HCFA notification specified in paragraph (b)(6) of this section, the State submits evidence satisfactory to the Administrator of HCFA which demonstrates diligent efforts by the facilities in question to met the staffing requirements.

(8) HCFA will publish a notice of the revocation of the State's authority to allow waivers of the nurse staffing requirements in a Statewide periodical or the major newspapers of the State, which includes—

(i) The effective date of the revocation;

(ii) A statement that waivers granted by the State remain in effect until their expiration the date the HCFA specifically revokes them (whichever comes first); and

(iii) The procedures by which a facility may apply to HCFA for a waiver of the nurse staffing requirements.

(Catalog of Federal Domestic Assistance Program No. 93.714, Medical Assistance Program; No 93.773, Medicare Hospital Insurance)

Dated: January 22,1991.

Gail R. Wilensky,

Administrator, Health Care Financing Administration.

Approved: August 14, 1991.

Louis W. Sullivan,

Secretary.

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