Dated: November 4, 1993.

J.E. Dombroski,

CAPT, JAGC, U.S. Navy, Acting Judge Advocate General.

[FR Doc. 93–28637 Filed 11–22–93; 8:45 am]

BILLING CODE 3810–AE–P

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972; Amendment

AGENCY: Department of the Navy, DOD.

ACTION: Final rule.

SUMMARY: The Department of the Navy is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Judge Advocate General of the Navy has determined that USS PORT ROYAL (CG 73) is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with certain provisions of the 72 COLREGS without interfering with its special functions as a naval cruiser. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

EFFECTIVE DATE: November 4, 1993.

FOR FURTHER INFORMATION CONTACT: Captain R.R. Rossi, JAGC, U.S. Navy, Admiralty Counsel, Office of the Judge Advocate General, Navy Department, 200 Stovall Street, Alexandria, VA 22332–2400, Telephone number: (703) 325–9744.

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 33 U.S.C. 1605, the Department of the Navy amends 32 CFR part 706. This amendment provides notice that the Judge Advocate General of the Navy, under authority delegated by the Secretary of the Navy, has certified that USS PORT ROYAL (CG 73) is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with 72 COLREGS, Annex I, section 3(a), pertaining to the location of the forward masthead light in the forward quarter of the ship, the placement of the after masthead light, and the horizontal distance between the forward and after masthead lights, without interfering with its special functions as a naval cruiser. The Judge Advocate General of the Navy has also certified that the aforementioned lights are located in closest possible compliance with the applicable 72 COLREGS requirements.

Moreover, it has been determined, in accordance with 32 CFR parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on this vessel in a manner differently from that prescribed herein will adversely affect the vessel's ability to perform its military functions.

List of Subjects in 32 CFR Part 706

Marine safety, Navigation (Water), Vessels.

PART 706—[AMENDED]

Accordingly, 32 CFR part 706 is amended as follows:

1. The authority citation for part 706 continues to read:

Authority: 33 U.S.C. 1605.

§ 706.2 [Amended]

2. Table Five of § 706.2 is amended by adding the following vessel:

TABLE FIVE

Vessel	Number	Masthead lights not over all other lights and obstructions. Annex I, sec. 2(f)	Forward masthead light not in forward quarter of ship. Annex I, sec. 3(a)	After masthead light less than ½ ship's length aft of forward masthead light. Annex I, sec. 3(a)	Percentage horizontal separation attained
* * *	*	*	*	*	*
USS PORT ROYAL	CG 73	N/A	X	X	38

Dated: November 4, 1993.

J.E. Dombroski,

CAPT, JAGC, U.S. Navy, Acting Judge Advocate General.

[FR Doc. 93–28639 Filed 11–22–93; 8:45]

BILLING CODE 3810–AE–P

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972; Amendment

AGENCY: Department of the Navy, DOD.

ACTION: Final rule.

SUMMARY: The Department of the Navy is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Judge Advocate General of the Navy has determined that USS SANTA FE (SSN 763) is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with certain provisions of the 72 COLREGS without interfering with its special functions as a naval submarine. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

EFFECTIVE DATE: November 4, 1993.

FOR FURTHER INFORMATION CONTACT: Captain R.R. Rossi, JAGC, U.S. Navy, Admiralty Counsel, Office of the Judge Advocate General, Navy Department, 200 Stovall Street, Alexandria, VA 22332–2400, Telephone number: (703) 325–9744.

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 33 U.S.C. 1605, the Department of the Navy amends 32 CFR part 706. This amendment provides notice that the Judge Advocate General of the Navy, under authority delegated by the Secretary of the Navy, has certified that USS SANTA FE (SSN 763) is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with 72 COLREGS: Rule 21(c), pertaining to the arc of visibility of the sternlight; Annex I, section 2(a)(i), pertaining to the height of the masthead light; Annex I, section 2(k), pertaining to the height and relative positions of the anchor lights; and Annex I, section 3(b), pertaining to the location of the sidelights. Full compliance with the above-mentioned 72 COLREGS provisions would interfere with the special functions and purposes of the vessel. The Judge Advocate General of the Navy has also certified that the aforementioned lights are located in

closest possible compliance with the applicable 72 COLREGS requirements.

Notice is also provided to the effect that USS SANTA FE (SSN 763) is a member of the SSN–688 class of vessels for which certain exemptions, pursuant to 72 COLREGS, Rule 38, have been previously authorized by the Secretary of the Navy. The exemptions pertaining to that class, found in the existing tables of § 706.3, are equally applicable to USS SANTA FE (SSN 763).

Moreover, it has been determined, in accordance with 32 CFR parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on this vessel in a manner differently from that prescribed herein will adversely affect the vessel's ability to perform its military functions.

List of Subjects in 32 CFR Part 706

Marine Safety, Navigation (Water), Vessels.

PART 706—[AMENDED]

Accordingly, 32 CFR part 706 is amended as follows:

1. The authority citation for 32 CFR part 706 continues to read:

Authority: 33 U.S.C. 1605.

§ 706.2 [Amended]

2. Table One of § 706.2 is amended by adding the following vessel:

TABLE ONE

Vessel	Number	Distance in meters of forward masthead light below minimum required height. § 2(a)(i), Annex I
* * * * *		
USS SANTA FE	SSN–763	3.5

3. Table Three of § 706.2 is amended by adding the following vessel:

TABLE THREE

Vessel	Number	Masthead lights arc of visibility; Rule 21(a)	Side lights arc of visibility; Rule 21(b)	Stern light arc of visibility; Rule 21(c)	Side lights distance inboard of ship's sides in meters 3(b) Annex 1	Stern light, distance forward of stern in meters; Rule 21(c)	Forward anchor light, height above hull in meters; 2(K) Annex 1	Anchor lights relationship of aft light to forward light in meters 2(K) Annex 1
* *	*	*	*	*	*	*	*	*
USS SANTA FE	SSN–763	.....	.....	205	4.2	6.2	3.5	1.7 below.

Dated November 4, 1993.

J.E. Dombroski,

CAPT, JAGC, U.S. Navy, Acting Judge Advocate General.

[FR Doc. 93–28641 Filed 11–22–93; 8:45 am]

BILLING CODE 3810–AE–P

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 242

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 100

RIN 1018–AB43

Subsistence Management Regulations for Federal Public Lands in Alaska, Subpart D—1993–1994 Subsistence Taking of Fish and Wildlife Regulations; Correction

AGENCY: Forest Service, USDA; Fish and Wildlife Service, Interior.

ACTION: Correcting amendments to final rule.

SUMMARY: This document contains corrections to the final Subsistence Management Regulations for Federal Public Lands in Alaska, Subpart D—1993–1994 Subsistence Taking of Fish and Wildlife, which was published in the **Federal Register** on June 1, 1993 (58 FR 31252–31295). Changes in this document are made to correct errors and omissions in the original subpart D publication.

EFFECTIVE DATE: July 1, 1993.

FOR FURTHER INFORMATION CONTACT: Chair, Federal Subsistence Board, c/o Richard S. Pospahala, Office of Subsistence Management, U.S. Fish and Wildlife Service, 1011 E. Tudor Road, Anchorage, Alaska 99503; telephone (907) 786–3447. For questions specific to National Forest System lands, contact Norman R. Howse, Assistant Director—Subsistence, USDA, Forest Service, Alaska Region, P.O. Box 21628, Juneau, Alaska 99802–1628, telephone (907) 586–8890.

SUPPLEMENTARY INFORMATION: The 1993–1994 subpart D final regulations contain errors and omissions which require correction to maintain certain subsistence taking opportunities. The corrections are made in identical fashion at 36 CFR part 242 and 50 CFR part 100.

The Federal Subsistence Board (Board) finds these corrections to be exempt from Administrative Procedures Act (APA) requirements for public notice and public comments prior to publication. In this instance, the Board finds that such requirements are impracticable, unnecessary, and contrary to public interest. Corrections contained herein accurately reflect actions previously taken by the Board under full public review processes. Public notice and public comment opportunities on issues underlying these corrections were formerly afforded through the **Federal Register**, newspaper publications, public meetings, and other means. Further notice and public comment on these corrections would impede the regulatory process, would provide insignificant benefits in nature and impact, would unnecessarily restrict certain subsistence opportunities, and would generally fail to serve overall public interest. Therefore, the Board has not reapplied notice and public comment procedures prior to publication of these corrections.

The Board also finds good cause to implement these corrections as of July 1, 1993, the date on which these measures would have taken effect had inadvertent oversights not occurred. Minor errors in editing constitute the only reason that these provisions were omitted from the final rule published on June 1, 1993 (58 FR 31252–31295). The Board therefore

finds these corrections to be exempt from APA requirements for publication 30 days prior to the effective date.

List of Subjects

36 CFR Part 242

Administrative practice and procedure, Alaska, Fish, National forests, Public lands, Reporting and recordkeeping requirements, Wildlife.

50 CFR Part 100

Administrative practice and procedure, Alaska, Fish, Public lands, Reporting and recordkeeping requirements, Wildlife.

For reasons set forth in the preamble, 36 CFR part 242 and 50 CFR part 100 are corrected by making the following correcting amendments:

36 CFR PART 242—[AMENDED]

50 CFR PART 100—[AMENDED]

1. The authority: citation for both 36 CFR part 242 and 50 CFR part 100 continues to read as follows:

Authority: 16 U.S.C. 3, 472, 551, 668dd, 3101–3126; 18 U.S.C. 3551–3566; 43 U.S.C. 1733.

2. Section _____.25 is amended by revising paragraphs (b)(2)(i) introductory text, (b)(2)(iv) introductory text and (f) to read as follows:

§ _____.25 Subsistence taking of wildlife.

* * * * *

(b) * * *

(2) * * *

(i) Using a firearm other than a rifle, shotgun, muzzle-loaded rifle, or rifle or pistol using center-firing cartridges, for the taking of ungulates or bears except that—

* * * * *

(iv) Using bait for taking ungulates, bear, wolf, or wolverine; except, that an individual in possession of a valid trapping license may use bait to take wolves and wolverine, and, black bears may be taken with the use of bait in Units 14(A) between April 15–May 25; in Unit 14(B) between April 15–May 31; in Units 1(A)(B)(D), 2, 3, 5, 6, 7 (except Resurrection Creek and its tributaries), 11, 13 and 16 (except Denali State Park), 15 and 17, between April 15–June 15; and in Units 12, 19–21, 24, and 25, between April 15–June 30—

* * * * *

(f) Sealing of marten, lynx, beaver, otter, wolf, and wolverine. No person may possess or transport from Alaska the untanned skin of a marten taken in Units 1–5, 7, 13(E), and 14–16, or the untanned skin of a lynx, beaver, otter, wolf, or wolverine whether taken inside or outside the State, unless the skin has been sealed by an authorized representative of ADF&G in accordance with State regulations.

* * * * *

3. In addition, in the table at _____.25(m)(1) under the species listing of "GOAT", the entry for Unit 1 (D), is revised to read as follows:

§ _____.25 Subsistence taking of wildlife.

m * * *

(1) * * *

Bag limits	Open season
* * * * * * *	
GOAT:	
* * * * * * *	
Unit 1(D)—that portion lying north of the Katzehin River and northeast of the Haines highway—1 goat by State registration permit only..	
Unit 1(D)—that portion lying between Taiya Inlet and River and the White Pass and Yukon Railroad.	No open season.
Remainder of Unit 1(D)—1 goat by state registration permit only	Sept. 15–Oct. 15.
* * * * * * *	

Ronald B. McCoy,

Interim Chair, Federal Subsistence Board.

Michael A. Barton,

Regional Forester, USDA-Forest Service.

[FR Doc. 93–26390 Filed 11–22–93; 8:45 am]

BILLING CODE 4310–55–M

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 0

RIN 2900–AG27

Standards of Ethical Conduct and Related Responsibilities

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs is amending its regulations governing the conduct of VA employees to remove provisions which have been superseded by recently issued Office of Government Ethics (OGE) regulations which took effect on February 3, 1993, and to revise VA ethics program administrative regulations to conform to current legal requirements and refine VA ethics program responsibilities.

EFFECTIVE DATE: November 23, 1993.

FOR FURTHER INFORMATION CONTACT: Audley Hendricks, Assistant General Counsel (023), Office of the General Counsel, Veterans Administration, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 633–7081.

SUPPLEMENTARY INFORMATION: In 1989, the President issued Executive Order 12674 (later modified by E.O. 12731) directing the Office of Government Ethics (OGE) to "establish a single, comprehensive, and clear set of executive branch standards of conduct that shall be objective, reasonable, and enforceable" and giving OGE authority, with the concurrence of the Attorney General, to issue regulations interpreting 18 U.S.C. 207–209. The order also directed OGE to promulgate regulations establishing a system of confidential financial disclosure by executive branch employees, and to administer the training requirements of the order. Finally, the order required that the Secretary ensure that the Designated Agency Ethics Official's rank, responsibilities, authority, staffing and resources be sufficient to ensure the effectiveness of the VA ethics program.

The Office of Government Ethics, on August 7, 1992, published its final rule establishing Government-wide Standards of Ethical Conduct for Executive Branch Employees. 57 FR 35006. The new regulations, which are codified at 5 CFR part 2635, took effect on February 3, 1993, and, pursuant to the Executive order, have supplanted

most of the VA standards of conduct regulations. 57 FR 35006 (1992).

The Office of Government Ethics, on April 7, 1992, published its final rule establishing executive agency ethics training programs. 57 FR 11886. The new regulations, which are codified at 5 CFR part 2638, took effect May 7, 1992, and required each agency to provide initial ethics orientation to all its employees and annual ethics training for employees in certain sensitive positions 57 FR 11886 (1992).

The Office of Government Ethics, on April 7, 1992, published its interim rule on financial disclosure, including the new branch-wide confidential financial disclosure system. 57 FR 11800. The new regulations, which are codified at 5 CFR part 2634, require VA, *inter alia*, to establish a new confidential financial disclosure system.

The purposes of this rule are to remove those portions of VA's standards of conduct regulations, codified at subparts B and C of 38 CFR part 0, which have been superseded by the Government-wide regulations, and to revise the general provisions in subpart A of part 0 pertaining to the VA ethics program, which have also been affected by the new standards of conduct, the new financial disclosure regulations, and the new training regulations. In this rulemaking document, the VA is revising subpart A, and retaining and renumbering four residual provisions in subpart B which have not been superseded. Also included is a cross-reference to the executive branch-wide Standards of Ethical Conduct at 5 CFR part 2635 and the executive branch-wide financial disclosure regulation at 5 CFR part 2634.

Those regulations in subpart B not being removed will remain in effect for all purposes. There are four provisions in this category. Those four are section 0.735–20(e)(4), "intoxicants and drugs," section 0.735–20(e)(5), "patient abuse," section 0.735–21(e), "safety," and section 0.735–21(f), "furnishing testimony," now being renumbered as sections 0.735–11 and 0.735–12.

Pursuant to 5 CFR 2635.105(c)(3), the Department has obtained the concurrence of OGE in the view that the four provisions in subpart B need not be issued as regulations supplementary to part 2635. None of these provisions is intended to modify or amplify any of the standards in part 2635, and they do not involve the authority conveyed in the Executive orders. They are grounded instead in the general authority of section 501, title 38, United States Code, of the Secretary of Veterans Affairs to prescribe regulations "necessary or appropriate" to carry out the Department's mission. Accordingly, the Department is amending the Authority note at the beginning of part 0 to specify section 501 as well as other general provisions concerning rulemaking authority on the matter of employee conduct.

The VA conduct regulations in subpart C, which provide separate rules for special Government employees, are superseded by the OGE Government-wide standards of conduct. VA is repealing subpart C in its entirety. Following the OGE pattern in part 2635 of including special Government employees within the definition of "employee" in 5 CFR 2635.102(h) and delineating within the specific standards of conduct the few special rules that apply only to special Government employees, VA has also included special Government employees within the definition of "employee" in this rule. This rule contains no provisions that apply only to special Government employees; the VA regulations apply to all VA employees.

In addition to implementing the 1989 Executive order, this rule also gives effect to subpart I of part 2634 of title 5, Code of Federal Regulations, which overrode subpart D of part 0 of title 38, CFR. 57 FR 11800 (1992). Thus, the rule removes VA's superseded confidential financial disclosure regulations in subpart D from part 0.

The revisions to the general provisions in subpart A conform VA ethics program regulations to the new requirements imposed by the Executive Order and the implementing regulations. The revisions also set out the administrative responsibilities which the Secretary has assigned to VA ethics officials. New sections entitled "Agency ethics officials" and "Agency designees" replace the assignment of responsibilities in the repealed section entitled "Interpretation and advisory service" with assignments to ethics officials and agency designees identified by the nomenclature of the current OGE ethics program scheme: the designated agency ethics official (DAEO), deputy ethics officials, and agency designees. A section on ethics education implements the ethics training requirements, and replaces the section entitled "Informing employees." The portions of the section entitled "Interpretation and advisory service" which are not replaced by the new sections on ethics officials and agency designees are replaced by the new section on ethics advice. A new section is added which assigns responsibility within VA for both the public and confidential financial disclosure systems. The definition of "person" was removed as superfluous, because the revised part does not contain the term. The definition of special Government employee is no longer necessary, as it has no particular significance in the amended part and is codified at 18 U.S.C. 202. The introductory section on the purpose of the VA ethics program and the final section on violation of these regulations remain unchanged.

Because the VA is required pursuant to the Executive order to remove superseded provisions of part 0, there remains no justification for subpart D. The repeal of subpart C and portions of subparts A and B is necessary because those provisions were superseded by the new Government-wide standards of conduct, confidential disclosure regulations, and training regulations. Thus VA has no discretion in the matter, and VA finds, pursuant to 5 U.S.C. 553 (b)(B), and (d)(3), that there is good cause not to seek public comment on, or a 30-day delayed effective date for, this rule, as such comment and delayed effectiveness are unnecessary and would serve no purpose.

Because the amendments to subpart A are rules of agency organization, practice, or procedure, and a general statement of policy, a notice of proposed rulemaking is not required. 5 U.S.C. 553(b)(B).

Since a notice of proposed rulemaking is unnecessary and will not be published, these amendments do not come within the term "rule" as defined in, and are not made subject to the requirements of, the Regulatory Flexibility Act. 5 U.S.C. 601(2). Nevertheless, the Secretary hereby certifies that these regulatory amendments will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612.

There is no Catalog of Federal Domestic Assistance Program number.

List of Subjects in 38 CFR Part 0

Conflicts of interests, Government employees.

Approved: October 4, 1993.

Jesse Brown,

Secretary of Veterans Affairs.

For the reasons set out in the preamble, 38 CFR part 0 is amended as set forth below:

PART 0—STANDARDS OF ETHICAL CONDUCT AND RELATED RESPONSIBILITIES

1. The authority citation for part 0 is revised to read as follows:

Authority: 5 U.S.C. 301; 38 U.S.C. 501; see sections 201, 301, and 502(a) of E.O. 12674, 54 CFR 15159, 3 CFR, 1989 Comp., p. 215 as modified by E.O. 12731, 55 CFR 42547, 3 CFR, 1990 Comp., p. 306.

2. Subpart A is revised to read as follows:

Subpart A—General Provisions

Sec.

Subpart A—General Provisions

§ 0.735–1 Purpose.

For proper performance of the Government business and the maintenance of confidence by citizens in their Government, employees in the Department of Veterans Affairs shall maintain the highest possible standards of honesty, integrity, impartiality, and conduct. They shall avoid misconduct and conflicts of interest through informed judgment as an indispensable means to the maintenance of these high standards.

§ 0.735–2 Definitions.

For the purposes of this part, *employee* means an officer or employee of the Department of Veterans Affairs, including a special Government employee.

§ 0.735–3 Agency ethics officials.

(a) *Designated Agency Ethics Official (DAEO).* The Assistant General Counsel (023) is the designated agency ethics official (DAEO) for the Department of Veterans Affairs. The Deputy Assistant General Counsel (023C) is the alternate DAEO, who is designated to act in the DAEO's absence. The DAEO has primary responsibility for the administration, coordination, and management of the VA ethics program, pursuant to 5 CFR 2638.201–204.

(b) *Deputy ethics officials.* (1) The District Counsel are deputy ethics officials. They have been delegated the authority to act for the DAEO within their jurisdiction, under the DAEO's supervision, pursuant to 5 CFR 2638.204.

(2) The alternate DAEO, the DAEO's staff, and staff in the Offices of District Counsel, may also act as deputy ethics officials pursuant to delegations of one or more of the DAEO's duties from the DAEO or the District Counsel.

§ 0.735–4 Agency designees.

(a)The following officials are "agency designees" for purposes of the standards of conduct in 5 CFR part 2635:

Under Secretaries
Assistant Secretaries
Director, National Cemetery System
General Counsel
Inspector General
Chairman, Board of Veterans Appeals
Chairman, Board of Contract Appeals
Heads of Independent Facilities
Designated Agency Ethics Official
District Counsel.

(b) Agency designees are authorized, pursuant to 5 CFR 2635.102(b), to make specified determinations, grant approval, or take other specified action required or permitted by the standards of conduct with respect to another employee. An agency designee may seek the advice of the DAEO or a deputy ethics official in exercising his or her responsibilities as to any other employee.

§ 0.735–5 Ethics education.

(a) *Initial ethics orientation.* Each new agency employee shall receive initial ethics orientation, pursuant to 5 CFR 2638.703, within 90 days of his or her entrance on duty.

(b) *Annual ethics training.* (1) The following employees shall receive annual ethics training, pursuant to 5 CFR 2638.704:

(i) Employees appointed by the President.

(ii) Employees required to file public financial disclosure reports or confidential financial disclosure reports.

(iii) Officers or employees who have been authorized by the Secretary or his or her designee to enter into, administer, or terminate contracts and make related determinations and findings.

(iv) With respect to any procurement (including the modification or extension of a contract), any civilian or military official or employee of an agency, (including a contractor, subcontractor, consultant, expert, or advisor (other than a competing contractor) acting on behalf of, or providing advice to, the agency with respect to any phase of the agency procurement concerned), who has participated personally and substantially in the drafting of a specification developed for that procurement; the review and approval of a specification developed for that procurement; the preparation or issuance of a procurement solicitation in that procurement; the evaluation of bids or proposals for that procurement; the selection of sources for that procurement; the conduct of negotiations in that procurement; the review and approval of the award, modification, or extension of a contract in that procurement; or such other specific procurement as may be specified in the procurement integrity implementing regulations at 48 CFR 3.104.

(v) Other employees designated by the Secretary or his or her designee based on a determination that such training is desirable in view of their particular duties.

(2) For purposes of administering training, the DAEO, the alternate DAEO, the District Counsel, and attorneys which these individuals designate are "qualified individuals."

(c) *Other ethics education.* The DAEO and deputy ethics officials may conduct such other ethics education, training and orientation for employees as he, she, or they deem(s) appropriate, or as requested by VA management officials.

§ 0.735–6 Ethics advice.

(a) Employees may request and shall receive, upon such request, ethics advice from the DAEO or deputy ethics officials, in accordance with paragraphs (b) and (c) of this section. Former employees may request and shall receive, upon such request, ethics advice related to post-employment restrictions, in accordance with paragraphs (b) and (c) of this section. Employees need not follow the chain of command, and former employees need not follow their former chain of command, in seeking ethics advice from their District Counsel or the DAEO.

(b) The DAEO is authorized to:

(1) Interpret for the Department of Veterans Affairs the laws, executive orders, and regulations relating to employee ethics and conduct matters, and the regulations in this part;

(2) Coordinate counseling services on ethics and conduct matters for employees, and counseling services on post-employment restrictions for former employees;

(3) Resolve questions of conflict of interest, the appearance of conflict of interest and other matters covered in 5 CFR parts 2634, 2635 and this part, whether the questions arise directly from an employee or former employee; or indirectly from an agency designee or a deputy ethics official.

(4) Assure that counseling, advice and interpretations of a precedential nature are available to deputy ethics officials and, if appropriate, other employees, including agency designees;

(c) District Counsel may render advice and interpretations on questions of ethics and conduct matters to any employee, and on questions of post-employment restrictions to former

employees, within the District Counsel's jurisdiction. The District Counsel shall be guided by the interpretations of the DAEO on the pertinent law, executive orders, and regulations. In case of doubt regarding any question, or disagreement of interpretation between District Counsel and employee or former employees, or novel questions of broad application within VA, the District Counsel may submit the matter for consideration by the DAEO.

§ 0.735–7 Financial disclosure.

The DAEO shall administer the public financial disclosure program within the Department of Veterans Affairs. The DAEO shall administer the confidential financial disclosure program, and distribute, collect, review, certify and retain the confidential financial disclosure reports of Central Office employees. The District Counsel shall distribute, collect, review, certify and retain confidential financial disclosure reports for employees whose duty station is within their geographic jurisdiction. The DAEO and District Counsel shall maintain records and reports of the financial disclosure system(s) within their responsibility.

§ 0.735–8 Violation of regulations.

Violation of the regulations in this part by an employee may be cause for appropriate disciplinary action which may be in addition to any penalty prescribed by law.

3. Subpart B is revised to read as follows:

Subpart B—Standards of Ethical Conduct and Related Responsibilities of Employees

Sec.

Subpart B—Standards of Ethical Conduct and Related Responsibilities of Employees

§ 0.735–10 Cross-reference to employee ethical and other conduct standards and financial disclosure regulations.

Employees of the Department of Veterans Affairs (VA) should refer to the executive branch-wide Standards of Ethical Conduct at 5 CFR part 2635, the executive branch-wide Employee Responsibilities and Conduct at 5 CFR part 735, and the executive branch-wide financial disclosure regulation at 5 CFR part 2634.

§ 0.735–11 Other conduct on the job.

Relationship with beneficiaries and claimants. Employees are expected to be helpful to beneficiaries, patients and claimants, but:

(a) An employee shall not procure intoxicants or drugs for, or attempt to sell intoxicants or drugs to, patients or members, or give or attempt to give intoxicants or drugs to them unless officially prescribed for medical use;

(b) An employee shall not abuse patients, members, or other beneficiaries, whether or not provoked.

§ 0.735–12 Standards of conduct in special areas.

(a) *Safety.* (1) Employees will observe safety instructions, signs, and normal safety practices and precautions, including the use of protective clothing and equipment.

(2) An employee shall report each work-connected injury, accident or disease he or she suffers.

(b) *Furnishing testimony.* Employees will furnish information and testify freely and honestly in cases respecting employment and disciplinary matters. Refusal to testify, concealment of material facts, or willfully inaccurate testimony in connection with an investigation or hearing may be ground for disciplinary action. An employee, however, will not be required to give testimony against himself or herself in any matter in which there is indication that he or she may be or is involved in a violation of law wherein there is a possibility of self-incrimination.

Subparts C and D [Removed]

4. Subparts C and D are removed.

[FR Doc. 93–27912 Filed 11–22–93; 8:45 am]
BILLING CODE 8320–01–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 799

[OPPTS–42114B; FRL–4648–1]

RIN 2070–AB94

Testing Consent Agreement for N-methylpyrrolidone

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Consent Agreement.

SUMMARY: EPA has signed an Enforceable Consent Agreement (ECA) pursuant to the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 *et seq.*, with Arco Chemical Company, BASF Corporation, and International Specialty Products Company, hereinafter, "the Companies" who have agreed to perform certain health effects tests with *n*-methylpyrrolidone (CAS No. 872–50–4) (NMP). This document summarizes the ECA and amends 40 CFR 799.5000 by adding NMP to the list of chemical substances and mixtures subject to ECA's. Accordingly, the export notification requirements of 40 CFR part 707 apply to NMP.

EFFECTIVE DATE: November 23, 1993.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Rm. E–543B, 401 M St., SW., Washington, DC 20460, (202) 554–1404, TDD (202) 554–0551.

SUPPLEMENTARY INFORMATION: This document amends 40 CFR 799.5000 by adding NMP to the list of chemical substances and mixtures subject to ECAs and export notification requirements.

I. Background

NMP is a possible substitute for methylene chloride for use in paint stripper formulations. Its annual production volume exceeds 55 million pounds. Approximately 2.7 million consumers and more than 71,000 workers may be exposed to NMP.

On March 28, 1990 (55 FR 11398), EPA issued a Notice of Proposed Rulemaking, proposing that NMP manufacturers test NMP for oncogenicity, mutagenicity, developmental and reproductive toxicity, neurotoxicity, and subchronic toxicity. EPA deferred proposing pharmacokinetics testing in the NMP proposed rule because a test guideline for pharmacokinetics was not yet available. The NMP proposed test rule contained a chemical profile of NMP, a discussion of EPA's TSCA section 4(a) findings, and the proposed test standards and reporting requirements.

In addition, in the **Federal Register** of July 15, 1991 (56 FR 32292) EPA reopened the comment period on NMP to permit further comment in relation to EPA's proposed statement of policy for interpreting its legal authority to make TSCA section 4(a)(1)(B) findings.

After EPA issued the Notice of Proposed Rulemaking for NMP, it received data adequate for evaluating the potential mutagenicity and developmental and reproductive toxicity effects of NMP.

On January 29, 1992 EPA's Office of Pollution Prevention and Toxics placed NMP into risk management evaluation after an initial review of the data. On April 15, 1992, EPA informed the NMP manufacturers by letter that it was concerned that there is a potential for adverse health effects on reproduction

and development to persons exposed to NMP. In that letter, EPA also requested additional exposure information, industrial hygiene information, and historical control data not submitted with the reproductive toxicity study.

In response to EPA's April 15, 1992 letter, on May 20, 1992 and June 22, 1992 the manufacturers submitted additional information on use and exposure, glove permeability, on-going testing, and product stewardship.

II. Enforceable Consent Agreement Negotiations

EPA published a **Federal Register** Notice (57 FR 31714; July 17, 1992) announcing an "open season." The "open season" was a time during which manufacturers could submit to EPA proposals for testing chemical substances which had been proposed for testing by EPA but had not been subject to a final test rule. In that notice, EPA indicated that it would review the submissions and select candidates for negotiation of enforceable consent agreements (ECA) pursuant to 40 CFR part 790. EPA also indicated that it would later publish a **Federal Register** notice soliciting persons interested in participating in or monitoring negotiations for the development of consent agreements on the chemicals selected.

On September 11, 1992, the Synthetic Organic Chemical Manufacturers Association (SOCMA) on behalf of "The Companies" submitted a proposal for testing NMP under an ECA. On October 30, 1992, SOCMA sent EPA another letter that added a 2–year oncogenicity bioassay to their testing proposal.

EPA published a **Federal Register** notice (59 FR 16669; March 30, 1993) announcing candidates selected for consent order negotiations and requesting that interested parties identify themselves to EPA. The notice established EPA's priority for initiating negotiations on the chemicals selected, and because the proposal submitted by SOCMA was similar to the testing proposed in EPA's proposed test rule, NMP was among the chemicals assigned a high priority. This **Federal Register** notice also announced a tentative date for starting negotiations on NMP and the other high priority chemicals.

EPA met with identified interested parties, on April 28, 1993 to discuss the testing proposal submitted. EPA conducted subsequent negotiations by letter. Once EPA determined that consensus had been reached it provided a final ECA to the Companies for signature.

The Companies signed the ECA on September 9, 1993, and the Assistant Administrator for EPA's Office of Prevention, Pesticides, and Toxic Substances signed the ECA on November 15, 1993. Because EPA has determined that the data submitted for mutagenicity, developmental, and reproductive toxicity testing required in the proposed test rule is adequate, the final ECA does not require testing for those end points. This ECA is a final action by EPA on NMP; therefore, the NMP proposed test rule will not be adopted as final.

III. Testing Program

The following Table 1 describes the tests, the test standards, and reporting requirements for NMP under the ECA. This testing program will allow EPA to further characterize the potential health hazards resulting from exposure to NMP.

TABLE 1.—REQUIRED TESTING, TEST STANDARDS AND REPORTING REQUIREMENTS FOR NMP

Description of Tests	Test Standard (40 CFR citation)	Deadline for Final Report[1] (Months)	Interim Reports[2] Required Number
Pharmacokinetics; oral, dermal[3], inhalation, and intravenous routes.	795.232 as amended (Appendix I)	15	2
28 day subchronic toxicity range finding study	OECD guideline #407 (adopted in 1981) (Appendix II).	6	0
90 day subchronic toxicity range finding study	798.2650 as amended (Appendix III)	24	3
Functional Observation Battery: subchronic	798.6050 as amended (Appendix IV)	24	3
Motor Activity Test: subchronic	798.6200 as amended (Appendix V)	24	3
Neuropathology: subchronic	798.6400 as amended (Appendix VI)	24	3
Oncogenicity in the mouse and rat administered orally	798.3300 as amended (Appendix VII)	72	12

[1] Number of months after the effective date of the consent order. This reporting requirement includes 19 months for obtaining information from the 28– and 90–day range finding and pharmacokinetics studies.

[2] Interim reports are required every 6 months from the effective date until the final report is submitted. This column shows the number of interim reports required for each test.

[3] The dermal pharmacokinetics consists of a single administration, low dose, dermal exposure group.

IV. Export Notification

The issuance of the ECA subjects any persons who export or intend to export the chemical substance, NMP (CAS No. 872–50–4), of any purity, to the export notification requirements of section 12(b) of TSCA. The listing of the chemical substance at 40 CFR 799.5000 serves as a notification to persons who export or intend to export a chemical substance or mixture that is the subject of an ECA that 40 CFR part 707 applies.

V. Public Record

A. Supporting Documentation

EPA has established a record for this ECA under docket number OPPTS–42114B, which is available for inspection Monday through Friday, excluding legal holidays, in the TSCA Nonconfidential Information Center, East Tower, rm. G–102, 401 M St., SW., Washington, DC 20460 from 8 a.m. to 12 noon and from 1 p.m. to 4 p.m. Information claimed as Confidential Business Information (CBI), while part of the record, is not available for public review. This record contains the basic information considered in developing this Consent Order, and includes the following information:

(1) Testing Consent Agreement for NMP and associated testing protocols attached as appendices.

(2) **Federal Register** notices pertaining to this notice and consent order consisting of:

(a) Notice of Proposed Rulemaking for *N*-methylpyrrolidone, (March 28, 1990, 55 FR 11398)

(b) Notice announcing opportunity to initiate Negotiations for TSCA Section 4

Testing Consent Agreements (July 17, 1992, 57 FR 31714)

(c) Notice announcing Testing Consent Agreement Development for Tier I Chemical Substances; Solicitation for Interested Parties (March 30, 1993, 58 FR 16669)

(3) Communications consisting of:

(a) Written Letters.

(b) Contact reports of telephone summaries.

(c) Meeting summaries.

(4) Reports - published and unpublished factual materials.

VI. Regulatory Assessment Requirements

The Office of Management and Budget (OMB) has approved the information collection requirements contained in the Consent Agreement under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, and has assigned OMB control 2070–0033.

Public reporting burden for this collection of information is estimated to average 586 hours per response. The estimates include time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, 2131, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070–0033), Washington, DC 20503.

List of Subjects in 40 CFR Part 799

Environmental protection, Chemicals, Chemical export, Hazardous substances, Health effects, Laboratories, Reporting and recordkeeping requirements, Testing.

Dated: November 15, 1993.

Victor J. Kimm,

Acting Assistant Administrator for Prevention, Pesticides and Toxic Substances.

Therefore, 40 CFR chapter I, part 799 is amended as follows:

PART 799—[AMENDED]

1. The authority citation for part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

2. Section 799.5000 is amended by revising the section heading to read as set forth below and by adding *N*-methylpyrrolidone to the table in CAS Number order, to read as follows:

§ 799.5000 Testing Consent Agreements for Substances and Mixtures with Chemical Abstract Service Registry Numbers.

* * * * *

CAS Number	Substance or mixture name	Testing	FR Publication Date
*	*	*	*
872–50–4	*N*-methylpyrrolidone	Health effects	November 23, 1993
*	*	*	*

[FR Doc. 93–28734 Filed 11–22–93; 8:45 am]
BILLING CODE 6560–50–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 401, 488 and 489

[HSQ–159–F]

RIN 0938–AF17

Medicare Program; Granting and Withdrawal of Deeming Authority to National Accreditation Organizations

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

ACTION: Final rule.

SUMMARY: This rule implements section 1865(a) of the Social Security Act, as amended by sections 2345 and 2346 of the Deficit Reduction Act of 1984 and section 6019 of the Omnibus Budget Reconciliation Act of 1989. The amendments expand the types of providers and suppliers of services that we may consider to meet conditions of participation or certification, nursing home requirements, or conditions for coverage by virtue of their accreditation by a national accreditation program; these providers and suppliers are also subject to validation surveys. The rule also extends confidentiality to accreditation surveys, other than home health agency surveys, done by accreditation programs in addition to the Joint Commission on Accreditation of Healthcare Organizations, except that we may disclose survey and related information to the extent that such information relates to an enforcement action we take on the basis of accreditation survey findings. The rule also provides for: the release to, and use by, HCFA of all accreditation surveys and other relevant information even if a provider or supplier is not subject to a validation survey; the removing of deemed status of a facility based on a validation survey, an accreditation survey, or other information related to either; and appeal procedures for denied or withdrawn approval.

EFFECTIVE DATE: This rule is effective February 22, 1993. The provisions of this rule also apply as of the effective date to any accreditation organization that previously received approval of deeming authority.

FOR FURTHER INFORMATION CONTACT: Irene Gibson, (410) 966–6768.

SUPPLEMENTARY INFORMATION:

I. Background

In order to participate in the Medicare program, providers and most types of suppliers of health care services (such as hospitals and rural health clinics) must meet requirements specified in the Social Security Act (the Act) and any others specified by the Department of Health and Human Services. These requirements are called conditions of participation for providers, conditions for coverage for suppliers, conditions of certification for rural health clinics (RHCs), or long-term care requirements for skilled nursing facilities (SNFs). Any provider or supplier who does not meet these requirements is considered out of compliance and risks having its participation in the Medicare program terminated or may be subject to other adverse actions.

State health departments or similar agencies under contract with HCFA (in accordance with section 1864 of the Act) survey providers and some types of suppliers to ascertain compliance with the conditions of participation, conditions for coverage, or long term care requirements, and to certify their findings to HCFA. On the basis of these State survey agency certifications, HCFA determines whether the provider or supplier qualifies, or continues to qualify, for participation in the

Medicare program, whether deficiencies exist, and if they have been corrected.

Section 1865(a) of the Act provides that a hospital that is accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is deemed to meet, by virtue of that accreditation, the Medicare conditions of participation, except those on utilization review, discharge planning and any requirement promulgated by the Secretary under section 1861(e)(9) that is higher than JCAHO requirements for accreditation unless the Secretary determines that the JCAHO process in these areas is at least equivalent to the standards promulgated by the Secretary. This eliminates the need for State survey agencies to determine routinely whether these "deemed" hospitals comply with the requirements of section 1861(e).

Section 1864(c) of the Act authorizes the Secretary to enter into agreements with the State survey agencies to determine, through validation surveys, whether hospitals participating in Medicare on the basis of JCAHO accreditation are in fact meeting the conditions of participation. In order for a JCAHO accredited hospital to be deemed to meet the Medicare conditions of participation, the hospital must agree, if it is included in a validation survey, to authorize the JCAHO to release (and the JCAHO must release), to HCFA or a designated State agency, on a confidential basis, a copy of the most current JCAHO accreditation survey together with any other information related to the survey (including corrective action plans) that the Secretary requires.

Section 1865(b) provides that if a hospital is found to have significant deficiencies, based on a validation survey or any other information, it will no longer be deemed to meet the Medicare conditions of participation.

Section 1865(a) of the Act, until July 18, 1984, provided that if the Secretary found that accreditation of an institution or agency by the American Osteopathic Association (AOA) or another national accreditation organization provided reasonable assurance that any or all of the conditions of sections 1861(e) (for hospitals), 1861(j) (for skilled nursing facilities), and 1861(o) (for home health agencies (HHAs)), as the case may be, were met, to the extent the Secretary deemed it appropriate, the Secretary could treat the entity as meeting the conditions of participation. On July 18, 1984, legislation expanded the types of entities that could be deemed. (See the section entitled "LEGISLATION", below.) Up to the present, we have not determined that any accreditation organization except AOA (for hospitals) has provided these assurances.

Except for hospitals that are accredited by either the JCAHO or the AOA and HHAs that are accredited by the Community Health Accreditation Program (CHAP), no providers are deemed to meet our conditions of participation, long-term care requirements, or conditions for coverage. That is, although JCAHO accredits many other types of providers, such as SNFs, ambulatory surgical centers (ASCs), and RHCs, no members of these other provider categories have been granted deemed status by virtue of their accreditation by the JCAHO.

Section 1864(c) of the Act authorizes the Secretary to enter into an agreement with the State survey agency to survey JCAHO accredited hospitals, either on a selective-sample basis or in response to a substantial allegation that significant deficiencies exist. In a previous rule, under the authority provided in sections 1865(a) and 1871 of the Act, we extended these surveys to AOA-accredited hospitals in order to provide reasonable assurance that an AOA-accredited hospital meets the requirements of section 1861 of the Act.

Under section 1865(a) of the Act, we may deem as meeting conditions of participation a JCAHO accredited hospital only if the hospital authorizes the JCAHO to release to us, and the JCAHO releases to us, its most current accreditation survey together with any other information directly related to the survey (including corrective action plans) as the Secretary requires. This survey and other information is, in general, confidential. However, the survey and other information may be disclosed by us to the extent that it relates to an enforcement action we have taken.

There is no similar specific statutory statement for requiring entities accredited by another accreditation organization to authorize release of accreditation surveys to us. However, under the general authority of section 1865(a) of the Act, we also have required AOA-accredited hospitals to authorize release of their surveys in order to provide reasonable assurance that all the conditions of section 1861(e) (the statutory definition of "hospital") are met. Until July 18, 1984, other than for JCAHO's accreditation findings, there was no statutory authority to keep any accreditation finding confidential.

Current regulations at 42 CFR 488.5 (53 FR 22850, June 17, 1988) implement the statutory requirements of section 1865 of the Act insofar as JCAHO and AOA are concerned. Section 488.6, which applies to both JCAHO and AOA accredited hospitals, implements Section 1864(c) of the Act. This section discusses the basis for selecting a provider for a validation survey, what the provider must do if selected and the effect if it refuses to cooperate.

II. Legislation

July 18, 1984, the Deficit Reduction Act of 1984 (DEFRA, Pub. L. 98–369) was enacted. Section 2345 of DEFRA amended Section 1865(a) of the Social Security Act to require the Secretary to keep confidential the accreditation survey released to us by any accreditation body for any entity accredited by that body.

Section 2346 of DEFRA also amended Section 1865(a) of the Act. This amendment allows us to find that if the accreditation of the enumerated entities by any national accreditation organization provides reasonable assurance that the conditions of participation or certification (for RHCs), or conditions for coverage, are met for these entities, then we may deem these entities as meeting these conditions. These additional entities are: psychiatric hospitals; ASCs; RHCs; laboratories; hospices; HHAs; SNFs; comprehensive outpatient rehabilitation facilities (CORFs); and clinic, rehabilitation agency, or public health agency providers of outpatient physical therapy (which includes speech pathology services) or occupational therapy services.

Section 411 of the Medicare Catastrophic Coverage Act of 1988 (Pub. L. 100–360) also amended section 1865(a) of the Act. This amendment requires the Secretary to keep confidential the accreditation survey released to us by any accreditation organization for any entity other than a survey with respect to a home health agency.

However, section 6019 of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89) (Pub. L. 101–239), enacted December 19, 1989, further amended section 1865(a) of the Act to allow the Secretary to disclose an accreditation survey and information related to it to the extent the survey and information are related to an enforcement action taken by the Secretary. This provision was effective December 19, 1989. Section 6019 of OBRA '89 also amended section 1865(a), effective June 19, 1990, to require JCAHO-accredited hospitals to authorize the JCAHO to release to the Secretary upon request any other information (in addition to the accreditation survey) directly related to the survey as the Secretary may require (including

corrective action plans), if they are to be deemed to meet the conditions of participation. Also effective June 19, 1990, the JCAHO must release the survey and other information to the Secretary in order for the hospital to be deemed to meet the conditions of participation.

III. Provisions of the Proposed Regulations

On December 14, 1990, we published a proposed rule to implement the legislation (55 FR 51434). Below we discuss the proposed revisions.

1. Confidentiality and Disclosure Provisions

We proposed to revise 42 CFR 401.126(b)(2), which concerns information or records that are not available upon public request. We proposed to extend the confidentiality of accreditation surveys and related information to any national accreditation program recognized by HCFA under Section 1865 of the Act that accredits the specified providers or suppliers other than home health agencies (hospitals; psychiatric hospitals; SNFs; hospices; ASCs; RHCs; CORFs; laboratories; and clinic, rehabilitation agency, or public health agency providers of outpatient physical therapy services, speech pathology services, or occupational therapy services).

We would also simultaneously amend § 401.126(b)(2) and add a paragraph (d) to § 401.133, Availability of official reports on providers of services, State agencies, intermediaries, and carriers under Medicare, to indicate that we will disclose any survey and related information released to us by an accreditation organization to the extent they are related to an enforcement action taken by HCFA and the accreditation survey of any HHA. We would add a paragraph (e) to § 401.133 to show that home health agency surveys are available without regard to reason for disclosure. We would also revise the title of § 401.133 to include suppliers.

We also proposed to revise § 488.5, Effect of JCAHO and AOA accreditation, to show that hospitals accredited by JCAHO or AOA must authorize the release to HCFA of the most current accreditation surveys and any other related information (including corrective action plans) HCFA requires. We would also repeat the provision in revised § 401.126(b)(2) and new § 401.133(d) that accreditation surveys and related information may be disclosed to the extent they relate to an enforcement action taken by HCFA. In addition, the accreditation survey of any HHA can be disclosed. We proposed to state that we may determine, based on a validation survey, the accreditation survey or other related information, that the hospital does not meet Medicare conditions of participation.

2. Expansion of Types of Accredited Entities

We proposed to redesignate § 488.6, Validation survey, as § 488.7 and add a new § 488.6, Other national accreditation programs. This new section would amend the regulations to conform to the statute, which permits HCFA to deem entities other than hospitals to meet the conditions of participation or certification or conditions for coverage, if HCFA finds that a national accreditation organization has provided reasonable assurance that these conditions are met. The accreditation organization would have to provide us with reasonable assurance that the requisite conditions of participation or certification, long-term care requirements or conditions for coverage are met by the entities the accrediting body has accredited.

We proposed to revise the regulations to reflect our current policy of publishing in the **Federal Register** any change in organizations whose specified providers or suppliers may be deemed as meeting conditions of participation or certification or conditions for coverage. We would include parallel provisions in § 488.5 regarding the release and use of accreditation surveys. That is, we would disclose the accreditation survey of any HHA and the most current accreditation survey and related information on any provider or supplier to the extent they are related to an enforcement action taken by HCFA; the provider or supplier must authorize its accreditation organization to release to us a copy of its most current accreditation survey; and we may determine that a provider or supplier does not meet Medicare conditions based on its accreditation survey or related information.

3. Validation Surveys

We proposed that the redesignated § 488.7, Validation survey, would extend the validation survey to the specified types of providers and suppliers accredited by accreditation organizations other than the JCAHO and AOA.

In § 488.7(a), we would make a distinction between a survey done on the basis of a selective sample and one done on the basis of a substantial allegation of significant deficiencies. The first is comprehensive and addresses all conditions of participation or certification, long-term care requirements, or conditions for coverage; the latter is initially directed solely at the requirements related to the allegation. If the State survey agency substantiates the allegation, and HCFA determines that the provider or supplier is out of compliance with one or more conditions of participation, conditions for coverage, or long-term care requirements, the survey agency would then conduct a complete survey.

Paragraphs (b), (c), (d) and (e) would be revised to substitute "provider or supplier" for "hospital" so that our rules would apply to any approved accreditation organization that accredits providers or suppliers other than hospitals. We would also revise paragraph (b) to extend confidentiality to an accreditation survey of any accredited entity other than a home health agency.

4. Review of Accrediting Bodies

In a new section, § 488.9, Federal review of accreditation organizations, we proposed the standards for evaluating applications for deeming authority. We planned to evaluate an accreditation organization's accreditation requirements to determine whether they are equivalent to ours; the organization's survey process to determine the composition of the survey team, its qualifications and its ability to continue surveyor training; the comparability of survey procedures; the organization's monitoring procedures for providers or suppliers found out of compliance; the ability to provide HCFA with electronic data and reports necessary for effective validation and assessment of the survey process; the adequacy of staff and other resources; and the organization's ability to provide adequate resources for performing required surveys.

We proposed to include in HCFA's review of a national accreditation organization the organization's agreement with HCFA to allow the organization to release the most current accreditation survey to us with any information related to the survey that we may require, including corrective action plans. We also indicated that we would publish a notice in the **Federal Register** to notify the public of any organizations whose accredited, specified types of providers or suppliers are deemed to meet Medicare participation requirements. The notice would describe how the accreditation organization's accreditation program provides reasonable assurance that an entity accredited by the organization meets the Medicare requirements.

In this section, we would also establish the criteria and procedures for removing the deeming authority. At the end of a validation review period, HCFA would identify any accreditation programs for which validation survey results indicate a rate of disparity between certifications of the accreditation organization and those of the State agency validating the accreditations of 20 percent or more. We would also identify validation survey results of accreditation programs that indicate a pattern over 2 years or more of increasing disparity between the certifications of the accreditation organization and those of the State agency. In addition, we would assess the equivalency of the accreditation organization's accreditation requirements compared to our comparable requirements if an accreditation organization proposes to adopt new requirements. An organization must provide written notification to HCFA at least 30 days before the effective date of any proposed changes in its accreditation requirements.

We would provide written notification to an accreditation organization indicating that its approval to be an accreditation organization may be in jeopardy based on documentation identified through the validation review. We would include in the notification a statement concerning the discrepancies found; information explaining our deeming authority review; a description of the procedures the accreditation organization may follow to explain or justify findings made during validation review; and a description of what we may do as a result of the findings from the validation review.

We proposed that if we find an accreditation organization to have a disparity rate of 20 percent or more between its accreditation determinations and the certification determinations of the State survey agency or if we find that validation survey results over a period of two or more years show a pattern of increasing disparity between the certifications of the accreditation organization and certifications of the State agency, we would conduct a deeming authority review. We would reevaluate whether the accreditation organization meets all the criteria we have for initial determinations that an organization's specified providers or suppliers are deemed to meet conditions of participation. We defined "rate of disparity" and included an example in the definitions section, § 488.1.

If we determined, following the deeming authority review, that the organization's requirements were not comparable to ours, we would be able to give the organization a conditional approval of its deeming authority for a probationary period of up to 180 days to adopt comparable requirements. If we determined that the rate of disparity identified during the validation review indicates poor performance, we could (1) give conditional approval of its deeming authority for a period of up to one year, effective 30 days after the determination; (2) require the accreditation organization to release to us any facility-specific data we require for continued monitoring; (3) require the organization to provide us with a survey schedule for the purpose of intermittent onsite monitoring (by HCFA, State surveyors, or both) of the accreditation organization's survey process; and (4) publish in the Medicare Annual Report to Congress the name of any accreditation organization we give a probationary period.

Within 60 days after the conclusion of the probationary period, we would determine whether the organization continued to meet the criteria necessary for its accredited providers or suppliers to be deemed to meet conditions of participation or certification, conditions for coverage, or long-term care requirements and issue an appropriate notice. The determination would be based on any or all of the following:

(1) The evaluation of the most recent validation findings. For an organization to continue to have its providers or suppliers deemed to meet conditions of participation, the evaluation would have to show a significant reduction (from the prior two or more years) in the rate of disparity between the certifications of the State agency and the accreditation organization, and show a disparity rate of less than 20 percent;

(2) The evaluation of facility-specific data, as necessary, as well as other information;

(3) The evaluation of an accreditation body's surveyors in terms of qualifications, ongoing training, composition of survey team, etc.;

(4) The evaluation of survey procedures; and

(5) The evaluation of accreditation requirements.

We proposed that if the accreditation organization made no significant improvements during the probationary period, we would remove recognition of deemed authority, effective 30 days after we provided written notice to the organization that its deeming authority was removed. We would also publish a notice in the **Federal Register** giving the basis for removing the deeming authority from the accreditation organization and providing the reasons the organization's accreditation program no longer meets our requirements.

The regulations would state that the existence of any validation review, deeming authority review, probationary period, or any other action by HCFA does not affect or limit the conducting of any validation survey.

5. Other clarifying revisions.

a. We proposed to revise the definition of "accredited hospital" in § 488.1, Definitions, to "accredited provider or supplier" in order to include other providers and suppliers and to include accreditation programs other than the JCAHO and AOA.

b. We proposed to revise the definition of "substantial allegation" in § 488.1 in order to show that such an allegation may be a complaint from a variety of sources. We would clarify that a complaint need not be formal, be directed to HCFA or the survey agency, or be a result of first-hand experiences.

c. We proposed to add to § 488.1 a definition of "conditions of participation", in order to clarify that the requirements include conditions of certification for RHCs, and a definition of "conditions for coverage". We proposed to also define "Medicare condition" as any condition of participation or for coverage or any long term care requirement, in order to avoid repeating the entire list of possibilities every place it is applicable.

We also proposed to add a definition of "validation review period." The "validation review period" would be the period after the end of a fiscal year during which HCFA conducts a review of the previous year's validation surveys.

d. We proposed to add parts 416 and 485 to the list of applicable conditions of participation or conditions for coverage a provider must meet in order to participate in the Medicare program. These parts contain the conditions for ASCs and CORFs.

e. We would revise redesignated § 488.7(d) to parallel paragraph (c) of that section; i.e., we would add that a provider found out of compliance with Medicare conditions following a full State agency survey may be subject to termination of its provider agreement under § 489.53.

f. We proposed to delete current § 488.6(d)(2) concerning when a significant deficiency will be determined not to exist and revise redesignated § 488.7(b)(3) to clarify the necessity for the State agency to follow-up any flaw serious enough to threaten

the hospital's participation in the Medicare and Medicaid programs.

We would make a conforming change to redesignated § 488.7 by removing paragraph § 488.6(e)(3), which allows a hospital to regain its deemed status if it withdraws a prior refusal to authorize its accreditation organization to release periodic status reports of correction progress since the accreditation organization would no longer monitor its correction progress.

g. We also proposed to delete the informal review procedures now specified in § 488.6(f) to assure that the appeals process is applied uniformly for all facilities participating in the program regardless of accreditation status.

h. We would also amend § 488.10, State survey agency review; Statutory provisions, to include the additional types of providers and suppliers in the statutory provision in paragraph (d) that concerns treating accredited entities as meeting conditions of participation or conditions for coverage.

i. We would update the cross-reference in § 488.11, which refers to validation surveys, from § 488.6 to § 488.7.

IV. Comments and Responses

We received comments from 66 commenters in response to the proposed rule we published on December 14, 1990. Commenters included professional organizations, individual providers and suppliers, accreditation organizations, State governments, consumer advocacy organizations, and consumers. While the commenters expressed overall support for the proposed regulation and approval of HCFA's "deeming" process, they also addressed a wide variety of issues. These issues included:

- Confidentiality and disclosure of survey information;
- Cost shifting through accreditation fees;
- Enforcement and quality of surveys;
- Duplication of surveys and fragmentation of responsibilities among accreditation, certification and licensure; and
- Inconsistency with OBRA '87 requirements.

General Comments

General Comments: We have summarized below those comments which do not pertain to a single specific section of the proposed regulations but, rather, related to the proposed rule in general.

Comment: Commenters expressed overall support for the proposed regulations and the process by which HCFA will grant deeming authority to national accreditation organizations.

Response: We acknowledge the broad support for the proposed regulation and have developed a final rule consistent with that support.

Comment: We received several comments with respect to JCAHO. One commenter expressed explicit support for JCAHO being recognized as an accreditation organization. A few commenters expressed concern about JCAHO's current performance as an accreditation organization. A summary of those comments are as follows:

- Statistics show that when JCAHO finds fault with its accredited facilities, the problems it cites are usually limited to issues of recordkeeping and documentation.
- Given the history of serious violations of many JCAHO accredited facilities, close scrutiny of JCAHO's requirements and survey process is necessary. The commenters also expressed concern about the absence of a toll-free hotline telephone number and the unaffordable fee of $100.00 that the JCAHO charges the public and consumer advocate organizations for information pertaining to the facilities it accredits.

Response: We will examine these issues when we conduct a review of any accreditation organization requesting deeming authority or through the annual deeming authority review of these organizations. We will publish a proposed notice in the **Federal Register** describing the basis for granting an accreditation organization deeming authority and provide opportunity for comment. We will subsequently publish a final notice in the **Federal Register**. We will also publish a notice whenever deeming authority is removed. We also note that section 1865(a) of the Act already gives explicit deeming authority to the JCAHO with respect to hospitals, except for utilization review requirements and any standards promulgated by the Secretary that are higher than JCAHO accreditation requirements.

Comment: Nine commenters stated that the deeming authority application process should be outlined in the regulations and believed that accreditation organizations that have been denied approval for deeming authority should be afforded the opportunity to resubmit their applications. Additionally, the commenters recommended that a decision on all applications for deeming authority should be made by HCFA no later than 60 days after an application is filed or refiled.

Response: We have accepted the comment concerning the application process and inserted the application process at § 488.4 of this rule. We feel that the inclusion of the application process and requirements is appropriate and, by specifying those items the accreditation organization must furnish, we set forth additional general criteria that will be used in evaluating applications for approval of deeming authority.

We do not, however, agree with the recommendation that we make a decision on all applications for deeming authority within 60 days. We must reserve the right to establish and alter such timeframes to assure the flexibility necessary to respond appropriately to applications that could affect large numbers of facilities.

- With respect to the application process, accreditation organizations wishing to apply to HCFA for "deeming authority" must provide the following information:

* The provider or supplier type(s) for which the organization is requesting "deeming authority";

* A detailed comparison of individual accreditation requirements with the equivalent Medicare conditions; i.e., crosswalk;

* A description of the accreditation organization's automated data system, including the kinds of reports and tables generated by that system;

* A detailed description of the survey process, including:

—the frequency of surveys;
—whether surveys are announced or unannounced;
—copies of survey forms and survey guidelines and/or instructions;
—the accreditation survey review process and decision-making process; and
—the steps taken to monitor the correction of deficiencies;

* Detailed information about who performs accreditation surveys, including:

—the size and composition of individual accreditation survey teams;
—the education and experience requirements those surveyors must meet; and
—the content and frequency of the in-service training provided to survey personnel;

* Policies and procedures regarding withholding or removal of accreditation status for facilities that fail to meet the accreditation organization's standards, or any other remedial actions taken by the organization with respect to noncompliance with its own standards;

* Current procedures employed to investigate complaints against accredited facilities;

* Duration of accreditation;

* A listing of all currently accredited facilities that would achieve deemed status upon approval of deeming authority and the expiration date of each facility's current accreditation; and

* Additional supporting documentation, including an agreement to notify HCFA of certain events, such as the removal of accreditation from a provider or supplier, and to conform accreditation requirements to changes in Medicare conditions.

• HCFA will notify an organization if it finds that additional information is required.

• The accreditation organization will receive a formal notice from the HCFA Administrator stating whether the request for "deeming authority" has been approved or denied and an explanation of the reasons for the denial.

• Approval of an accreditation organization will be for a six-year term. We have established a six-year term of approval because we believe it would be irresponsible and unreasonable simply to approve an organization for an indefinite amount of time and not provide for further comprehensive reviews. Since HCFA has discretionary authority with respect to the approval of accreditation organizations, we must be able to impose reasonable conditions, such as the six-year approval term, in order to ensure the health and safety of patients and the general public.

• All requests for "deeming authority" should be mailed to: Administrator, Health Care Financing Administration, room 700 East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland 21207.

• A national accreditation organization whose request for deeming authority has been denied may request that its original application be reconsidered in accordance with the procedures in this rule or it may resubmit its application in its entirety as soon as the organization has made improvements in its accreditation program to meet Medicare requirements.

Comment: Eight commenters stated that it is not clear how the regulatory notice provisions would apply to individual accreditation organizations at the point of, or during, the process of application for deeming authority. Specifically, they requested clarification on:

• Whether public notice would be provided at the point an organization applies for deeming authority;

• Whether public notice would be provided that would identify the organizations that have not been granted deeming authority, including the basis for denial; and

• Whether there would be an opportunity for public comment on applications submitted by individual accreditation organizations.

Response: Because this rule could have broad applicability with respect to potentially large numbers of affected health care providers, facilities and consumers, we are enthusiastically committed to providing adequate notice and comment opportunities with respect to the approval of deeming authority for any accreditation organization. We believe that the proposed approval of deeming authority for an accreditation organization should be publicized and that the public should be offered the opportunity to comment on the proposed approval so that any final determination regarding such approval would be made only after consideration of all information and perspectives provided by interested and affected parties.

Therefore, we have revised the final rule to provide for publication in the **Federal Register** of a proposed notice with comment period whenever we determine that an accreditation organization has demonstrated that it can provide reasonable assurance that the entities it accredits meet the appropriate Medicare requirements and the rationale for the determination. At least six months after the publication of the proposed notice, we will publish a final notice before any approval of deeming authority becomes effective.

Comment: Four commenters believed that the proposed regulations should include State licensure agencies as organizations that can be approved for "deeming authority" if these agencies have both survey and enforcement programs that meet HCFA's standards. The commenters also believed that when the proposed regulations are implemented, the State should be given first "refusal rights" for recognition as the accreditation organization because State agency personnel have received training on the survey and certification processes and are knowledgeable about the Medicare certification requirements. One commenter also believed that in some situations a State or regional program may be better equipped to understand and accommodate State laws when ascertaining compliance.

Response: We cannot accept this comment because under the authority of section 1865(a) of the Act HCFA is permitted to grant deeming authority only to national accreditation organizations.

Comment: One commenter indicated that the term "national accreditation organization" needs to be clarified.

Response: A national organization is an accreditation organization that offers accreditation services that are available in every State to any provider or supplier of the type accredited by the organization wishing to obtain accreditation status.

Comment: Four commenters stated that granting authority to private accreditation organizations creates a significant potential for inhibiting redress of consumer grievances and fails to provide sufficient consumer and beneficiary representation.

Response: We do not agree with this comment. The deemed status validation process includes a complaint investigation process. As indicated in § 488.7(a)(2) of this rule, the State survey agency, in response to a substantial allegation of noncompliance, surveys for any condition, or requirement for SNFs, that HCFA determines is related to the allegation. We have defined the term substantial allegation of noncompliance to mean a complaint from a variety of sources (including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles), or any other source, that reflects on the health and safety of patients and raises doubts as to a provider's or supplier's compliance with any Medicare condition level requirement.

Comment: One commenter urged that HCFA work with entities such as the American Hospital Association, the JCAHO, the College of American Pathologists, the American Society of Internal Medicine, and the Commission on Office Laboratory Assessment, all of which potentially will request "deeming authority" as national accreditation organizations; the commenter added that these entities have the knowledge and expertise to provide HCFA with valuable information in finalizing these regulations. Four commenters suggested that HCFA consult with professional organizations to investigate alternatives to the proposed 20 percent rate of disparity. The commenters suggested that one alternative would be to engage an independent body to undertake a nation-wide, on-site review of a sample of the facilities accredited by an organization and report its findings back to HCFA. The commenters believed that such an approach would reduce the impact of varying State standards and survey techniques and would allow these important decisions about

possible withdrawal of deeming authority to be based on a larger and more diverse national sample.

Response: The standard process by which we respond to comments on a published notice of proposed rulemaking offers an efficient and effective means to request and obtain input from the broadest possible spectrum of the public. In addition, there will be a proposed notice published in the **Federal Register**, and an opportunity for comment before the final approval of deeming authority for any accreditation organization. To include only a few organizations in drafting final regulations would, at best, be soliciting repetitive and subjective comments from these parties, and, at worst, allow for inequitable opportunity of certain parties to influence the agency's reaction to public comments and the ultimate formulation of policy. We will not allow an outside organization to develop criteria to measure the equivalency of standards nor to conduct a nationwide validation activity on our behalf because of the importance of ensuring sound, consistent, national policy on these issues.

Comment: One commenter stated that the proposed regulation does not refer to laboratories; there is no mention of how this regulation will be applied and its relationship to the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88).

Response: We acknowledge the commenter's concerns that the proposed regulation did not discuss the deeming of accreditation of laboratories in significant detail nor does it explain the relationship between this rule and the implementation of the requirements of CLIA '88.

Regulations implementing CLIA '88 were published on February 28, 1992 (57 FR 7002) and January 19, 1993 (58 FR 5215): Medicare, Medicaid and CLIA Programs; Regulations Implementing the Clinical Laboratories Improvement Amendments of 1988 (CLIA '88). We also published, on July 31, 1992, a rule entitled, HSQ–81–F: Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and of CLIA Exemption Under State Laboratory Programs (57 FR 33992), to implement CLIA '88 requirements concerning deeming authority for accreditation organizations and States that accredit or license, respectively, laboratories. CLIA '88 has specific requirements for deeming laboratories as meeting CLIA requirements by virtue of their accreditation or licensure.

This final rule includes provisions only with respect to the granting and withdrawal of deeming authority to national accreditation organizations for the other provider and supplier types specified in the proposed rule, and only with regard to non-laboratory service requirements. Of the provider and supplier types for which national accreditation organizations may apply for approval of deeming authority, three have condition level requirements for laboratory services: hospitals; long-term care facilities; and ambulatory surgery centers. These condition level Medicare certification requirements require that a laboratory in an accredited facility meet the applicable requirements for a CLIA certificate and that the CLIA approved laboratory services be adequate to the needs of the patients in the facility. For example, once the CLIA certification requirements are effective, laboratories in accreditated hospitals will not have deemed status by virtue of their hospital accreditation by JCAHO or AOA. Therefore, a national accreditation organization may apply for deeming authority for all conditions for these provider types under this rule. However, if an organization wishes to have deeming authority for CLIA requirements, it must make separate application for that approval under the laboratory deeming rule. In all cases, a provider or supplier must provide CLIA certified laboratory services, either directly or under arrangement, in order to meet Medicare certification requirements.

Comment: Two commenters recommended that before issuing a final regulation, HCFA should commission an independent study comparing the private accreditation systems (including their ability to find violations that affect patients' health, safety or welfare, and to secure elimination of those violations) and the certification system mandated by the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) (a system that is an outcome-oriented process that evaluates the standard of care furnished to residents based on outcomes of care, protection of resident rights, and then ensuring that the residents' well-being is not compromised).

Response: As provided for in § 488.9 of this rule, each accreditation organization applying to HCFA for deeming authority will be reviewed on a case-by-case basis. This process will evaluate accreditation systems more effectively than doing an overall comparative study. HCFA's evaluation of accreditation systems does not focus on the relative merits of one organization against another but on each organization's equivalency to the applicable Federal requirements.

Comment: Two commenters asked how the "deemed status" would work when a nursing home participates in both Medicare and Medicaid and questioned whether only the Medicare portion would be "deemed" if it had a Medicare distinct part.

Response: Because there is no statutory authority for granting deemed status to Medicaid nursing facilities, the deemed status granted by an accreditation organization would only apply to the Medicare certification of a dually participating facility or its dually participating distinct part(s). This may result in multiple surveys if any accreditation organizations request approval to grant deemed status to nursing homes and their accredited facilities participate in both Medicare and Medicaid. One survey would be conducted by the accreditation organization for the Medicare certification and another survey would be conducted by the State survey agency for Medicaid participation. The only instances where eligibility for Medicaid participation can be established through deemed status are for providers and suppliers that are only required under Medicaid regulations to comply with the Medicare participation requirements for that provider or supplier type. In such instances, if the accreditation body has received approval of deeming authority under Medicare, and if the provider or supplier is deemed to meet Medicare requirements by virtue of its accreditation by the approved accreditation body, that provider or supplier has met Medicaid requirements. Under present Medicaid rules, the only facilities subject to Medicare participation requirements are hospitals, home health agencies, laboratories and rural health clinics. We have revised §§ 488.5 and 488.6 to include deeming of Medicaid providers and suppliers where applicable.

OBRA '87 Comments

The Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100–203) mandated nursing home reform and was comprised of numerous provisions addressing comprehensive requirements for resident health, safety and rights in order for nursing homes to participate in Medicare and Medicaid. OBRA '87 also specified an innovative survey and enforcement mechanism to ensure facility compliance with these requirements. We received several comments about how our proposed rule is affected by OBRA '87 changes.

Comment: Twelve commenters questioned the legality of "deemed

status" and its consistency with the intent of the nursing home reform provisions of OBRA '87. The commenters believed that accreditation organizations will not be able to demonstrate that their standards are equivalent to the equivalent standards of OBRA '87.

Response: Section 1865(a) of the Act specifies that if HCFA finds that the accreditation of certain listed entities by a national accreditation organization provides reasonable assurance that the Medicare conditions imposed on those entities are met, it may treat such an entity as meeting those conditions. Included in the list of entities in section 1865 of the Act are skilled nursing facilities. The ability of an accreditation organization to demonstrate that its standards are equivalent to corresponding standards of OBRA '87 cannot be ascertained until that organization applies for deeming authority and HCFA completes a comparative analysis. Only if the accrediting organization conclusively demonstrates that its standards are at least equivalent to the OBRA '87 requirements for skilled nursing facilities would we consider granting deeming authority for these types of facilities.

OBRA '87 made sweeping changes in nursing home requirements, survey and enforcement, with which an accrediting organization could have difficulty demonstrating equivalence. The law requires public accountability and access to public information that goes well beyond the deeming provisions of the statute and that requires State agencies to use their survey responsibilities in administering a complex system of quality assurance initiatives.

The likelihood that any national accreditation organization will request approval of deeming authority for long-term care facilities appears to be low because only 870 of the currently 16,297 certified long-term care facilities participate only in the Medicare program. The number of Medicare-only facilities has steadily decreased as more facilities elect to participate in both Medicare and Medicaid, and we anticipate this trend continuing. Facilities that participate in both programs may decide not to seek accreditation for purposes of deeming since the facility would then be subject to two surveys; that is, an accreditation survey for deeming of the Medicare requirements and a survey by the State agency for Medicaid participation. The increasingly limited number of facilities that could benefit from accreditation for deeming purposes would make an unattractive market for accreditation organizations as the survey system necessary to support a deeming authority program would prove costly to the organization.

Comment: Six commenters expressed concern that accreditation organizations would not be required to use interpretive guidelines consistently that were developed for surveyors to survey nursing homes and home health agencies.

Response: Although the use of HCFA's interpretive guidelines would not be required, the accreditation organization must demonstrate that it can provide reasonable assurance that the requirements of the nursing home reform provisions of OBRA '87 are met. We expect an accreditation organization applying for deeming authority to have survey guidelines and procedures that will assure consistent application of their standards and provide reasonable assurance to HCFA that the participation requirements would be met if the facility were surveyed for compliance with those requirements.

Comment: One commenter suggested that delegating oversight authority to an accreditation body is not sound policy, especially in light of changes mandated by OBRA '87, which radically revised how we determine whether a nursing home may participate in Medicare and Medicaid.

Response: Congress has granted deeming status to JCAHO since the inception of the Medicare program. Congress further authorized the Secretary at section 1865 of the Act to permit other types of providers and suppliers to be deemed by accreditation bodies if those accreditation bodies provide reasonable assurance that the applicable participation requirements are met. By granting deeming authority the Secretary does not delegate oversight authority. The oversight authorization with respect to participating facilities remains with HCFA, who may take enforcement actions on the basis of surveys performed by the accreditation organization, the State survey agency, or both. The approval of deeming authority for OBRA '87 nursing home provisions will only occur if an accreditation body applies for such deeming authority and provides reasonable assurance that its accredited facilities meet the OBRA '87 nursing home requirements.

Comment: Two commenters believe that important issues such as improper and overuse of chemical and physical restraints, pharmacy care and resident rights could easily be overlooked by private accreditation organizations.

Response: As we have stated earlier, when an accreditation organization requests approval to grant deemed status, that organization must provide reasonable assurance that Federal requirements for each type of provider to which it wishes to grant deemed status will be met and that it can consistently survey accurately for those requirements. If these assurances are not provided, we will not approve the organization.

Comment: One commenter said there appeared to be a direct conflict with OBRA '87 provisions, which require the imposition of incremental fines for repeated or uncorrected deficiencies, and the concept of reasonable assurance and findings of significant deficiencies that appear to provide for an acceptable level of noncompliance.

Response: There is no acceptable level of noncompliance with Federal requirements. Only through a careful comparative analysis can we determine whether an accreditation organization provides reasonable assurance that all Federal requirements are met by accredited facilities. We will not grant approval of deeming authority to any organization whose standards or survey process permit noncompliance with the applicable Federal requirements. The use of the sanction provisions of OBRA '87, that is, denial of payment for new admissions, civil money penalties, temporary management, etc., can be used in addition to any actions an accreditation organization takes when it finds noncompliance, because the Omnibus Budget Reconciliation Act of 1989 (OBRA '89) specifies that we can take action based on an accreditation organization's findings. Accordingly, we may impose incrementally more severe fines for repeated or uncorrected deficiencies cited by the accreditation organization in its survey documentation. We may also impose sanctions based on our own survey when HCFA removes a provider's deemed status. For cases in which HCFA takes an adverse action based on an accreditation organization's findings, we have included a requirement in § 488.4 that in its application for deeming approval an accreditation organization must agree to permit its surveyors to serve as witnesses.

Comment: One commenter stated that since no final rules have been issued to implement any OBRA '87 provision, there exists no basis for consideration of granting deemed status to nursing facilities and home health agencies at this time.

Response: The process involved in approving accreditation organizations for deeming purposes does not require

that the provisions of OBRA '87 be implemented. We will grant deeming approval to accreditation organizations whose accreditation requirements are equal to or more stringent than the requirements we have in effect at the time. However, we do note that the OBRA '87 provisions have been included in several regulations: "BPD–396–FC: Requirements for Long Term Care Facilities", published February 2, 1989 (54 FR 5316), "BPD–396–F: Requirements for Long Term Care Facilities", published on September 26, 1991 (56 FR 48826), and "BPD–76–F: Home Health Agencies; Conditions of Participation", published on July 18, 1991 (56 FR 32973).

Comment: One commenter believed that approving an accreditation organization that uses a medical model rather than patient outcomes is contrary to nursing home reform provisions of OBRA '87, which stress quality of life for residents and pays closer attention to social and emotional needs.

Response: Although historically accreditation organizations have focused on compliance with process standards, any accreditation organization seeking approval to grant deemed status must demonstrate that it has requirements equivalent to all of the HCFA requirements for the same facility type, including those addressing social and emotional needs and patient outcomes in general. We also expect an organization to demonstrate a survey procedure and overall philosophy compatible with the OBRA '87 requirements, which mandated a survey process that evaluates resident outcomes, rather than focusing on policies and procedures, and provides for enforcement sanctions other than termination if facilities are out of compliance. These issues will be examined when an organization applies for approval to grant deemed status to any type of provider or supplier.

Comment: Four commenters expressed concern that the Joint Commission routinely announces its surveys three months in advance, which gives facilities ample time to prepare for the accreditation survey, while OBRA '87 requires that surveys be unannounced so that facilities will not be able to cover up the failings and inadequacies of the facility cosmetically.

Response: Any accreditation organization requesting approval to grant deemed status must assure and demonstrate to the Secretary that its surveys conform to Federal survey requirements. In fact, our policy is also to announce hospital surveys. We will examine the survey process of any accreditation organization wishing to grant deemed status to nursing homes to determine if it includes a survey policy consistent with the requirements of the law and HCFA operating policy.

Comment: Fifteen commenters believed there will be duplication, overlap and fragmentation of responsibilities if the Secretary allows accreditation organizations to grant deemed status to nursing homes and home health agencies (HHAs). They argued that nursing homes and HHAs would have to be licensed by the State and, additionally, by the accreditation organization. They stated that these surveys would be conducted at different intervals.

Response: In nursing homes and HHAs, State licensure and HCFA surveys are separate but in most cases are conducted concurrently. OBRA '87 requires that surveys be unannounced and allows the State survey agency to conduct a survey up to 15 months from the last survey as long as the Statewide average does not exceed 12 months. Any accreditation organization requesting approval would likely demonstrate a similar mechanism to assure an unannounced aspect and an acceptable frequency of surveys, and we are revising § 488.8(1)(ii)(B) (proposed § 488.9(1)(ii)(B)) to cite specifically whether surveys are announced or unannounced as one of the survey procedures we will include in determining comparability.

Comment: Three commenters asked that accreditation organizations be held to the same timeframes for conducting surveys and releasing the survey findings to providers as the State survey agency. One commenter further asked that the length of accreditation should be flexible based on the facility's ability to meet standards; another expressed concern that accreditation status was generally conferred for a three-year period.

Response: Accreditation organizations will have to demonstrate to HCFA that they use survey processes, survey frequencies and other timeframes that provide reasonable assurance that Medicare requirements, whether designated in law, regulations, or manual instructions, are met for the types of facilities for which the accreditation organization is seeking approval to grant deemed status. The statute does permit survey intervals of as much as 15 months for nursing homes and HHAs, and there is nothing to preclude such intervals from being set by an accreditation organization based on the facility's past performance. The specific timeframes and other procedures used by an accreditation organization will be evaluated by HCFA during the application process, as will the mechanisms used by the organization to monitor facilities and ensure compliance with requirements during the periods between surveys.

Comment: Twenty-one commenters questioned the advisability of dividing the survey and enforcement functions when an accreditation organization is approved to grant deemed status. Commenters stated that—

- The quality of the survey will be compromised by possible differences in interpretation of Federal regulations.
- Survey and enforcement processes are inextricably linked. Results of the surveys dictate the enforcement remedies, and enforcement needs must guide the survey (i.e., assuring that the survey documentation will withstand legal challenges).
- When the survey is performed by an outside entity, there will be no information released on substandard facilities and no enforcement actions taken while residents live in poor quality and sometimes life-threatening circumstances.
- Granting approval to an accreditation organization undermines the government's ability to perform quality assurance and protection of nursing home residents from abuse and neglect.

Response: All accreditation organizations must provide reasonable assurance that applicable standards will be met, as ascertained by HCFA through our comparative analysis, before an organization will be approved for granting deemed status. Accreditation organizations will be applying their own standards and will not be interpreting Federal regulations. Further, we are authorized to accept the accreditation organization's survey as our own in imposing sanctions, so the survey and enforcement processes remain closely associated. The government expects accreditation organizations to enforce requirements for quality assurance and for assuring resident protection. The validation activity will further demonstrate whether the organization's application of its standards meets HCFA enforcement needs and provides reasonable assurance of compliance. Additionally, the validation authority for State survey agencies to survey accredited facilities encompasses both routine validation reviews and other reviews stemming from complaints and can help to ensure the health and safety of patients and residents. Finally, we can require accreditation survey information to be available for substandard facilities to the extent the

information results in an enforcement action.

Comment: Nine commenters stated that the proposed rule does not take into account the interrelationships of the survey to other critical quality assurance functions and that no accreditation organization could be responsive in a consistent and timely manner to investigations of abuse since the accreditation organization would not share its findings and has no jurisdiction or authority to act on behalf of someone found to need assistance. The commenters added that, although the proposed rule requires an accreditation organization to have the ability to investigate complaints, there is no requirement for the investigations to be coordinated with other responsible agencies.

Response: The relationship between an accreditation organization, the State ombudsman for long term care and the State will be evaluated to assure that the accreditation organization meets the coordination requirements of OBRA '87. We will consider such relationships in determining whether the organization that seeks deeming authority for skilled nursing facilities has a survey process that provides reasonable assurance that the standards dictated by OBRA '87 and codified in section 1819(g) of the Act will be met and should therefore be approved for deeming authority. Specifically, an accreditation organization seeking approval for skilled nursing facilities will be expected to have procedures in place to notify the State ombudsman when it identifies deficiencies in an accredited facility with respect to its accreditation standards as well as any adverse action taken with respect to the facility's accreditation status. The accreditation organization will also be expected to notify each attending physician and the State board that licenses nursing home administrators whenever the accreditation organization identifies one or more instances of substandard care in an accredited facility.

Comment: Two commenters believed that granting deeming authority to an accreditation organization increases the time between the discovery of a deficiency and the application of a remedy because the survey agency would need to conduct another survey before imposing remedies.

Response: While the State agency is not precluded from conducting another survey, Section 1865(b) of the Act as amended by section 6019(b) of OBRA '89 permits HCFA to accept the accreditation organization's findings as its own and impose remedies immediately. To further ensure the protection of the health and safety of patients and residents in accredited facilities, we will require in § 488.4(b)(3)(vi) an approved accreditation organization to agree to notify HCFA within ten days whenever it identifies a deficiency that poses an immediate jeopardy to those patients or residents.

Comment: Two commenters recommended that validation/complaint surveys be conducted by a disinterested party, such as the Office of the Inspector General, and not by HCFA agents, to yield more objective and fair results.

Response: As stipulated in Section 1864(c) of the Social Security Act, there is no statutory authority for the Secretary to delegate this function to any entity other than the State survey agency.

Comment: One commenter believed that if more than one national accreditation organization exists, competition for contracts with nursing homes could undermine the survey process by creating a potential conflict of interest between the facility and an organization that accredits it.

Response: Accreditation is strictly voluntary. While it is possible that a facility could "shop around" for an accreditation organization whose standards the facility could meet, if the accrediting organization has approval of deeming authority its standards as a whole will have been found to provide reasonable assurance that equivalent Federal requirements would be met.

Cost Issues

Comment: One commenter believed that diverting survey dollars to an accreditation organization would weaken the capacity of the designated government survey agency to respond to substandard conditions.

Response: Accreditation fees for hospitals have always been an allowable cost under the Medicare program and included in a facility's indirect costs or in its prospective payment rate for inpatient services. The allowable costs considered reasonable are allocable on the basis of Medicare patient days or are reflected in a hospital's prospective payment rate for inpatient services. This rule will not divert survey dollars or reduce the enforcement funding of survey agencies. The level of funding of the State's survey agency will continue to be based on its survey and enforcement workload. Funding of State survey agencies will be commensurate with workload and number of facilities involved and will take into account the responsibility to "respond to substandard conditions".

Comment: One commenter believed that extending an accreditation program to nursing homes is not appropriate because it increases the administrative costs of regulating nursing homes. He believed these funds should go for direct care services for residents.

Response: As explained above, extending an accreditation program to nursing homes will not increase administrative costs since the Federal government will either pay the accreditation fees allocable to the Medicare program or pay the cost of a State agency survey of the facility.

Comment: Twenty commenters believed that "deemed status" shifts costs to the public from one budget to another. They stated that fees to accreditation organizations are paid by providers, which are in turn reimbursed for their expenses as part of their allowable operating costs of doing business. The commenters were concerned that this fee-for-service arrangement reduces public accountability and objectivity and that, consequently, the Federal government will still be paying for the accreditation surveys.

Response: While it is true that accreditation fees are considered an allowable cost, those costs are allocable on the basis of the Medicare population in a facility or are reflected in the calculation of a hospital's prospective payment rate for inpatient services. Since the remaining accreditation costs will be borne by the facility, there is not a dollar-for-dollar shifting of survey costs. We will evaluate factors such as cost, public accountability, conflict of interest, and objectivity through the review of an accreditation organization's application for approval of deeming authority.

Specific comments: The following are comments we received on specific regulatory sections:

§ 401.126 Information or records that are not available.

§ 401.133 Availability of official reports on providers and suppliers of services, State agencies, intermediaries, and carriers under Medicare.

Comment: Twenty-seven commenters believed that, based on the OBRA '87 provisions related to public accountability and access to public information, all survey results, including accreditation surveys, should be made available to allow consumers to make comparative judgements about certified providers and suppliers. Moreover, the commenters believed that the accreditation survey confidentiality requirements are inconsistent with OBRA '87 provisions on disclosure and

will abridge the effectiveness of ombudsmen as a source of information about a facility.

Response: Section 1865(a) of the Act prohibits disclosure of accreditation surveys or related information by the Secretary except to the extent that these surveys and information relate to an enforcement action taken by the Secretary. Copies of all accreditation survey information will be available to HCFA, which will monitor accreditation organizations and the facilities they accredit. We will take enforcement action if deficiencies are not corrected by the facility; the accreditation survey and related information with respect to the enforcement action will be available to the public. In this way, there is access by the public to information about poor performance on the part of accredited entities. Although this provision at Section 1865(a) of the Act does not speak to the release of information on good performance by nursing homes, the primary objective of the nursing home provisions of OBRA '87 was the protection of the health and safety of residents. Disclosure of information on poor performers that the public would want to avoid is certainly consistent with that objective of OBRA '87. While Section 1819(g)(5)(A)(i), as added by OBRA '87, requires us to make available to the public survey and certification information about all SNFs (not only those that are subject to enforcement actions), Section 1819 of the Act mentions only surveys conducted by the State or the Federal government and is silent on those conducted by accreditation organizations. However, when we evaluate an accreditation organization's application for deeming authority, we will consider all of the issues raised in the above comment. In addition, while Section 1865(a) of the Act prohibits us from disclosing accreditation survey information, unless an enforcement action is taken on the basis of that survey, or any accreditation survey of a home health agency, there is nothing in the statute to preclude the accrediting organization from releasing this information. In addition, we do not prohibit the release of this information by the individual facilities. The responsiveness of an accreditation organization to public inquiries about surveys of individual facilities, or a facility's willingness to release survey information, are factors consumers can consider in evaluating the facility. Based on these factors, the consumers can reach their own conclusion about a facility's performance and management philosophy, and the relative value to consumers that accreditation by a certain organization may have. As mentioned previously, we will evaluate an accreditation organization's level of coordination and cooperation with State ombudsmen programs when we receive the organization's application for deeming authority.

Finally, where ombudsmen function as an agency or otherwise are under the aegis of the State government, Federal law does not preclude the enforcement of State laws requiring the disclosure of accreditation information, for example, under State licensure programs.

Comment: One commenter requested clarification on the kinds of actions HCFA will consider as "enforcement actions" under § 401.126(b)(2)(B) of this rule.

Response: An enforcement action may include any action the Secretary takes in response to noncompliance with Federal requirements. Such sanctions include termination and other remedies that are alternatives to termination. We have amended the text at §§ 401.126(b)(2)(B) and 401.133(d) to include some examples of enforcement actions.

Comment: Two commenters recommended that § 401.133(d) be revised to require (rather than allow) the Secretary to release the accreditation survey and related information upon request. The commenters believed that this change is needed to achieve equivalency to the current Federal survey policy.

Response: We accept this recommendation and have amended the text at § 410.133 (d) and (e) to state that HCFA will release the information, rather than that we may release it. We are also changing, in other sections, all references to "the Secretary" to "HCFA" to correspond to other HCFA regulations. For consistency with the release of accreditation surveys of entities other than HHAs, in paragraph (e) we will require the release of HHA surveys only upon written request.

Comment: Two commenters objected to the proposed provisions in §§ 401.126 and 401.133, which state that the Secretary may release the accreditation survey of any home health agency. One commenter believed that in accordance with Section 1864(a) of the Act, the Secretary is authorized, at most, to release only certain accreditation survey information concerning significant deficiencies with respect to patient care to the State survey agencies so that they may make that information available over the home health hotline. The commenters believed that the disclosure of home health agency accreditation survey information should be similar to disclosure for other providers or suppliers.

Response: Section 1865(a) explicitly prohibits the Secretary from disclosing the accreditation survey released to HCFA by any accreditation organization for any entity other than a survey with respect to a home health agency (except that the Secretary may disclose survey results and information related to the survey for any type of facility to the extent that the survey and additional information are related to an enforcement action the Secretary takes). Accordingly, the law does not prohibit the Secretary's disclosure of accreditation surveys of home health agencies. Therefore, based on the law, we do not accept these comments.

Section 488.1—Definitions

Comment: Four commenters recommended that the definition of a substantial allegation be revised to define the sources of complaints more specifically. The commenters believed that the revision will reduce instances of rumor and speculation.

Response: We do not agree that specifying or explaining the sources of complaints in regulations will reduce unsubstantiated allegations. Our administrative procedures manuals provide guidance to Federal and State surveyors to evaluate all complaints. Those complaints that pertain to charges and billing, health insurance coverage, and personal complaints that are clearly subjective are not authorized for investigation. We believe, however, that all complaints, regardless of the source, concerning the quality of care and other participation requirements must be investigated. Specific investigative procedures are included in the procedure manuals. However, writing regulations to this level of specificity would unnecessarily limit HCFA's flexibility in applying its administrative policies.

Comment: One commenter asked that we define the term "reasonable assurance" as specified in section 1865 of the Act and as it relates to the accreditation process in § 488.1.

Response: We have accepted this comment and are defining "reasonable assurance" in § 488.1 to mean that an accreditation organization has demonstrated to HCFA that its standards, taken as a whole, are at least as stringent as those established by HCFA, taken as a whole. This does not mean that the requirements of the accreditation organization must be identical to HCFA requirements. The accreditation requirements may vary from and be organized differently than the Federal requirements for a specific

service or facility. It is possible that an accreditation organization may impose less stringent requirements in one area that are balanced by more stringent requirements in a closely related requirement elsewhere in the standards. The main consideration in determining reasonable assurance is the level of protection afforded to the accredited facility on the basis of the accreditation requirements taken as a whole. We have revised the proposed § 488.6 to reflect this policy.

Comment: One commenter stated that a definition for "pattern of increasing disparity" should be developed.

Response: We have deleted references to increasing rate of disparity and have revised our approach in using the rate of disparity in determining whether a comprehensive review of an accreditation organization's deeming authority should be undertaken. As provided in the final rule, at the close of a validation review period, we will evaluate the findings of the validation program, including the rate of disparity. If the rate of disparity is 20 percent or more, we will initiate a deeming authority review. On the basis of validation review findings where the rate of disparity is less than 20 percent, we may implement deeming authority review if the validation review findings indicate widespread or systematic problems in an organization's accreditation process that provide evidence that there is no longer reasonable assurance that accredited entities meet Medicare requirements.

Section 488.5—Effect of JCAHO or AOA Accreditation of Hospitals

Comment: Two commenters stated that under § 488.5(b) all accreditation findings for any hospital should be automatically released to HCFA.

Response: Section 1865(a) of the Social Security Act provides that only if an accredited hospital authorizes the accreditation organization to release its most recent accreditation survey will a hospital be deemed to meet the Medicare requirements. The regulation at § 488.5(b) simply restates this statutory provision. We will determine administratively when and under what circumstances (e.g., validation survey, complaint investigation, enforcement action, etc.) we will exercise our rights to secure this information as we do not necessarily have a need for records of all accreditation surveys.

Comment: One commenter believed that a provision needs to be included in § 488.5 that requires providers and suppliers to report substandard surveyors and erroneous accreditation survey reports to HCFA.

Response: Surveyor performance and accuracy of accreditation survey reports are issues that will be evaluated as part of the validation review process. When reviewing the performance and accuracy as part of the comparability review process, we will ensure that an accreditation organization has a quality control process, and evaluate the effectiveness of that process.

In determining whether the accreditation organization provides reasonable assurance that Medicare requirements are met, HCFA will review how the organization assures its surveyors are competent and that survey results are accurate. For this reason, we have declined to accept this comment. In addition, affected providers will have the opportunity to comment prospectively on the survey process and personnel qualifications at the time the proposed notice of approval is published. Finally, there is nothing to preclude any provider from notifying HCFA or the accreditation organization whenever the provider encounters problems in the accreditation process or survey personnel.

Section 488.6—Other National Accreditation Programs for Hospitals and Other Providers and Suppliers

Comment: Seven commenters disagreed with the proposed provision in § 488.6 that permits partial accreditation for providers that meet "any or all of the Medicare conditions". The commenters believed that such services as dietary, nursing, assessment, and quality of care are all interrelated. They stated that under an outcome-oriented system, a surveyor must look at the whole picture before determining compliance; partial accreditation would segment the information available to the public and segment enforcement efforts.

Response: The term partial accreditation is misleading. We have no authority over the services, facilities, or requirements that an accreditation organization chooses to evaluate and accredit. Based on an organization's scope of interest, we could be faced with the issue of partial deeming. We agree with the commenters that this concept could be problematic. As the commenters point out, many of the participation requirements are inextricably related and cannot be properly evaluated without careful examination of the related requirements. We also believe, however, that there could be effective accreditation organizations whose standards address individual participation requirements or groups of requirements that are less than the full range of requirements that a specific facility type must meet in order to participate in the Medicare program.

The statute gives the Secretary explicit authority to deem compliance with "any or all" of the Medicare conditions if equivalent accreditation standards are met. While we can see no advantage to recognizing partial accreditation at this time, the authority to do so is reflected in this rule. Deeming compliance with only a portion of the Medicare certification requirements could create an extreme administrative burden, but it can also provide the necessary flexibility to administer the certification program effectively. In addition to those cases where the accreditation organization accredits less than the full range of Federal requirements, there are those instances where we have imposed specific requirements that are more stringent than comparable requirements imposed by an accreditation organization. In such cases, deeming authority for the majority of the requirements could be an effective device that allows us or our agent to survey directly for some requirements and to allow for the deeming of others by a specific entity.

For example, currently accredited psychiatric hospitals are deemed to meet all of the hospital conditions for participation except the special psychiatric hospital staffing and records requirements, which HCFA surveys through other means. Other similar arrangements could prove desirable, and we must maintain the authority to exercise flexibility in the scope of deeming authority that is approved.

Comment: Two commenters strongly recommended that the proposed deletion of the informal review process currently specified in § 488.6(f) be retained and extended to all providers whether or not they are accredited.

Response: We do not accept this comment. As indicated in the preamble of the proposed regulation, we will implement a uniform appeals process for both accredited and nonaccredited providers and suppliers. Eliminating the informal review process for accredited providers and suppliers, which is not available to nonaccredited providers and suppliers, is part of our effort to establish this uniform appeals process.

Comment: One commenter believed that the proposed language in § 488.6 deviates substantially from the intent of the language specified in section 1865 of the Act. The commenter recommended that the language in § 488.6 be changed to specify that conditions precedent to accreditation recognition by HCFA include the requirement that the accreditation organization demonstrate

that it imposes the Medicare condition(s) or other requirements that serve substantially the same purpose or standards that HCFA determines are at least equivalent to the Medicare standards imposed by HCFA.

Response: Section 488.9 satisfies the intent of the law by outlining the general criteria an accreditation organization must meet in order to provide reasonable assurance to HCFA that its standards are equivalent to those standards established by HCFA. Therefore, we are not revising § 488.6 as suggested.

§ 488.7—Validation Survey

Comment: Two commenters supported the use of private accreditation survey results as the basis for triggering a validation survey but strongly objected to the initiation of enforcement actions based on an accreditation survey without independent verification of noncompliance through a Medicare survey.

Response: Under section 6019(b) of OBRA '89 HCFA may use a validation survey, an accreditation survey, or other information related to the survey to determine that a facility does not meet the Medicare conditions of participation. HCFA may, based on the results of an accreditation survey, remove "deemed" status and initiate an enforcement action against a facility based simply on a review of the accreditation organization's documents. Such immediate action is necessary to protect the health and safety of patients and residents in accredited facilities.

Comment: One commenter believed that significant deviations currently exist among regional offices and between regional offices and HCFA central office concerning the interpretations of the conditions of participation and that HCFA has not given instructions to its own surveyors on when to cite standard versus condition level deficiencies. He stated that surveyors' classifications of deficiencies vary and will likely continue to do so until HCFA develops more specific instructions on weighing systems for establishing consistency.

Response: The HCFA survey and certification procedures applied by the State survey agencies and Federal surveyors are not the subject of this rule. However, we point out that the survey and certification process includes review mechanisms to ensure that surveyors, in exercising their best professional judgement in identifying and citing deficiencies, are consistent in their application of the requirements. Based on our experience in evaluating State agency performance, we disagree with the comment that HCFA and the State agency survey are inconsistent with respect to citing deficiencies.

Comment: One commenter believed that providers certified on the basis of "deemed status" should be allowed to request a review by the State agency or the HCFA surveyors where accreditation findings indicate deemed noncompliance with Federal conditions; in such cases, the State or regional office surveyors could confirm the accreditation organization's findings or conclude that Federal requirements are met whether or not all standards of the accreditation organization are met.

Response: The law provides no authority for providers or suppliers certified on the basis of "deemed status" to choose to have a State survey when accreditation findings indicate noncompliance with accreditation standards and, therefore, presumed noncompliance with Federal requirements. Only HCFA has the authority to determine which accreditation survey results will be validated. A State agency survey will be available to a facility if the facility voluntarily discontinues its accreditation status or loses its accreditation due to noncompliance with accreditation requirements and formally requests certification by the survey agency. Otherwise, State agency surveys of accredited facilities will be done on a sample basis or in response to complaints, as explained below. Except in the situations noted above, neither HCFA nor the State agency will intervene in any dispute between an accreditation organization and its accredited providers or facilities.

Comment: Two commenters questioned whether the terms "significant deficiencies" and "reasonable assurances that conditions were met to the extent appropriate" allow an acceptable amount of facility noncompliance with HCFA requirements.

Response: We do not agree with this comment. As we indicated in the preamble of the proposed regulations, it is in the public's interest to follow up any deficiency serious enough to threaten a provider or supplier's participation in the Medicare program and we are revising the proposed regulations at § 488.7(a) to permit us to survey in response to substantial allegations of any deficiencies (instead of significant deficiencies). We have no authority to change the statutory provision that requires "reasonable assurances that conditions were met to the extent appropriate". However, we believe the criteria for determining reasonable assurance, as presented in this final rule, will assure that accredited facilities meet Medicare requirements. Our evaluation of an accreditation organization will determine the equivalency of the accreditation organization's facility standards, taken as a whole, and its survey and inspection requirements to the applicable Federal requirements. Equivalency means that the organization's requirements correspond to and provide at least the same protection as the applicable Medicare condition level requirements established by HCFA. It is acceptable for an accreditation organization's requirements to vary from and be organized differently from the HCFA requirements, as long as all of the accreditation organization's requirements, taken as a whole, are at least equal to the HCFA requirements, taken as a whole.

Comment: One commenter believed that § 488.7(b)(1), which requires the provider or supplier to authorize the release of its survey to HCFA, should be deleted because it is redundant of §§ 488.5(b) and 488.6(b).

Response: We agree with the commenter that the provision at § 488.7(b)(1) is essentially duplicative of the provisions at §§ 488.5(b) and 488.6(b) and have deleted that provision. To conform to the requirements of the statute, we have revised §§ 488.5(b) and 488.6(b) to reflect that a hospital or other facility deemed to meet Medicare requirements by virtue of accreditation must authorize the release of its accreditation survey to the State survey agency as well as to HCFA.

Comment: One commenter stated that § 488.7(a)(1) of the proposed regulation should be amended to allow the validation survey to focus on specific conditions when appropriate. This validation survey approach was permitted in a HCFA letter to the Joint Commission.

Response: We agree with the commenter and have revised the regulation at § 488.7(a)(1) to reflect that the validation survey may be focused on specific conditions or requirements when appropriate.

Comment: One commenter stated that the proposed regulation does not require validation surveys to be conducted with sufficient frequency, according to accepted scientific standards. Another commenter stated that under § 488.7(a), HCFA should conduct validation surveys within 60 days of the latest accreditation organization report to ensure the accuracy of the survey.

Response: Historically, the establishment of time limits for performing validation surveys of hospitals has been included within HCFA's internal operating instructions. Such time limits and procedures are subject to adjustment in response to changes in workload, staff resources, etc., as well as statistical reliability. The maximum allowable timeframe provided in our instruction manual for the interval between an accreditation survey and a corresponding validation survey is 60 days. However, based on recently revised procedures, we will also include in the representative sample of facilities for validation surveys facilities that have not had a recent accreditation survey (i.e., those that are at the midpoint of their accreditation cycle). When a validation survey is scheduled in a facility that has not had a recent accreditation survey, the State agency will be directed to perform the survey within 60 days of the survey request. We anticipate maintaining this threshold for accredited providers and suppliers subject to a validation survey.

Comment: One commenter recommended that HCFA clarify in § 488.7(e)(3), which concerns once again permitting deeming of a provider or supplier if we find it meets all the Medicare conditions, what effect condition level deficiencies will have on reimbursement. The commenter stated that current HCFA policy allows laboratories not in compliance with Medicare's conditions of participation to be reimbursed for a period of time when plans of correction are being implemented. He added that, accordingly, HCFA's administrative and operating procedures concerning termination and reinstatement should be included in the preamble.

Response: Reimbursement and laboratory issues do not come under the purview of this rule. Provider and supplier termination and reinstatement procedures are addressed in part 498, which addresses appeals procedures. The removal of a provider's or supplier's deemed status by HCFA for condition-level deficiencies is the customary first step in the termination process. HCFA procedures provide for a 23 or 90 day timeframe for termination depending on the scope and severity of the cited deficiencies. Providers and suppliers who are able to address the deficiencies to HCFA's satisfaction before the effective date of the proposed termination are not terminated.

Comment: One commenter believed that in § 488.7(a) (which lists the criteria under which we will review a national accreditation organization) the makeup of the team that will conduct any validation surveys should be specified; section 1819 of the Act, for example, recognizes the importance of specifying the makeup of the survey team.

Response: We do not accept this comment because we want to maintain the flexibility to ensure that the specific composition of validation survey teams is appropriate to the type of facility and to the circumstances of survey. For example, a complaint survey may be partial, focusing on certain requirements and may not require a full team.

Comment: Six commenters stated that the Joint Commission accreditation problems identified in testimony before the Subcommittee on Health of the House Committee on Ways and Means held in June 1990 have not been adequately addressed in the proposed regulation. One of the commenters believed that, based on this testimony, § 488.7(a) should be amended to include the following: (a) A minimum of five percent of all accredited providers of each provider type for each approved accreditation organization will receive a validation survey; (b) the rule should specify that a full survey shall be conducted for every instance in which the State agency substantiates a complaint regarding inappropriate treatment or inadequate quality of care; and (c) the terms "substantial allegations of significant deficiencies" should be changed to read, "a substantial allegation validated by the State survey agency." The commenter thought that more than one allegation is not necessary and the term "significant deficiencies" is very subjective and is not defined.

Response: In determining whether an accreditation organization provides reasonable assurance of compliance with Medicare requirements, all aspects of its survey and accreditation process will be subjected to examination. Concerning the size of the validation sample, we note that the statute does not require a particular sample size for validation surveys, and we do not believe it is necessary to establish such a sample size through regulation. Further, § 488.7(a)(2) specifically states that "If the State survey agency substantiates a deficiency * * * the State conducts a full Medicare survey." Accordingly, any substantiated instances of inappropriate treatment and inadequate care would trigger a full Medicare survey. As we have indicated earlier we are deleting references to significant deficiencies because we believe it is in the public's interest to follow up any alleged deficiency with respect to Medicare requirements. We have amended § 488.7(a) of the rule to reflect this policy.

Comment: Three commenters recommended that § 488.7(d) be revised to reflect that accredited facilities found out of compliance with Medicare requirements should be subject to the requirements for enforcement remedies applied to non-accredited facilities. The commenters believed that this section needs clarification to indicate that if found out of compliance during the validation survey the facility will be subject to the same enforcement remedies that may be imposed on a non-accredited facility.

Response: We have accepted this recommendation and have incorporated clarifying language in the text at § 488.7(d) of this rule.

Comment: Four commenters indicated their belief that the triggers for a validation survey as proposed by HCFA are seriously lacking. OBRA '87 requires that facilities meet "all" requirements, not just "substantial" and "significant" ones.

Response: We believe our triggers for a validation survey are consistent with the intent of OBRA '87; we will respond to every possible deficiency of any requirement that reflects on the health and safety of patients or residents or raises doubts as to a provider's or supplier's compliance with those requirements. As indicated earlier, we have deleted references to the term "significant deficiencies" and amended § 488.1 to reflect this policy.

Comment: Three commenters stated that the proposed regulation requires that a facility found through a validation survey to be out of compliance must be subject to termination. They believed that this proposal, by naming termination alone as a response to noncompliance, ignores the range of sanctions available under State law and under OBRA '87, which include denial of payment for new admissions, temporary management, and civil money penalties.

Response: We have revised § 488.7(d) to state that a facility may be subject to intermediate sanctions, if applicable to that type of provider, as well as termination. We have not included sanctions available under State law because Medicare participation does not fall under the State's jurisdiction.

Comment: One commenter believed there will be an increased burden on HCFA and State agencies due to performing validation surveys of deeming authorities.

Response: Under this rule, the State survey agencies, acting as HCFA's agents, will conduct validation surveys of accredited facilities. Since the States

are currently conducting all surveys, conducting only validation surveys for a sample of accredited facilities could represent a significant decrease in workload.

Section 488.9—Federal Review of Accreditation Organizations

A few commenters expressed opposition to the implementation of the provision at § 488.9(c)(2), which establishes the criteria and procedures for removing deeming authority based on validation reviews. A summary of the concerns expressed follows:

- One commenter indicated that the calculation for determining the rate of disparity assumes that HCFA will be able to develop a "crosswalk" to identify correspondences between Federal and private standards and that the private standards will be organized in the same manner as the Federal so that they can be aggregated to the "condition level".
- Two commenters recommended that the concept of a disparity rate be eliminated or held in abeyance until sufficient experience has been gained in inspecting laboratories under CLIA conditions.
- One commenter believed that tolerating a rate of disparity of up to 20 percent between findings of the accreditation organization and HCFA or its agents is acceptable only if this amount of disparity could have occurred by chance. The commenter stated that the proposed regulation does not provide enough information to assess whether a 20 percent rate of disparity would be statistically significant.

Response: It will be the responsibility of any accreditation organization seeking approval of deeming authority to develop and present the referenced crosswalk as part of its application package. It is acceptable for an accreditation organization to organize its requirements differently than HCFA does, and to have requirements that are not identical but are at least equivalent to Federal requirements. The accreditation organization must be able to provide reasonable assurance that all applicable Medicare conditions would be met. It will be HCFA's responsibility to determine if the accreditation organization's requirements as presented in its application are at least equivalent to HCFA's standards and are organized in such a way to enable HCFA to accept accreditation as providing reasonable assurance that all the Medicare conditions would be met.

In evaluating an accreditation organization's performance under validation review, HCFA will calculate a rate of disparity between the findings of the accreditation organization and the validation survey results. This calculation will be based on condition level deficiencies (or deficiencies in HCFA's requirements for long term care facilities) where the accreditation organization failed to identify the same or similar deficiencies. In addition, if an organization has received approval of an accreditation structure that is not exact in its replication of Medicare requirements, but which compensates in other areas so that its overall standards are at least equivalent to those established under the Act (for example, a lower constituent standard in one area of a condition level requirement is offset by a more stringent standard elsewhere in the requirements pertaining to the condition), HCFA will accommodate those distinctions in conducting validation surveys and in making conclusions with respect to the performance of accreditation organizations on the basis of the validation survey findings.

The 20 percent level of disparity that will be used in monitoring the effectiveness of accreditation organizations in providing reasonable assurance that accredited facilities meet Federal requirements is not indicative of an acceptable level of noncompliance with Federal requirements for accredited facilities. This figure was based on statistical analyses of historical validation survey findings for accredited hospitals for the period 1974 to 1991.

We cannot accept the comment that the use of a disparity rate be phased in or eliminated. As explained elsewhere, the 20 percent rate is simply a threshold that triggers a notice from HCFA to the accreditation organization that its deeming authority is in jeopardy and that its accreditation system is under rigorous scrutiny. Based on further evaluation, we could remove deeming authority, but the removal is not mandatory on the 20 percent criterion alone nor is a 20 percent rate of disparity an absolute requirement that must be met before HCFA can withdraw its approval of an accreditation organizations deeming authority. While deeming authority review will always be implemented when the rate of disparity is 20 percent or more, HCFA can institute such a review at any time validation findings indicate widespread or systematic problems in an organization's accreditation process that may indicate that there is no longer reasonable assurance that accredited entities meet Medicare requirements.

As stated earlier, an accreditation organization's approval period will not exceed a period of six years; we will conduct a validation review at the end of the term of approval. We reserve the right to determine if the reapplication process should occur more frequently than every six years. The frequency of the application and the nature of the reapplication materials will be based on a range of issues, such as:

An evaluation to determine if the accreditation organization follows its own procedures in imposing corrective action plans on providers and/or suppliers that do not meet its standards and in monitoring those plans with follow-up surveys.

An evaluation to determine if the accreditation organization is ensuring that identified deficiencies are corrected within the timeframes established in the organization's procedures.

An evaluation of whether deemed status is removed from those providers and suppliers that fail to correct their deficiencies in accordance with the established timeframes.

An evaluation to determine if the complaints are investigated timely and if onsite visits were required.

Paragraphs (d)(1)(iii) and (3) of § 488.8 now reflect the reapplication requirements.

Comment: One commenter stated that under § 488.9(c)(2)(i), the rate of disparity will not be needed if HCFA has the authority to impose termination or intermediate sanctions rather than removing deeming authority as an interim step.

Response: Section 488.9(c)(2)(i) of the proposed regulation (§ 488.8(d)(2)(i) in this final rule) refers to the term "rate of disparity" that applies strictly to the validation review process for accreditation organizations. The rate of disparity is used to determine if the removal of deeming authority from an organization is warranted. This provision does not, per se, refer to individual facilities. On the other hand, HCFA can remove deemed status from an individual facility whenever a condition level requirement is found out of compliance. HCFA has the authority to impose termination or intermediate sanctions at any time, based on its own survey findings or the survey findings of the accreditation organization.

Comment: Two commenters indicated that the calculation for determining the rate of disparity considers only deficiencies identified by HCFA that are not identified by the accreditation organization, effectively assuming that deficiencies identified by the accreditation organization, but not by HCFA, are irrelevant. They stated that State survey findings are the sole basis for judging the accreditation program findings, which assumes the validity

and reliability of the State agency surveys.

Response: In order to perform a comparative analysis of any kind, certain baseline standards must be established. Congress has charged HCFA with the authority to determine which requirements and standards are necessary for carrying out in good faith the laws related to the Medicare and Medicaid programs. Our validation program is concerned chiefly with the equivalency of accreditation standards to Federal requirements, and assuring that Medicare participating facilities deemed by virtue of accreditation would meet those requirements if surveyed against them. While it will be helpful for HCFA to examine its survey findings in light of deficiencies identified by accreditation organizations but not by HCFA, these findings have no place in evaluating the effectiveness of accreditation in satisfying existing Medicare requirements. We have clarified the definition of "rate of disparity" in § 488.1 to state more clearly that the calculation of the percentage rate is based on an organization's most recent surveys of providers or suppliers of the same type.

Comment: Four commenters stated that HCFA should define the phrase "significant reduction in the rate of disparity" in § 488.9(e)(iv)(B). One commenter indicated that § 488.9(c)(2)(i) mentions validation surveys and a disparity rate of 20 percent or more. The commenter questioned the use of a 20 percent "rate of disparity" to determine whether an accreditation organization meets requirements for retaining deeming authority. He stated that it is not uncommon to have differences in a validation survey, which upon review do not result in finding of significant noncompliance; perhaps, the issue could be clarified to specify the relative importance of various areas under review.

Response: As discussed previously, we have revised our approach to the use of validation review findings in evaluating the performance of accreditation organizations, and significant reduction in the rate of disparity will no longer be used. If an accreditation organization is subject to deeming authority review because its rate of disparity is 20 percent or more, its rate of disparity for validation review findings during the period of conditional approval must be reduced to less than 20 percent before it can be returned to unconditional approval status. If deeming authority review is undertaken on the basis of validation review findings where the rate of disparity was less than 20 percent, HCFA will make a determination, on the basis of its review, including review of recent validation findings, whether accreditation by the organization continues to provide reasonable assurance that the applicable Medicare requirements are met.

Comment: Two commenters suggested that the validation review required in § 488.9(c) should be replaced with the State Agency Evaluation Program (SAEP). They stated that SAEP uses a comprehensive approach in the evaluation of State survey agency performance. Another commenter indicated that the 1989 Federal monitoring surveys of unaccredited hospitals certified by State agencies for Medicare participation revealed that in this sample State agencies were judged to have had a 25 percent rate of disparity by Regional Office staff. The commenter believed that if a 25 percent rate of disparity is a reasonable performance standard for HCFA's own agents, it would seem a reasonable performance standard for accreditation organizations as well.

Response: The State agency evaluation program (SAEP) is a comprehensive evaluation protocol used in the administration of the contractual relationship between HCFA and the State survey agencies. The agreements between HCFA and the States are governed by Section 1864 of the Act as well as Federal and Departmental acquisition regulations, and the criteria used to evaluate accreditation organizations are not derivative of the SAEP. Therefore, it is inappropriate for us to act on this commenter's suggestion. We will continue to use the 20 percent rate stipulated in the proposed rule as a threshold indication that the accreditation organization is not meeting the regulatory requirements. The 20 percent rate will be the point at which HCFA will notify the organization that its approval for deeming authority is in jeopardy.

Comment: Six commenters stated that the rate of disparity and pattern of increasing disparity are discussed in relation to compliance with condition level deficiencies. The commenters believed that this is too permissive and leaves too many people at risk for too long a period of time, and that, further, it is based on condition level compliance, a construction not in use in nursing homes. They believed that this hierarchical approach would allow an accreditation organization to ignore, for example, inappropriate restraint use, inadequate social services, violations of residents' rights provision, inadequate activities, or improper nurse aide training to be tolerated indefinitely.

Response: We have revised our definition of "Medicare condition" at § 488.1 to include "long term care requirements"; therefore references to rates of disparity based on conditions include nursing home requirements. These requirements must be addressed in the crosswalk that organizations submit in their application for approval of deeming authority. A final rule pertaining to the requirements for long term care facilities eliminated the hierarchical system and the final enforcement rule allows the determination of the seriousness of deficiencies based on how far the nursing home deviates from HCFA's requirements. (See "BPD–396–F, Requirements for Long-Term Care Facilities" (56 FR 48826).) For other types of facilities, the hierarchial system of conditions, standards and elements is still in place. These conditions essentially represent clusters of standards, regardless of the type of facility accredited. Similarly, the accreditation organizations for these facilities must submit a crosswalk showing equivalency between their requirements and HCFA's clusters of standards. The evaluation of accreditation organizations' initial requests for deeming authority, as well as periodic validation and deeming authority reviews thereafter, provides continuing Federal oversight to assess the equivalency of the accreditation organization's standards to Federal requirements, including use of restraints, social services, residents' rights, etc.

Comment: One commenter recommended that both the triggering of a State agency survey and the provisions related to a deeming authority review should be based on determinations of a significant level of noncompliance with the requirements for participation for long term care facilities. The commenter further recommended that the definition of significant noncompliance be based on the citing of deficiencies and the imposition of a sanction or sanctions for a violation or violations that have resulted in negative outcomes, including the violation of residents' rights, causing actual or life-threatening harm or death; and/or based on the failure of the facility to meet administrative requirements to the degree that negative outcomes have occurred in sufficient number or with sufficient regularity.

Response: Now that the hierarchical system of nursing home requirements is eliminated, all requirements are equally enforceable. Therefore, deficiencies

with any requirements detected during a validation survey will be considered in computing the rate of disparity if comparable deficiencies were not detected by the accreditation survey.

Comment: One commenter believed that recognizing an accreditation organization under "deemed status" would result in duplicative staffing and a substantial increase in staff training for the State survey agencies.

Response: Under deemed status, the State agencies will continue to conduct surveys under the Federal requirements in effect for the facility type at the time of the survey. Inasmuch as the State agencies will conduct validation surveys only on a sample basis and in response to complaints, the granting of deemed status should not necessitate increased staffing levels or increased training needs at the State survey agencies.

Comment: One commenter requested that HCFA consider voluntary accreditation standards for the providers of rehabilitation services including rehabilitation agencies, comprehensive outpatient rehabilitation facilities, skilled nursing facilities, home health agencies, and public health agencies.

Response: We are not sure what the commenter means by "voluntary standards". Since accreditation organizations are not required to request approval for granting deemed status for various providers, any standards they develop are voluntary. However, the standards developed by accreditation organizations must be equivalent to HCFA's standards in order for the organization to receive approval to grant deemed status. Accreditation is also voluntary on the part of providers and suppliers. (Facilities can voluntarily choose to be accredited by an organization with deeming authority in lieu of having periodic certification surveys and ongoing monitoring by the State.) However, to be considered for deeming authority, an accreditation organization's standards must be requirements and, as such, may not be voluntary or optional. The provider/supplier categories mentioned by the commenter would be eligible for deemed status through means of accreditation if an accreditation organization applies for and receives approval of deeming authority.

Comment: Two commenters urged that the deeming authority review process be carried out in a rigorous and objective manner to ensure that quality of care will not be compromised.

Response: We agree with the commenters and believe that the review process set forth in § 488.9 insures a thorough and unbiased evaluation.

Comment: One commenter recommended that § 488.9 be revised to include the process for continued participation of a deemed facility when an accreditation organization loses its deeming authority. The commenter suggested two options: the first option would be to consider the facility as deemed until the expiration of its accreditation certificate even though the accreditation organization has lost its deeming authority; and the second option would be to include in the regulation a notice requirement to deemed facilities explaining that the accreditation organization has lost its deeming authority and informing the deemed facility of its options.

Response: Section 488.9 (now § 488.8) has been revised to add a paragraph that stipulates that facilities be notified of HCFA's removal of an accreditation organization's deeming authority, and the options available to each facility that had received deemed status based on its accreditation by that organization. Specifically, a provider's or supplier's deemed status will continue in effect for 60 days following notification and can be extended for an additional 60 days if we determine that the provider or supplier submitted a timely application to another approved accreditation organization or to us. A provider's or supplier's failure to do so will jeopardize its participation in the Medicare program and, where applicable, in the Medicaid program. These procedures will apply regardless of the provider's accreditation schedule to allow time for a State agency survey or accreditation by another approved organization.

Comment: Five commenters stated that the proposed rule establishes a prolonged process of negotiation when serious discrepancies exist due to lack of comparability between requirements and/or problems of poor performance. Further, one commenter believed there should be a continuum of sanctions including probation, suspension, termination and various forms of civil monetary penalties, depending on the degree of seriousness of the problem. The commenter believed that HCFA should not allow poor performance to continue for up to a year as is proposed nor allow protracted delays to occur before considering suspension of an organizations's deeming authority.

Response: HCFA only agrees to accept an approved accreditation organization's reasonable assurance that a deemed facility would meet HCFA's requirements if surveyed against them. HCFA has no statutory authority to impose sanctions on accreditation organizations, other than removal of deeming authority.

Section 488.8 sets forth two types of probationary periods. A probationary period of 180 days is provided when HCFA determines that an accreditation organization's standards are no longer equivalent to the applicable Federal requirements. This will allow a reasonable time for that organization to revise its standards to achieve equivalency with HCFA's requirements and to implement the revised standards. A probationary period of up to one year is provided when an accreditation organization's standards are determined to be equivalent to Federal requirements but the results of validation surveys indicate that the accreditation organization is incorrectly or inconsistently surveying for those requirements. This period of time is intended to provide the accreditation organization a reasonable opportunity to examine and improve its survey process and for HCFA to validate that the organization is once again surveying consistently with respect to its own requirements. For those facilities for which HCFA identifies deficiencies, the facilities' deemed status is removed and enforcement action can be taken immediately, regardless of the approval status of the accreditation organization.

The probationary periods provided for under deeming review do not apply, if at any time HCFA determines the continued approval of deeming authority of any accreditation organization poses an immediate jeopardy to the patients of the entities accredited by that organization, or such continued approval otherwise constitutes a significant hazard to the public health. In such cases, as provided in § 488.8(g), HCFA may immediately withdraw the approval of deeming authority of that accreditation organization. For example, if we determine, based on a validation review, comparability review, or an onsite visit to an approved accreditation organization, that the organization can no longer fulfill its obligation to perform surveys due to inadequate resources (e.g., financial hardship or lack of qualified personnel), we will institute measures to withdraw the approval of deeming authority immediately.

Comment: One commenter believed that the requirement in § 488.9 for 30 days' notice regarding changes in an organization's requirements is unduly burdensome. The commenter suggests that the rule be revised so that 30 days' advance notice is required only for changes that substantially affect an organization's accreditation standards

and not be required for checklist modifications.

Response: We cannot accept this recommendation because it is not administratively feasible to evaluate and sort each proposed change depending on the type or substance of the change.

Comment: One commenter stated that under § 488.9 the requirement to provide electronic data in ASCII equivalent code is meaningless without specification of format and other details. The commenter suggested the proposed rule should be modified to indicate that HCFA requires only "reasonably necessary information in an agreed upon computer-usable format necessary for validation and/or assessment of the organization's survey process."

Response: All references to ASCII code may be interpreted as the ability to generate Standard electronic data files that are capable of being processed on main frame computers. EBCDIC STANDARD 6250 BPI tape is an acceptable alternative to ASCII. File formats, record layouts, edits and procedures have not yet been designed. When these parameters are decided upon, we will require that they be submitted to HCFA electronically, either on magnetic tape or through electronic data transmission.

Comment: One commenter urged HCFA to specify in detail at § 488.9(a)(1)(ii)(A) the composition of the inspection team.

Response: We do not believe that this level of specificity in the regulation is warranted and, therefore, have not accepted this comment. In addition, these specific requirements will vary depending on the types of facilities for which the accreditation organization in seeking approval of deeming authority.

Comment: Two commenters suggested that when a facility is found, through a validation survey, to be out of compliance, the facility must be subject to the State survey requirements and may be subject to termination. The commenters argued that when HCFA removes the facility's deemed status and requires the facility to use HCFA's standards that it is an acknowledgement that the accreditation organization's standards are not equal to HCFA's standards.

Response: The issue of equivalent standards does not apply in this instance. An accreditation organization has the ability to survey a facility, but no authority to impose sanctions other than to withhold accreditation. When a facility is found to be out of compliance by the State survey agency, HCFA removes the facility's deemed status. Once the facility's deemed status is removed it is no longer under the accreditation body's standards and must meet HCFA's requirements. However, we will have found the accreditation organization's standards to provide reasonable assurance that Medicare conditions or requirements for long term care will be met. When HCFA evaluates the results of all validation surveys for a given accreditation organization, it may be that the organization's standards are no longer found to provide reasonable assurance that Medicare requirements are met. Similarly, HCFA may determine that the organization fails to demonstrate that it can consistently survey for its own standards. In either case, HCFA will take appropriate action under deeming authority review.

Comment: One commenter suggested that in § 488.9(a)(1)(ii)(B), which requires HCFA to review the organization's ability to investigate complaints, HCFA also be required to review the organization's ability to respond appropriately to them. The commenter also asked that the monitoring procedures an accreditation organization is proposing to use when a facility is out of compliance (required at § 488.9(a)(1)(ii)(C)) be developed and published.

Response: We accept the comment concerning the response to complaints and have revised the regulation accordingly. However, we do not believe we should require an accreditation organization to publish its procedures. By publishing a notice in the **Federal Register** that the organization's requirements are equivalent to ours, we are endorsing its monitoring procedures. Thus, we do believe it is unnecessarily burdensome to require the organization to publish these procedures.

Comment: Seven commenters believed that an administrative hearing process is absent from the proposed rule. The commenters believed that an administrative hearing process should be developed for accreditation organizations whose deeming authority applications are rejected or whose status is threatened with withdrawal of previously granted deeming authority.

Response: In response to this comment, we have revised the regulation to provide such a reconsideration process. We include a new subpart D in part 488 to provide a reconsideration for both denial of initial applications and withdrawal of deeming authority approval. The process described in subpart D affords the accreditation organization several opportunities to furnish information and evidence relative to the circumstances of the adverse action, including a hearing before a hearing officer.

Comment: Five commenters suggested that HCFA consider adding two additional criteria to the evaluation process for deemed authority applicants. The commenters suggested that experience with a specific type of provider be considered; the second criterion suggested was that the accreditation organization consult with professional associations. Two commenters further requested that a cost comparison per survey between accreditation organizations and State agencies be considered in evaluating the organization.

Response: We consider experience as part of the adequacy of staff and other resources in our evaluation of each accreditation organization's application for approval of deeming authority. We do not believe that consultation with professional associations should be part of the evaluation criteria since there is no direct link between an organization's standards equivalency to Federal requirements or survey performance and consultation with professional organizations. Finally, the costs incurred by an accreditation organization in conducting its surveys is immaterial to the deeming process, except as they relate to reimbursement by Medicare to individual facilities for the portion of accreditation fees allocable to the Medicare program. Accreditation fees determined to be not reasonable will be disallowed. We will also examine an organization's financial strength and commitment to the accreditation program to ensure that the organization can finance its surveys and related activities.

We have added a provision (§ 488.9, Onsite observation of accreditation organization operations) to the final rule that permits HCFA to conduct an onsite evaluation of the organization's accreditation operations, to verify information provided by the organization and to ensure that the organization follows its own policies and procedures. This observation may be in response to our review of an application or a validation review or as part of our continuing oversight of accreditation organizations.

Comment: Two commenters believed that efficient administration of the CLIA and Medicare programs requires the Secretary to establish consistent policies for the Federal review and approval of accreditation organizations seeking deeming authority for the purpose of laboratory compliance with CLIA and Medicare program conditions of participation and should be specifically addressed in the regulations so that

private accreditation organizations can be assured that inconsistent requirements under the two programs are efficiently resolved.

Response: We agree that the review of laboratory accreditation standards for deeming authority for both CLIA and Medicare requirements should be conducted in accordance with consistent policies. While these issues are addressed in separate regulations, the processes are essentially similar and singularly consistent. As discussed previously, CLIA laboratory requirements and Medicare laboratory requirements are one and the same. The approval process for deeming authority for laboratories, as opposed to other providers, was published in the July 31, 1992 rule (57 FR 33992).

Comment: We received five comments related to notice requirements. Two commenters recommended that under § 488.9(a)(1)(ii), which concerns the circumstances under which we will do a comparability review, a new section be added to read: "The ability of the organization to report deficiencies to the surveyed facility, and respond to the facility's plan of correction in a timely manner." The commenters believed that this revision is needed to achieve equivalency with Federal survey procedures. Three commenters asked that a paragraph be added in § 488.9 to require accreditation organizations to explain their procedures for notifying the State survey agency immediately when any serious problem exists that cannot be corrected in a very short period of time.

Response: We have revised proposed § 488.9(a)(1)(ii) (now § 488.8(a)(1)(ii)) to add a requirement that an accreditation organization must demonstrate its ability to report deficiencies to the surveyed facility. We do not believe it is necessary for an accreditation organization to notify the State agency of deficiencies in a facility, since the State agency is not authorized to take any action in these cases. Since HCFA will have access to all accreditation surveys, we can take necessary enforcement action on the basis of the accreditation survey.

Comment: Two commenters recommended that to the comparability of survey procedures in § 488.9(a)(ii)(B) we add a requirement that we review "the focus of the survey on resident outcomes; and the inclusion of procedures to assure survey consistency and surveyor accountability." The commenters believed that these additions are essential components of the survey currently included in the Federal survey procedures or anticipated through future OBRA survey and certification rulemaking.

Response: We have not accepted this comment. We believe that these proposed additions to the regulations are unnecessary because these issues are specifically evaluated in our initial review of an organization's application for approval of deeming authority and in our periodic review of deeming authority. Since a great number of the Medicare requirements and Federal survey procedures focus on patient outcomes and include provisions for surveyor consistency and accountability, an accreditation organization must demonstrate that its requirements focus on patient outcomes, as appropriate, that its survey process can consistently survey for those requirements on the basis of outcomes, and that the organization evaluates its surveyors and holds them accountable for their findings and performance.

Comment: Three commenters recommended that we revise § 488.9(a)(ii)(A), which requires us to determine the composition of the survey team, survey qualifications, and the ability of the organization to provide continuing surveyor training. The commenters wanted to add to these access to surveyor competency tests. The commenters indicated that a significant mandate of OBRA '87 toward achieving competency and consistency in the survey of nursing facilities is competency testing of surveyors. An equivalent test or demonstration of competency should be required of the accreditation organization's surveyors.

Response: The OBRA '87 requirement for continuing surveyor training and surveyor competency is a statutory requirement for nursing homes only and not a general requirement for all providers and suppliers. As we have stated earlier, each accreditation organization's standards must be equivalent to HCFA's participation requirements for the facility or facilities involved. The surveyor training and competency requirements are no exception and will be evaluated by HCFA.

Comment: One commenter stated that the proposed rule does not sufficiently articulate the procedures that accreditation organizations must follow in monitoring providers found not to be in compliance. The commenter suggested that HCFA should look at standards and elements as well as conditions.

Response: The proposed rule does not articulate any standards or procedures that accreditation organizations must follow. The concept of voluntary accreditation must provide an accreditation organization the opportunity to develop standards it believes will ensure the highest quality of care and services. When determining an organization's eligibility for deeming authority by means of accreditation, HCFA will evaluate the accreditation organization's standards and procedures to ascertain if they are at least equivalent to the Federal minimum requirements. An accreditation organization is expected to enforce its requirements rigorously whether they are organized based on standards and elements, or some other hierarchy.

Comment: Seven commenters stated that the criteria for actually qualifying to be approved as a deeming authority remain extremely general. The commenters urged HCFA to publish criteria for qualifications for approval as a deeming authority as a formal notice of proposed rulemaking with a minimum of a 60-day comment period.

Response: As with other statutory provisions for which HCFA is responsible, we have sought public comments on our interpretation of the statute and resulting regulatory policies. The provider-specific criteria mentioned by the commenter do not depend on statutory interpretation but on program policy, although the statute does stipulate some specific requirements from most providers and suppliers. To publish the qualifying criteria for each provider-type in the **Federal Register** to seek public comments would unnecessarily delay implementation of the regulation. We do recognize our responsibility to publish the general criteria, contained in § 488.9, and we also believe that the items that an accreditation organization must furnish in its application serve to define additional criteria.

Comment: One commenter recommended that specific criteria developed to evaluate accreditation organizations be applied by HCFA in evaluating its own survey process. The commenter believed that HCFA's guidelines are not specific and have no specific directions for translating findings into deficiencies.

Response: The criteria developed to evaluate accreditation organizations are based on Federal requirements. The evaluation criteria for the accreditation organization will be designed to determine whether an organization is capable of meeting HCFA's requirements. Using these evaluation criteria to evaluate HCFA's survey process serves no purpose since it is a tool to compare equivalency between the accreditation organization and HCFA. HCFA is continually evaluating the effectiveness of its survey programs

and implements enhancements to those programs at every opportunity. We have not accepted this comment.

Comment: Five commenters stated that the proposed rule at § 488.9(a)(1) (i) and (ii) should specify that the requirements and survey procedures be "equivalent" because all residents of certified nursing homes are entitled to the same protection under the Federal law. The commenters believed that since States are required to use HCFA's procedures, forms and guidelines that an accreditation organization must also use HCFA's procedures, forms and guidelines.

Response: HCFA will determine through its evaluation process whether an accreditation organization has equivalent requirements and acceptable survey procedures. HCFA will only approve accreditation organizations to grant deemed status to various providers if those accreditation organizations provide reasonable assurance that Medicare conditions, or requirements for long term care, will be met. We believe that when an accreditation organization's standards are found to be equivalent, those standards will provide the same protection to Medicare beneficiaries as HCFA requirements.

Comment: Eighteen commenters believed that § 488.9(a)(1)(i) is confusing as to what constitutes equivalent criteria. The commenters believed that the rule should specify the process used to determine equivalent standards.

Response: HCFA will use its provider-specific participation requirements and survey expertise to determine whether an accreditation organization has equivalent requirements. Specific criteria will be applied as necessary in making these determinations. We will not include provider-specific evaluation criteria in this rule for the following reasons:

- Evaluation criteria will be based on the participation requirements for each type of provider.
- Including this level of specificity limits HCFA's flexibility in evaluating accreditation organizations applying for the granting of deemed status, and limits the broad authority accorded to the Secretary to determine when accreditation provides reasonable assurance that Medicare requirements are met.
- This rule is a general rule to apply to all national accreditation organizations except those for laboratories. It is not intended to be an encyclopedic recapitulation of the various facility requirements, already specified elsewhere in our regulations.

Comment: Six commenters thought that allowing "equivalent" standards negates the public rulemaking process under the Administrative Procedure Act by allowing standard setting by accreditation organizations without public review and comment.

Response: The standard setting by the accreditation organization must be equivalent to HCFA participation requirements in order for HCFA to approve that organization to grant deemed status. Since the public has an opportunity to comment on all Federal participation requirements and those requirements are equal to any approved accreditation organization's requirements, the public has, in fact, had an opportunity to comment on the spirit of those requirements. Additionally, we do not believe that it would be appropriate to require an accreditation organization to seek public comments on its standards, although it may decide to do so on a voluntary basis. Therefore, we see no violation of the Administrative Procedure Act and have not revised our rule in this regard.

Comment: One commenter pointed out that in § 488.9(b) we state that facilities accredited by an approved accreditation organization are deemed to meet our conditions of participation except for those Federal conditions or standards which HCFA identifies as being more stringent or more precise than the requirements for accreditation. The commenter asked that those "more stringent" areas be specified in the final rule.

Response: We cannot specify in this rule any conditions or standards that HCFA identifies as being "more stringent" than the standards of any given accreditation organization. These areas will be identified through the application of provider-specific considerations in evaluating applications for approval of deeming authority. We do not believe that specifying conditions or requirements pertaining to different providers or suppliers in a general rule is appropriate. An accreditation organization's standards must be at least equivalent to Federal requirements for all condition-level requirements for which deeming authority is sought. Currently the only exceptions are the requirement for utilization review in all hospitals and the additional special staffing and medical records requirements that are necessary for the provision of active treatment in psychiatric hospitals. However, any participating hospital, accredited or unaccredited, can continue to meet the utilization review requirement as long as the hospital is subject to review by the appropriate utilization and quality control peer review organization. We have also revised the regulation to state more clearly that deeming authority is approved for a specific condition or conditions for each accreditation organization.

Comment: One commenter believed that HCFA's agents should not be permitted to use their standards to restrain others from providing services or practitioners from qualifying for positions that HCFA would allow them to fill. He stated that, for example, outside accreditation organizations should not be allowed to refuse recognition to physical therapy programs acceptable to HCFA nor should such a group be permitted to require laboratory directors with higher qualifications than HCFA recognizes.

Response: Seeking deemed status from an accreditation organization is strictly voluntary and does not affect any provider's or supplier's ability to participate in Medicare. An accreditation organization's standards must be equivalent but nothing prohibits the standards from being more stringent. We have no authority to restrict an accreditation organization's more stringent requirements.

Comment: One commenter asked that § 488.9(a)(1)(ii)(C) specify the types of providers for which this subsection applies. The commenters were unclear whether this provision applies to entities that sought but were denied accreditation or to entities that received accreditation and only later were found to be out of compliance with program requirements.

Response: This paragraph only speaks to areas which HCFA will evaluate when an accreditation organization is applying for deemed status. HCFA's evaluation of monitoring procedures is an assurance that when an accreditation organization finds noncompliance the organization has procedures to monitor those facilities appropriately. This provision applies to any and all of the providers or suppliers for which an accreditation organization seeks approval of deeming authority.

IV. Summary of Revisions

After review and consideration of comments, as described above, we are adopting as final the rule as proposed on December 14, 1990, except as follows:

A. To §§ 401.126(b)(2)(ii)(A) and 401.133(d), we add examples of enforcement actions that we may take and to which releasable information relates. We also add to §§ 401.126(b)(2)(i) and 401.133(d), for the sake of consistency, national accreditation organizations of laboratories meeting the requirements of

§ 493.506 to the entities to which the provisions of these paragraphs apply.

B. We change the provision in § 401.133(d) and (e) that allows us to release certain information so that it requires us to release it. In paragraph (e) we add a provision for consistency with paragraph (d) to be able to require a written request for home health agency surveys.

C. Section 488.1 is amended by adding a definition of "reasonable assurance" and we have revised the definitions of "accredited provider or supplier", "Medicare condition", "rate of disparity", "substantial allegation of noncompliance" and "validation review period".

D. We are updating statutory citations and regulation citations in § 488.3.

E. We add § 488.4 to specify application procedures.

F. In §§ 488.5 and 488.6, we are adding the State survey agency as an entity to which a hospital must authorize the release of its most recent survey (deleted from proposed § 488.7). We also provide for deeming status of providers and suppliers participating in the Medicaid program where applicable.

G. In § 488.6, we clarify that the requirements of an accreditation organization must be at least as stringent as HCFA's, when taken as a whole. We add to the list of accredited providers and suppliers in this section and in § 488.10 screening mammography services and rural primary care hospitals.

H. In § 488.7, we change "selective" sample to "representative sample", specify that the validation survey may be focused on a specific condition or conditions, and make technical changes. In paragraph (d), we specify that the requirements to which providers and suppliers will be subject are the participation and enforcement requirements and that they may be subject to applicable intermediate sanctions and remedies as well as termination of the provider agreement if applicable.

I. We are incorporating the contents of current § 488.8, Civil rights requirements, into § 489.10, Basic requirements [concerning provider and supplier agreements].

Section 489.10 currently requires providers and suppliers to agree to meet the civil rights requirements of 45 CFR parts 80, 84 and 90; § 488.8 requires surveyed providers and suppliers to meet the requirements of 45 CFR parts 80 and 84 and other pertinent requirements. Since § 488.8 in essence duplicates § 489.10, and we believe part 489 is a more logical place to impose civil rights requirements, we are revising § 489.10 to contain both the contents of current § 488.8 and § 489.10. We are also adding a description of the requirements of 45 CFR part 90 to the cross-reference to that section to match the descriptions of 45 CFR parts 80 and 84 currently in 42 CFR 488.8. 45 CFR part 90 prohibits discrimination on the basis of age.

J. In § 488.8 (proposed § 488.9) we include an accreditation organization's ability to (1) respond appropriately to complaints and (2) report deficiencies to the surveyed facility and respond to the facility's plan of correction in a timely manner as part of our evaluation and review of accreditation organizations. We clarify in § 488.8(b) what the notice we will publish will contain when an accrediting organization's application is approved. We revise paragraph (d)(2) so that an increasing rate of disparity over a two-year period will not be one of two mandatory triggers for a review; rather, any indication of decreasing performance may trigger a review. Paragraph (d)(1)(iii) adds the end of the approved term as a trigger for a comparability review; new paragraph (d)(3) adds reapplication procedures. New paragraph (e)(5) discusses submission of reapplication materials. In § 488.8(e)(4)(i) (designated as § 488.9(c)(4)(iv)(A) in the proposed rule), we specify that the results of an evaluation must indicate an acceptable rate of disparity instead of a significant reduction in the rate of disparity. We add two paragraphs, § 488.8(f)(8) and (9), to indicate our policy concerning continued deemed status of providers and suppliers if we remove our approval of an accreditation organization's deeming authority. We add a new paragraph (g) to permit immediate withdrawal of HCFA approval in cases involving immediate jeopardy to patients. We also make several technical clarifying changes.

K. We add a new § 488.9, Onsite observation of accreditation organization operations.

L. We also make a number of technical changes to conform the provisions of this rule to those of our rule concerning accreditation organizations for laboratories found in part 493.

M. We amend reconsideration procedures in subpart D of part 488 to include national accreditation organizations of entities other than laboratories.

V. Regulatory Impact Statement

A. Economic Impact

This rule does not, in itself, establish terms or conditions for Federal spending and does not impose any requirements that would precipitate changes in the conduct of private businesses. Inasmuch as the provisions of this rule could represent a striking departure from existing processes, it is impossible to gauge the impact of this rule with any precision, or to quantify any programmatic, budgetary, or economic impact. Nevertheless, our analyses of possible effects of this rule are detailed below.

Compliance with specific conditions and standards has always been required for certain health care providers and suppliers (e.g., hospitals, SNFs, HHAs) to establish eligibility for participation in the Medicare program. Currently, compliance with applicable requirements is established through an inspection and verification process, known as survey and certification, either directly by HCFA or by agencies of State government under an agreement with HCFA. However, hospitals can establish compliance either through routine survey and certification or through accreditation by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) or the American Osteopathic Association (AOA). Accredited hospitals are deemed to meet Medicare requirements by virtue of their accreditation and are said to have deemed status. A decision to seek accreditation is voluntary on the part of each hospital; accreditation is never required for Medicare eligibility or participation. This rule expands the availability of deemed status to health care providers and suppliers other than hospitals if they are accredited by private organizations who apply for and receive approval of their accreditation programs.

Accreditation is an approval status conferred by an accrediting body and indicates that accredited member facilities meet the standards established by that body. Reminiscent of the long-standing tradition in the educational establishment, accreditation is perceived by many as a commitment on the part of the accredited entities to delivery of the highest quality services through voluntary adherence to requirements and standards that reflect sound policies and procedures, state of the art diagnostic and treatment strategies, and a philosophy that accents quality assurance. Accreditation programs not only set standards for their member facilities and assess their performance against those standards but also provide their members with educational and training programs, and technical assistance that may be necessary to meet their standards and enhance the quality of services

delivered. In certain cases, private insurance carriers reimburse accredited providers at higher rates than unaccredited ones, and, similarly, certain accreditation costs have historically been paid by the Medicare program.

The implementation of this rule and the subsequent availability of accreditation as an alternative to traditional survey and certification will afford a new flexibility to the health care provider community in determining how to most effectively and efficiently demonstrate compliance with Medicare requirements and establish eligibility for program reimbursement.

Currently, most of the costs of the survey and certification program are paid by the Federal government to State governmental agencies under the terms of a formal agreement. These State agencies perform onsite evaluations of compliance with Federal participation requirements and certify their findings to HCFA. HCFA also performs some survey activities directly, and the survey of special requirements for most psychiatric hospitals is performed by a private contractor.

The number and type of facilities surveyed by HCFA, its contractor and the State agencies as well as the available cost data are detailed below. The data are up-to-date as of 3/31/93.

Facility type	No. certified	Annual survey cost [1]
Medicare SNF	870	$13,749
SNF/NF [2]	10,226	14,793
Nonaccredited Hospital	1,330	[3] 8,450
JCAHO–AOA Accredited Hospital	5,107	
Psychiatric Hospital	720	10,450
Home Health Agency	6,596	4,590
Home visits [4]		118
End-stage renal disease facility	2,362	2,809
Hospice	1,259	1,467
Screening Mammography [5]	6,639	450
All others [6]	4,824	1,489

[1] Reflects total survey and certification costs per facility including follow-up and complaint surveys and administrative costs. Costs are those reflected in Congressional budget projections for FY 1994.

[2] Dually participating Medicare skilled nursing facilities and Medicaid nursing facilities.

[3] Validation costs for JCAHO and AOA accredited hospitals are included: 5% of the accredited hospitals are surveyed as part of HCFA's validation program.

[4] Costs associated with surveyors' visits to homes of patients of HHAs.

[5] New provider category.

[6] All others include ambulatory surgery centers, rural health clinics, outpatient physical therapy, X-ray facilities and comprehensive outpatient rehabilitation facilities.

There are two major variables associated with the implementation of this rule that preclude any projected impact assessment: First, the number of accreditation organizations that will apply for and receive approval of deeming authority; and second, the number of each facility type that will avail themselves of the accreditation alternative.

There is no direct statutory authority for deemed status under the Medicaid program. Therefore, it is extremely unlikely that certain dually participating facilities, especially SNFs/NFs, would seek to demonstrate compliance through accreditation since that would double the number of surveys performed in the facility. Specifically, a dually participating SNF/NF could be subject to both an accreditation survey that could be used to satisfy Medicare requirements and a State agency survey to determine compliance with Medicaid requirements.

No substantial economic or budgetary impact is expected as a result of this rule. Federal expenditures to ensure compliance with requirements will continue either in payments to States to perform compliance surveys or to facilities in reimbursement for the reasonable and allocable accreditation costs for cost reimbursed facilities or as reflected in a facility's payment rates when paid under another mechanism (for example, the prospective payment system).

B. Regulatory Flexibility Act

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 rule does not have a significant economic impact on a substantial number of small entities. As discussed above, we believe that the provisions of this regulation do not, in themselves, have an economic impact. Indirectly, this rule may result in future issuances whereby small entities might be affected. However, in each of these cases, procedures consistent with the RFA will be followed and a regulatory flexibility analysis performed, if warranted. Therefore, we conclude, and the Secretary certifies, that this rule does not have a significant economic impact on a substantial number of small entities.

C. Rural Hospital Impact Statement

Section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a rule may have significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital with fewer than 50 beds located outside of a Metropolitan Statistical Area.

We are not preparing a rural impact statement since we have determined, and the Secretary certifies, that this rule, in itself, does not have a significant economic impact on the operations of a substantial number of small rural hospitals.

VI. Paperwork Burden

These changes do not impose paperwork collection requirements. Consequently, they need not be reviewed by the Executive Office of Management and Budget under the authority of the Paperwork Reduction Act of 1980 (44 U.S.C. 3801 *et seq.*).

List of Subjects

42 CFR Part 401

Claims, Freedom of information, Health facilities, Medicare, Privacy.

42 CFR Part 488

Health facilities, Survey and certification, Forms and guidelines.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR chapter IV is amended as follows:

A. Part 401, subpart B is amended as follows:

PART 401—GENERAL ADMINISTRATIVE REQUIREMENTS

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

Authority: Secs. 205, 1102, 1106, 1865 and 1871 of the Social Security Act (42 U.S.C. 405, 1302, 1306, 1395bb and 1395hh); the Freedom of Information Act (5 U.S.C. 552); and the Privacy Act (5 U.S.C. 552a).

2. Paragraph (b)(2) of § 401.126 is revised to read as follows:

§ 401.126 Information or records that are not available.

* * * * *

(b) *Materials exempt from disclosure by statute.*

(1) * * *

(2)(i) Except as specified in paragraph (b)(2)(ii) of this section, HCFA may not disclose any accreditation survey or any

information directly related to the survey (including corrective action plans) made by and released to it by the Joint Commission on Accreditation of Healthcare Organizations, the American Osteopathic Association or any other national accreditation organization that meets the requirements of § 488.6 or § 493.506 of this chapter. Materials that are confidential include accreditation letters and accompanying recommendations and comments prepared by an accreditation organization concerning the entities it surveys.

(ii) *Exceptions.*

(A) HCFA may release the accreditation survey of any home health agency; and

(B) HCFA may release the accreditation survey and other information directly related to the survey (including corrective action plans) to the extent the survey and information relate to an enforcement action (for example, denial of payment for new admissions, civil money penalties, temporary management and termination) taken by HCFA; and

* * * * *

3. In § 401.133, the introductory text is republished, the section heading is revised and the section is amended by adding new paragraphs (d) and (e) to read as follows:

§ 401.133 Availability of official reports on providers and suppliers of services, State agencies, intermediaries, and carriers under Medicare.

The following shall be made available to the public under the conditions specified:

* * * * *

(d) *Accreditation surveys.* Upon written request, HCFA will release the accreditation survey and related information from an accreditation organization meeting the requirements of § 488.5, § 488.6 or § 493.506 of this chapter to the extent the survey and information relate to an enforcement action taken (for example, denial of payment for new admission, civil money penalties, temporary management and termination) by HCFA;

(e) Upon written request, HCFA will release the accreditation survey of any home health agency.

PART 488—SURVEY AND CERTIFICATION PROCEDURES

B. Part 488 is amended as follows:

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

Authority: Secs. 1102, 1138(b), 1814, 1819, 1832, 1861, 1864, 1865, 1866, 1871, 1880, 1881, 1883, and 1919 of the Social Security Act (42 U.S.C. 1302, 1320b–5(b), 1395f, 1395i–3, 1395k, 1395x, 1395aa, 1395bb, 1395cc, 1395hh, 1395qq, 1395rr, 1395tt, and 1396r).

2. Section 488.1 is amended by revising the definition of "Substantial allegation", removing "Accredited hospital", and adding definitions for "Accredited provider or supplier", "Conditions for coverage", "Conditions of participation", "Medicare condition", "Rate of disparity", "Reasonable assurance", and "Validation review period" to read as follows:

§ 488.1 Definitions.

As used in this part—

Accredited provider or supplier means a provider or supplier that has voluntarily applied for and has been accredited by a national accreditation program meeting the requirements of and approved by HCFA in accordance with § 488.5 or § 488.6.

* * * * *

Conditions for coverage means the requirements suppliers must meet to participate in the Medicare program.

Conditions of participation means the requirements providers other than skilled nursing facilities must meet to participate in the Medicare program and includes conditions of certification for rural health clinics.

* * * * *

Medicare condition means any condition of participation or for coverage, including any long term care requirements.

* * * * *

Rate of disparity means the percentage of all sample validation surveys for which a State survey agency finds noncompliance with one or more Medicare conditions and no comparable condition level deficiency was cited by the accreditation organization, where it is reasonable to conclude that the deficiencies were present at the time of the accreditation organization's most recent surveys of providers or suppliers of the same type.

Example: Assume that during a validation review period State survey agencies perform validation surveys at 200 facilities of the same type (for example, ambulatory surgical centers, home health agencies) accredited by the same accreditation organization. The State survey agencies find 60 of the facilities out of compliance with one or more Medicare conditions, and it is reasonable to conclude that these deficiencies were present at the time of the most recent survey by an accreditation organization. The accreditation organization, however, has found deficiencies comparable to the condition level deficiencies at only 22 of the 60 facilities. These validation results would yield ((60–22)/200) a rate of disparity of 19 percent.

Reasonable assurance means that an accreditation organization has demonstrated to HCFA's satisfaction that its requirements, taken as a whole, are at least as stringent as those established by HCFA, taken as a whole.

* * * * *

Substantial allegation of noncompliance means a complaint from any of a variety of sources (including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles) that, if substantiated, would affect the health and safety of patients and raises doubts as to a provider's or supplier's noncompliance with any Medicare condition.

* * * * *

Validation review period means the one year period during which HCFA conducts a review of the validation surveys and evaluates the results of the most recent surveys performed by the accreditation organization.

3. In § 488.3, the section heading is revised, the introductory paragraph (a) is republished and paragraphs (a)(1) and (a)(2) are revised to read as follows:

§ 488.3 Conditions of participation; conditions for coverage; and long-term care requirements.

(a) *Basic rules.* In order to be approved for participation in or coverage under the Medicare program, a prospective provider or supplier must—

(1) Meet the applicable statutory definition in section 1138(b), 1819, 1832(a)(2)(F), 1861, 1881, or 1919 of the Act; and

(2) Be in compliance with the applicable conditions or long-term care requirements prescribed in subpart N, Q or U of part 405, part 416, subpart C of part 418, part 482, part 483, part 484, part 485, subpart A of part 491, or part 494 of this chapter.

* * * * *

4. A new § 488.4 is added to read as follows:

§ 488.4 Application and reapplication procedures for accreditation organizations.

(a) A national accreditation organization applying for approval of deeming authority for Medicare requirements under § 488.5 or 488.6 of this subpart must furnish to HCFA the information and materials specified in paragraphs (a)(1) through (10) of this section. A national accreditation organization reapplying for approval must furnish to HCFA whatever information and materials from

paragraphs (a)(1) through (10) of this section that HCFA requests. The materials and information are—

(1) The types of providers and suppliers for which the organization is requesting approval;

(2) A detailed comparison of the organization's accreditation requirements and standards with the applicable Medicare requirements (for example, a crosswalk);

(3) A detailed description of the organization's survey process, including—

(i) Frequency of the surveys performed;

(ii) Copies of the organization's survey forms, guidelines and instructions to surveyors;

(iii) Accreditation survey review process and the accreditation status decision-making process;

(iv) Procedures used to notify accredited facilities of deficiencies and the procedures used to monitor the correction of deficiencies in accredited facilities; and

(v) Whether surveys are announced or unannounced;

(4) Detailed information about the individuals who perform surveys for the accreditation organization, including—

(i) The size and composition of accreditation survey teams for each type of provider and supplier accredited;

(ii) The education and experience requirements surveyors must meet;

(iii) The content and frequency of the in-service training provided to survey personnel;

(iv) The evaluation systems used to monitor the performance of individual surveyors and survey teams; and

(v) Policies and procedures with respect to an individual's participation in the survey or accreditation decision process of any facility with which the individual is professionally or financially affiliated;

(5) A description of the organization's data management and analysis system with respect to its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system;

(6) The organization's procedures for responding to and for the investigation of complaints against accredited facilities, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and ombudsmen programs;

(7) The organization's policies and procedures with respect to the withholding or removal of accreditation status for facilities that fail to meet the accreditation organization's standards or requirements, and other actions taken by the organization in response to noncompliance with its standards and requirements;

(8) A description of all types (for example, full, partial, type of facility, etc.) and categories (provisional, conditional, temporary, etc.) of accreditation offered by the organization, the duration of each type and category of accreditation and a statement specifying the types and categories of accreditation for which approval of deeming authority is sought;

(9) A list of all currently accredited facilities, the type and category of accreditation currently held by each facility, and the expiration date of each facility's current accreditation; and

(10) A list of all full and partial accreditation surveys scheduled to be performed by the organization.

(b) The accreditation organization must also submit the following supporting documentation—

(1) A written presentation that demonstrates the organization's ability to furnish HCFA with electronic data in ASCII comparable code;

(2) A resource analysis that demonstrates that the organization's staffing, funding and other resources are adequate to perform the required surveys and related activities; and

(3) A statement acknowledging that as a condition for approval of deeming authority, the organization will agree to—

(i) Notify HCFA in writing of any facility that has had its accreditation revoked, withdrawn, or revised, or that has had any other remedial or adverse action taken against it by the accreditation organization within 30 days of any such action taken;

(ii) Notify all accredited facilities within 10 days of HCFA's withdrawal of the organization's approval of deeming authority;

(iii) Notify HCFA in writing at least 30 days in advance of the effective date of any proposed changes in accreditation requirements;

(iv) Within 30 days of a change in HCFA requirements, submit to HCFA an acknowledgement of HCFA's notification of the change as well as a revised crosswalk reflecting the new requirements and inform HCFA about how the organization plans to alter its requirements to conform to HCFA's new requirements;

(v) Permit its surveyors to serve as witnesses if HCFA takes an adverse action based on accreditation findings;

(vii) Notify HCFA in writing within ten days of a deficiency identified in any accreditation entity where the deficiency poses an immediate jeopardy to the entity's patients or residents or a hazard to the general public; and

(viii) Conform accreditation requirements to changes in Medicare requirements.

(c) If HCFA determines that additional information is necessary to make a determination for approval or denial of the accreditation organization's application for deeming authority, the organization will be notified and afforded an opportunity to provide the additional information.

(d) HCFA may visit the organization's offices to verify representations made by the organization in its application, including, but not limited to, review of documents and interviews with the organization's staff.

(e) The accreditation organization will receive a formal notice from HCFA stating whether the request for deeming authority has been approved or denied, the rationale for any denial, and reconsideration and reapplication procedures.

(f) An accreditation organization may withdraw its application for approval of deeming authority at any time before the formal notice provided for in paragraph (e) of this section is received.

(g) Except as provided in paragraph (i) of this section, an accreditation organization that has been notified that its request for deeming authority has been denied may request a reconsideration of that determination in accordance with subpart D of this part.

(h) Except as provided in paragraph (i) of this section, any accreditation organization whose request for approval of deeming authority has been denied may resubmit its application if the organization—

(1) Has revised its accreditation program to address the rationale for denial of its previous request;

(2) Can demonstrate that it can provide reasonable assurance that its accredited facilities meet applicable Medicare requirements; and

(3) Resubmits the application in its entirety.

(i) If an accreditation organization has requested, in accordance with part 488, subpart D of this chapter, a reconsideration of HCFA's determination that its request for deeming approval is denied, it may not submit a new application for deeming authority for the type of provider or supplier that is at issue in the reconsideration until the reconsideration is administratively final.

5. Section 488.5 is revised to read as follows:

§ 488.5 Effect of JCAHO or AOA accreditation of hospitals.

(a) *Deemed to meet.* Institutions accredited as hospitals by the JCAHO or AOA are deemed to meet all of the Medicare conditions of participation for hospitals, except—

(1) The requirement for utilization review as specified in section 1861(e)(6) of the Act and in § 482.30 of this chapter;

(2) The additional special staffing and medical records requirements that are considered necessary for the provision of active treatment in psychiatric hospitals (section 1861(f) of the Act) and implementing regulations; and

(3) Any requirements under section 1861(e) of the Act and implementing regulations that HCFA, after consulting with JCAHO or AOA, identifies as being higher or more precise than the requirements for accreditation (section 1865(a)(4) of the Act).

(b) *Deemed status for providers and suppliers that participate in the Medicaid program.* Eligibility for Medicaid participation can be established through Medicare deemed status for providers and suppliers that are not required under Medicaid regulations to comply with any requirements other than Medicare participation requirements for that provider or supplier type.

(c) *Release and use of hospital accreditation surveys.*

(1) A hospital deemed to meet program requirements must authorize its accreditation organization to release to HCFA and the State survey agency a copy of its most current accreditation survey together with any other information related to the survey that HCFA may require (including corrective action plans).

(2) HCFA may use a validation survey, an accreditation survey or other information related to the survey to determine that a hospital does not meet the Medicare conditions of participation.

(3) HCFA may disclose the survey and information related to the survey to the extent that the accreditation survey and related survey information are related to an enforcement action taken by HCFA.

6. Section 488.6 is redesignated as § 488.7 and is revised to read as follows:

§ 488.7 Validation survey.

(a) *Basis for survey.* HCFA may require a survey of an accredited provider or supplier to validate its organization's accreditation process. These surveys will be conducted on a representative sample basis, or in response to substantial allegations of noncompliance.

(1) When conducted on a representative sample basis, the survey is comprehensive and addresses all Medicare conditions or is focused on a specific condition or conditions.

(2) When conducted in response to a substantial allegation, the State survey agency surveys for any condition that HCFA determines is related to the allegations.

(3) If the State survey agency substantiates a deficiency and HCFA determines that the provider or supplier is out of compliance with any Medicare condition, the State survey agency conducts a full Medicare survey.

(b) *Effect of selection for survey.* A provider or supplier selected for a validation survey must—

(1) Authorize the validation survey to take place; and

(2) Authorize the State survey agency to monitor the correction of any deficiencies found through the validation survey.

(c) *Refusal to cooperate with survey.* If a provider or supplier selected for a validation survey fails to comply with the requirements specified in paragraph (b) of this section, it will no longer be deemed to meet the Medicare conditions but will be subject to full review by the State survey agency in accordance with § 488.11 and may be subject to termination of its provider agreement under § 489.53 of this chapter.

(d) *Consequences of finding of noncompliance.* If a validation survey results in a finding that the provider or supplier is out of compliance with one or more Medicare conditions, the provider or supplier will no longer be deemed to meet any Medicare conditions. Specifically, the provider or supplier will be subject to the participation and enforcement requirements applied to all providers or suppliers that are found out of compliance following a State agency survey under § 488.24 and to full review by a State agency survey in accordance with § 488.11 and may be subject to termination of the provider agreement under § 439.53 of this chapter and any other applicable intermediate sanctions and remedies.

(e) *Reinstating effect of accreditation.* An accredited provider or supplier will again be deemed to meet the Medicare conditions in accordance with this section if—

(1) It withdraws any prior refusal to authorize its accreditation organization to release a copy of the provider's or supplier's current accreditation survey;

(2) It withdraws any prior refusal to allow a validation survey; and

(3) HCFA finds that the provider or supplier meets all the applicable Medicare conditions. If HCFA finds that an accredited facility meets the Life Safety Code Standard by virtue of a plan of correction, the State survey agency will continue to monitor the facility until it is in compliance with the Life Safety Code Standard.

7. A new § 488.6 is added to read as follows:

§ 488.6 Other national accreditation programs for hospitals and other providers and suppliers.

(a) In accordance with the requirements of this subpart, a national accreditation program for hospitals; psychiatric hospitals; SNFs; HHAs; ASCs; RHCs; CORFs; hospices; screening mammography services; rural primary care hospitals; or clinic, rehabilitation agency, or public health agency providers of outpatient physical therapy, occupational therapy or speech pathology services may provide reasonable assurance to HCFA that it requires the providers or suppliers it accredits to meet requirements that are at least as stringent as the Medicare conditions when taken as a whole. In such a case, HCFA may deem the providers or suppliers the program accredits to be in compliance with the appropriate Medicare conditions. These providers and suppliers are subject to validation surveys under § 488.7 of this subpart. HCFA will publish notices in the **Federal Register** in accordance with § 488.8(b) identifying the programs and deeming authority of any national accreditation program and the providers or suppliers it accredits. The notice will describe how the accreditation organization's accreditation program provides reasonable assurance that entities accredited by the organization meet Medicare requirements. (See § 488.5 for requirements concerning hospitals accredited by JCAHO or AOA.)

(b) Eligibility for Medicaid participation can be established through Medicare deemed status for providers and suppliers that are not required under Medicaid regulations to comply with any requirements other than Medicare participation requirements for that provider or supplier type.

(c)(1) A provider or supplier deemed to meet program requirements under paragraph (a) of this section must authorize its accreditation organization to release to HCFA and the State survey agency a copy of its most current accreditation survey, together with any information related to the survey that HCFA may require (including corrective action plans).

(2) HCFA may determine that a provider or supplier does not meet the Medicare conditions on the basis of its own investigation of the accreditation survey or any other information related to the survey.

(3) Upon written request, HCFA may disclose the survey and information related to the survey—

(i) Of any HHA; or

(ii) Of any other provider or supplier specified at paragraph (a) of this section if the accreditation survey and related survey information relate to an enforcement action taken by HCFA.

8. Section 488.8 is revised to read as follows:

§ 488.8 Federal review of accreditation organizations.

(a) *Review and approval of national accreditation organization.* HCFA's review and evaluation of a national accreditation organization will be conducted in accordance with, but will not necessarily be limited to, the following general criteria—

(1) The equivalency of an accreditation organization's accreditation requirements of an entity to the comparable HCFA requirements for the entity;

(2) The organization's survey process to determine—

(i) The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training;

(ii) The comparability of survey procedures to those of State survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities;

(iii) The organization's procedures for monitoring providers or suppliers found by the organization to be out of compliance with program requirements. These monitoring procedures are to be used only when the organization identifies noncompliance. If noncompliance is identified through validation surveys, the State survey agency monitors corrections as specified at § 488.7(b)(3);

(iv) The ability of the organization to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner;

(v) The ability of the organization to provide HCFA with electronic data in ASCII comparable code and reports necessary for effective validation and assessment of the organization survey process;

(vi) The adequacy of staff and other resources;

(vii) The organization's ability to provide adequate funding for performing required surveys; and

(viii) The organization's policies with respect to whether surveys are announced or unannounced; and

(3) The accreditation organization's agreement to provide HCFA with a copy of the most current accreditation survey together with any other information related to the survey as HCFA may require (including corrective action plans).

(b) *Notice and comment.*

(1) HCFA will publish a proposed notice in the **Federal Register** whenever it contemplates approving an accreditation organization's application for deeming authority. The proposed notice will specify the basis for granting approval of deeming authority and the types of providers and suppliers accredited by the organization for which deeming authority would be approved. The proposed notice will also describe how the accreditation organization's accreditation program provides reasonable assurance that entities accredited by the organization meet Medicare requirements. The proposed notice will also provide opportunity for public comment.

(2) HCFA will publish a final notice in the **Federal Register** whenever it grants deeming authority to a national accreditation organization. Publication of the final notice will follow publication of the proposed notice by at least six months. The final notice will specify the effective date of the approval of deeming authority and the term of approval (which will not exceed six years).

(c) *Effects of approval of an accreditation organization.* HCFA will deem providers and suppliers accredited by an approved accreditation organization to meet the Medicare conditions for which the approval of deeming authority has specifically been granted. The deeming authority will take effect 90 days following the publication of the final notice.

(d) *Continuing Federal oversight of equivalency of an accreditation organization and removal of deeming authority.* This paragraph establishes specific criteria and procedures for continuing oversight and for removing the approval of deeming authority of a national accreditation organization.

(1) *Comparability review.* HCFA will compare the equivalency of an accreditation organization's accreditation requirements to the comparable HCFA requirements if—

(i) HCFA imposes new requirements or changes its survey process;

(ii) An accreditation organization proposes to adopt new requirements or change its survey process. An accreditation organization must provide written notification to HCFA at least 30 days in advance of the effective date of any proposed changes in its accreditation requirements or survey process; and

(iii) An accreditation organization's approval has been in effect for the maximum term specified by HCFA in the final notice.

(2) *Validation review.* Following the end of a validation review period, HCFA will identify any accreditation programs for which—

(i) Validation survey results indicate a rate of disparity between certifications of the accreditation organization and certification of the State agency of 20 percent or more; or

(ii) Validation survey results, irrespective of the rate of disparity, indicate widespread or systematic problems in an organization's accreditation process that provide evidence that there is no longer reasonable assurance that accredited entities meet Medicare requirements.

(3) *Reapplication procedures.*

(i) Every six years, or sooner as determined by HCFA, an approved accreditation organization must reapply for continued approval of deeming authority. HCFA will notify the organization of the materials the organization must submit as part of the reapplication procedure.

(ii) An accreditation organization that is not meeting the requirements of this subpart, as determined through a comparability review, must furnish HCFA, upon request and at any time, with the reapplication materials HCFA requests. HCFA will establish a deadline by which the materials are to be submitted.

(e) *Notice.* If a comparability or validation review reveals documentation that an accreditation organization is not meeting the requirements of this subpart, HCFA will provide written notice to the organization indicating that its deeming authority approval may be in jeopardy and that a deeming authority review is being initiated. The notice provides the following information—

(1) A statement of the requirements, instances, rates or patterns of discrepancies that were found as well as other related documentation;

(2) An explanation of HCFA's deeming authority review on which the final determination is based;

(3) A description of the process available if the accreditation organization wishes an opportunity to explain or justify the findings made during the comparability or validation review;

(4) A description of the possible actions that may be imposed by HCFA based on the findings from the validation review; and

(5) The reapplication materials the organization must submit and the deadline for their submission.

(f) *Deeming authority review.*

(1) HCFA will conduct a review of an accreditation organization's accreditation program if the comparability or validation review produces findings as described at paragraph (d)(1) or (2), respectively, of this section. HCFA will review as appropriate either or both—

(i) The requirements of the accreditation organization; or

(ii) The criteria described in paragraph (a)(1) of this section to reevaluate whether the accreditation organization continues to meet all these criteria.

(2) If HCFA determines, following the deeming authority review, that the accreditation organization has failed to adopt requirements comparable to HCFA's or submit new requirements timely, the accreditation organization may be given a conditional approval of its deeming authority for a probationary period of up to 180 days to adopt comparable requirements.

(3) If HCFA determines, following the deeming authority review, that the rate of disparity identified during the validation review meets either of the criteria set forth in paragraph (d)(2) of this section HCFA—

(i) May give the accreditation organization conditional approval of its deeming authority during a probationary period of up to one year (whether or not there are also noncomparable requirements) that will be effective 30 days following the date of this determination;

(ii) Will require the accreditation organization to release to HCFA upon its request any facility-specific data that is required by HCFA for continued monitoring;

(iii) Will require the accreditation organization to provide HCFA with a survey schedule for the purpose of intermittent onsite monitoring by HCFA staff, State surveyors, or both; and

(iv) Will publish in the Medicare Annual Report to Congress the name of any accreditation organization given a probationary period by HCFA.

(4) Within 60 days after the end of any probationary period, HCFA will make a final determination as to whether or not an accreditation program continues to meet the criteria described at paragraph (a)(1) of this section and will issue an appropriate notice (including reasons for the determination) to the accreditation organization and affected providers or suppliers. This determination will be based on any of the following—

(i) The evaluation of the most current validation survey and review findings. The evaluation must indicate an acceptable rate of disparity of less than 20 percent between the certifications of the accreditation organization and the certifications of the State agency as described at paragraph (d)(2)(i) of this section in order for the accreditation organization to retain its approval;

(ii) The evaluation of facility-specific data, as necessary, as well as other related information;

(iii) The evaluation of an accreditation organization's surveyors in terms of qualifications, ongoing training composition of survey team, etc.;

(iv) The evaluation of survey procedures; or

(v) The accreditation requirements.

(5) If the accreditation program has not made improvements acceptable to HCFA during the probationary period, HCFA may remove recognition of deemed authority effective 30 days from the date that it provides written notice to the organization that its deeming authority will be removed.

(6) The existence of any validation review, deeming authority review, probationary period, or any other action by HCFA, does not affect or limit the conducting of any validation survey.

(7) HCFA will publish a notice in the **Federal Register** containing a justification of the basis for removing the deeming authority from an accreditation organization. The notice will provide the reasons the accreditation organization's accreditation program no longer meets Medicare requirements.

(8) After HCFA removes approval of an accreditation organization's deeming authority, an affected provider's or supplier's deemed status continues in effect 60 days after the removal of approval. HCFA may extend the period for an additional 60 days for a provider or supplier if it determines that the provider or supplier submitted an application within the initial 60 day timeframe to another approved accreditation organization or to HCFA so that a certification of compliance with Medicare conditions can be determined.

(9) Failure to comply with the timeframe requirements specified in paragraph (f)(8) of this section will jeopardize a provider's or supplier's participation in the Medicare program and where applicable in the Medicaid program.

(g) If at any time HCFA determines that the continued approval of deeming authority of any accreditation organization poses an immediate jeopardy to the patients of the entities accredited by that organization, or such continued approval otherwise constitutes a significant hazard to the public health, HCFA may immediately withdraw the approval of deeming authority of that accreditation organization.

(h) Any accreditation organization dissatisfied with a determination to remove its deeming authority may request a reconsideration of that determination in accordance with subpart D of this part.

9. Section 488.9 is added to read as follows:

§ 488.9 Onsite observation of accreditation organization operations.

As part of the application review process, the validation review process, or the continuing oversight of an accreditation organization's performance, HCFA may conduct an onsite inspection of the accreditation organization's operations and offices to verify the organization's representations and to assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to, the review of documents, auditing meetings concerning the accreditation process, the evaluation of survey results or the accreditation decision-making process, and interviews with the organization's staff.

10. Section 488.10(d) is revised to read as follows:

§ 488.10 State survey agency review; Statutory provisions.

* * * * *

(d) Section 1865(a) of the Act also provides that if HCFA finds that accreditation of a hospital; psychiatric hospital; SNF; HHA; hospice; ASC; RHC; CORF; laboratory; screening mammography service; rural primary care hospital; or clinic, rehabilitation agency, or public health agency provider of outpatient physical therapy, occupational therapy, or speech pathology services by any national accreditation organization provides reasonable assurance that any or all Medicare conditions are met, HCFA may treat the provider or supplier as meeting the conditions.

§ 488.11 [Amended]

11. In § 488.11(b), the reference to § 488.6 is revised to read "§ 488.7."

12. Section 488.201(a)(1) is revised to read as follows:

§ 488.201 Reconsideration.

(a) *Right to reconsideration.* (1) A national accreditation organization dissatisfied with a determination that its accreditation requirements do not provide (or do not continue to provide) reasonable assurance that the entities accredited by the accreditation organization meet the applicable long-term care requirements, conditions for coverage, conditions of certification, conditions of participation, or CLIA condition level requirements is entitled to a reconsideration as provided in this subpart.

* * * * *

C. Part 489 is amended as follows:

PART 489—PROVIDER AND SUPPLIER AGREEMENTS

1. The authority citation continues to read as follows:

Authority: Secs. 1102, 1861, 1864, 1866, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x, 1395aa, 1395cc, and 1395hh).

2. Section 489.10 is revised to read as follows:

§ 489.10 Basic requirements.

(a) Any of the providers specified in § 489.2 may request participation in Medicare. In order to be accepted, it must meet the conditions of participation or requirements (for SNFs) set forth in this section and elsewhere in this chapter.

(b) In order to participate in the Medicare program, the provider must meet the requirements of:

(1) Title VI of the Civil Rights Act of 1964, as implemented by 45 CFR part 80, which provides that no person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subject to discrimination under, any program or activity receiving Federal financial assistance (section 601);

(2) Section 504 of the Rehabilitation Act of 1973, as implemented by 45 CFR part 84, which provides that no qualified handicapped person shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subject to discrimination under any program or activity receiving Federal financial assistance;

(3) The Age Discrimination Act of 1975, as implemented by 45 CFR part 90, which is designed to prohibit discrimination on the basis of age in programs or activities receiving Federal financial assistance. The Age Discrimination Act also permits federally assisted programs and activities, and recipients of Federal funds, to continue to use certain age distinctions, and factors other than age, that meet the requirements of the Age Discrimination Act and 45 CFR part 90; and

(4) Other pertinent requirements of the Office of Civil Rights of HHS.

(c) In order for a hospital, SNF, HHA, or hospice to be accepted, it must also meet the advance directives requirements specified in subpart I of this part.

(d) The State survey agency will ascertain whether the provider meets the conditions of participation or requirements (for SNFs) and make its recommendations to HCFA.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 23, 1993.

Bruce C. Vladeck,

Administrator, Health Care, Financing Administration.

Dated: August 9, 1993.

Donna E. Shalala,

Secretary.

[FR Doc. 93–28436 Filed 11–22–93; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43–CFR Public Land Order #7011

[WY–930–4210–06; WYW–83357]

Partial Revocation of Secretarial Order Dated April 20, 1921; Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.

SUMMARY: This order revokes a Secretarial order insofar as it affects 160 acres of National Forest system land withdrawn for Stock Driveway No. 144, Wyoming No. 18. The land is no longer needed for this purpose, and the revocation is needed to permit disposal of the land through land exchange under the General Exchange Act of 1922. This action will open the land to such forms of disposition as may by law be made of National Forest System land. The land is temporarily closed to mining by a Forest Service exchange proposal.The land has been and will remain open to mineral leasing.

EFFECTIVE DATE: December 23, 1993.

FOR FURTHER INFORMATION CONTACT: Duane Feick, BLM Wyoming State Office, P.O. Box 1828, Cheyenne, Wyoming 82003, 307–775–6127.

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (1988), it is ordered as follows:

1. Secretarial Order dated April 20, 1921, which withdrew National Forest System land for Stock Driveway No. 144, Wyoming No. 18, is hereby revoked insofar as it affects the following described land:

Sixth Principal Meridian

Medicine Bow National Forest

T. 30 N., R. 77 W.,
Sec. 32, SE¼SE¼;
Sec. 33, S½SW¼ and SW¼SE¼.

The area described contains 160 acres in Converse and Natrona Counties.

2. At 9 a.m. on December 23, 1993, the land shall be opened to such forms of disposition as may by law be made of National Forest System land, subject to valid existing rights, the provisions of existing withdrawals, other segregations of record, and the requirements of applicable law.

Dated: November 12, 1993.

Bob Armstrong,

Assistant Secretary of the Interior.

[FR Doc. 93–28640 Filed 11–22–93; 8:45 am]

BILLING CODE 4310–22–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 90

[PR Docket No. 93–60; FCC 93–450]

Private Land Mobile Radio Services; Co-Channel Protection Criteria Above 800 MHz

AGENCY: Federal Communications Commission.

ACTION: Final rule; correction.

SUMMARY: This document contains a correction to the final regulations [PR Docket No. 93–60, FCC 93–450] which were published Friday, October 15, 1993, (58 FR 53431). The regulations related to certain co-channel protection criteria for private land mobile radio stations operating in the 800/900 MHz bands.

EFFECTIVE DATE: November 15, 1993.

FOR FURTHER INFORMATION CONTACT: Eugene Thomson, Rules Branch, Land Mobile and Microwave Division, Private Radio Bureau, (202) 634–2443.

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are subject to this correction concern co-channel

protection criteria for private land mobile radio systems operating in the 800 MHz and 900 MHz frequency bands and specify procedures to be followed by persons applying for such frequencies pursuant to 47 CFR part 90.

Need for Correction

As published, the final regulations did not include a revision to § 90.615(b)(2)(ii) to change the cross reference to § 90.621(c). Because the final regulations amended § 90.621(c), the reference in § 90.615(b)(2)(ii) to § 90.621(c) is no longer applicable and requires correction.

Correction of Publication

Accordingly, the publication on October 15, 1993 of the final regulations [PR Docket No. 93–60, FCC 93–450] which were the subject of FR Doc. 93–25261, is corrected as follows:

On page 53433, in the first column below the Table, add paragraph 3 at the end of the amendatory text, to read as follows:

3. Section 90.615 is amended by revising paragraph (b)(2)(ii) to read as follows:

§ 90.615 Frequencies available in the General Category.

* * * * *

(b) * * *

(2) * * *

(ii) Each application must include a written signed statement from each co-channel licensee located within 113 km (70 mi) of the primary site of the trunked system verifying that each such licensee has agreed to the proposed trunked use (see exceptions at § 90.621(b)). The statement(s) must include each licensee's call sign.

* * * * *

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 93–28645 Filed 11–22–93; 8:45 am]

BILLING CODE 6712–01–M

OFFICE OF MANAGEMENT AND BUDGET

Office of Federal Procurement Policy

48 CFR Part 9903

Cost Accounting Standards Board; Applicability and Thresholds for Cost Accounting Standards Coverage

AGENCY: Cost Accounting Standards Board, Office of Federal Procurement Policy, OMB.

ACTION: Correction to final rule.

SUMMARY: This document contains a correction to the final rule revising applicability, thresholds and procedures for the application of Cost Accounting Standards to negotiated government contracts, which was published Thursday, November 4, 1993 (58 FR 58798).

EFFECTIVE DATE: November 4, 1993.

FOR FURTHER INFORMATION CONTACT: Richard C. Loeb, Executive Secretary, Cost Accounting Standards Board (telephone: 202–395–3254).

The final rule published Thursday, November 4, 1993, at 58 FR 58798 is corrected as follows.

§ 9903.201–3 [Corrected]

Instruction paragraph 4. for § 9903.201–3 which begins on page 58801, at the bottom of the third column, and continues at the top of page 58802 in the first column, is corrected on page 58802 by adding the following instruction in the third line after the first semicolon:

4. * * * by removing the amount "$10 million" in the "Caution" statement at the end of paragraph (c)(4) in Part I of the clause and adding the amount "$25 million" in its place; * * *

Dated: November 17, 1993.

[FR Doc. 93–28677 Filed 11–22–93; 8:45 am]

BILLING CODE 3110–01–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 625

[Docket No. 930615–3215; I.D. 110793A]

Summer Flounder Fishery

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic Atmospheric Administration (NOAA), Commerce.

ACTION: Notification of commercial quota transfer.

SUMMARY: NMFS issues this notification to announce that 7,815 pounds (3,545 kg) of summer flounder commercial quota available to the State of North Carolina has been transferred to the State of New Jersey. The summer flounder allocated to New Jersey by this transfer can only be harvested under the conditions of a net-mesh selectivity study authorized by the Regional Director. This notification advises the public that the quota adjustment has been made and that the adjusted commercial quota for the State of North Carolina is 3,256,750 pounds (1,477,252 million kg), and the State of New Jersey is 2,073,354 pounds (940,467 million kg).

DATES: Effective November 18, 1993 through December 31, 1993.

ADDRESSES: Comments or questions regarding the experimental fishery for summer flounder should be sent to Richard B. Roe, Regional Director, One Blackburn Drive, Gloucester, MA 01930.

FOR FURTHER INFORMATION CONTACT: Hannah Goodale, Fishery Policy Analyst, 508–281–9101.

SUPPLEMENTARY INFORMATION: Regulations governing the summer flounder fishery are found at 50 CFR part 625 (December 4, 1992, 57 FR 57358). The regulations require the annual specification of a commercial quota that is apportioned among the coastal states from North Carolina through Maine. The process to set the annual commercial quota and the percent allocated to each state are described in § 625.20.

The commercial quota for summer flounder for the 1993 calendar year was set equal to 12.35 million pounds (5.6 million kg) (January 22, 1993, 58 FR 5658). The percent allocated to each state was adjusted by Amendment 4 to the Fishery Management Plan for the Summer Flounder Fishery (September 24, 1993, 58 FR 49937) with 16.72499 percent, or 2,065,539 pounds (936,922 million kg) allocated to New Jersey, and 27.44584 percent, or 3,389,565 pounds (1,537,497 kg) allocated to North Carolina.

An emergency interim rule published August 26, 1993, (58 FR 45075) allows two or more states, under mutual agreement and with the concurrence of the Regional Director, to transfer or combine summer flounder commercial quota. The Regional Director is required to consider the criteria set forth in § 625.20(f)(1) to evaluate requests for quota transfers or combinations.

Further, the Regional Director is required to publish a notification in the **Federal Register** advising a state and notifying Federal vessel and dealer permit holders that, effective upon a specific date, a portion of a state's commercial quota has been transferred to or combined with the commercial quota of another state.

On November 8, 1993, a notification was published announcing a transfer of 125,000 pounds (56,700 kg) of summer flounder commercial quota from the State of North Carolina to the Commonwealth of Virginia (58 FR 59196). The quota for the State of North Carolina was thus reduced to 3,264,565 pounds (1,480,797 kg).