DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD09–97–014]

RIN 2115–AE47

Drawbridge Operation Regulations; Manistee River, MI

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is revising the regulation governing the operations of the Maple Street bridge and U.S. Route 31 bridge, miles 1.1 and 1.4, respectively, over the Manistee River in Manistee, MI. This revision was made at the behest of recreational vessel owners on Manistee River to provide for better bridge operating hours during navigation season.

DATES: This regulation is effective September 17, 1997.

ADDRESSES: Documents concerning this regulation are available for inspection and copying at 1240 East Ninth Street, Room 2019, Cleveland, OH 44199–2060 between 6:30 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (216) 902–6084.

FOR FURTHER INFORMATION CONTACT: Mr. Scot M. Striffler, Project Manager, Bridge Branch at (216) 902–6084.

SUPPLEMENTARY INFORMATION:

Regulatory History

The Coast Guard published a notice of proposed rulemaking (NPRM) and temporary deviation from regulations which appeared in the **Federal Register** on Thursday, May 22, 1997 (62 FR 27962 and 27990). The proposed schedule was submitted by the city of Manistee, MI at the request of recreational vessel users to provide later bridge operating hours. Under current regulations, between May 1 and October 31 each year, the bridge is required to open on signal for recreational vessels between 6 a.m. and 10 p.m. The revised regulation will require the bridge to open on signal between the hours of 7 a.m. and 11 p.m. No comments were received in response to either of the notices. A public hearing was not requested and, therefore, was not held.

The Coast Guard determined that the revised schedule fulfills the needs of recreational boating traffic on Manistee River without adversely impacting regular commercial users. Therefore, the final rule is unchanged from the NPRM.

Regulatory Evaluation

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has been exempted from review by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040, February 26, 1979).

The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), the Coast Guard must consider whether this rule will have a significant economic impact on a substantial number of small entities. *Small entities* include independently owned and operated small businesses that are not dominant in their field and otherwise qualify as ''small business concerns'' under section 3 of the Small Business Act (15 U.S.C. 632). The revised operating hours were requested by the City of Manistee on behalf of recreational boaters and the businesses that serve them on Manistee River. This rule was designed to enhance the economic potential of businesses on Manistee River while still providing for the reasonable needs of commercial navigation.

By virtue of the preceding, the Coast Guard certifies under 5 U.S.C. 605(b) that this rulemaking will not have a significant impact on a substantial number of small entities.

Collection of Information

This rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 et seq.).

Federalism

The Coast Guard has analyzed this rule under the principles and criteria contained in Executive Order 12612 and has determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard considered the environmental impact of this rule and concluded that, under section 2.B.2.e.(32)(e) of Commandant Instruction M16475.1B, promulgation of operating requirements or procedures for drawbridges is categorically excluded from further environmental documentation.

List of Subjects in 33 CFR Part 117

Bridges.

For reasons set out in the preamble, part 117 of Title 33, Code of Federal Regulations, is amended as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues to read as follows.

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05–1(g); Section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

2. Section 117.637 is amended by revising paragraph (a)(1) to read as follows:

§ 117.637 Manistee River.

(a) * * *

(1) From May 1 through October 31, between 7 a.m. to 11 p.m., the bridges shall open on signal. From 11 p.m. to 7 a.m., the bridges need not open unless notice is given at least two hours in advance of a vessel's time of intended passage through the draws.

* * * * *

Dated: August 8, 1997.

J.F. McGowan,

Rear Admiral, U.S. Coast Guard, Commander, Ninth Coast Guard District.

[FR Doc. 97–21813 Filed 8–15–97; 8:45 am]

BILLING CODE 4910–14–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 431, 442, 488, 489, and 498

[HSQ–139–F]

RIN 0938–AC88

Medicare and Medicaid Programs: Effective Dates of Provider Agreements and Supplier Approvals

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

ACTION: Final rule.

SUMMARY: This rule establishes uniform criteria for determining the effective dates of Medicare and Medicaid provider agreements and of the approval of Medicare suppliers when the provider or supplier is subject to survey and certification as a basis for determining participation in those programs. It also establishes appeal

rights and procedures for entities that are dissatisfied with effective date determinations.

DATES: *Effective date:* This rule is effective September 17, 1997.

FOR FURTHER INFORMATION CONTACT: Diane Bavaria, (410) 786–6773 or Sandra Farragut, (410) 786–3503.

SUPPLEMENTARY INFORMATION:

A. Background

Under sections 1866 and 1902 of the Social Security Act (the Act), providers of services seeking to participate in Medicare or Medicaid must enter into an agreement with the Secretary or the State Medicaid agency, as appropriate. Under HCFA rules, suppliers of Medicare services must be approved for coverage of the services they furnish to Medicare beneficiaries.

Generally, in order to enter into a provider agreement or obtain approval as a supplier, an entity must first be surveyed by HCFA or the State survey agency to ascertain whether it complies with the conditions of participation, conditions for coverage, or long-term care requirements. However, under section 1865 of the Act, HCFA may ''deem'' that an entity meets the Federal requirements if that entity is accredited by a national accrediting organization whose program is approved by HCFA.

Medicare or Medicaid payment may not be made for services furnished before the effective date of the provider agreement or supplier approval.

B. Notice of Proposed Rulemaking

On October 8, 1992, we published a Notice of Proposed Rulemaking (at 57 FR 46362) to establish uniform criteria for determining the effective date of provider agreements and supplier approvals. We received 6 letters of comment from two States, one health care association, the Small Business Administration, one lawyer, and one citizen. Those comments and our responses to them are detailed below.

C. Discussion of Comments

1. Level of Compliance

Comment: One commenter noted that the proposed rule was not consistent with Federal statutes that require full compliance for skilled nursing facilities (SNFs) and nursing facilities (NFs) or automatic termination within 6 months after survey. The commenter disagreed with our references to level A and level B requirements, and the provision that would permit initial certification of SNFs and NFs that have lower level deficiencies.

Response: As noted by the commenter, under the Omnibus Budget Reconciliation Act of 1987 (OBRA '87), we must, for SNFs and NFs, replace our hierarchical requirement scheme (condition level or level A, and standard level or level B) with a scheme built on the premise that all requirements must be met and enforced. However, because the final rule for implementing the OBRA '87 amendments had not been published, we had to continue using the hierarchical ''level A and Level B'' scheme in the proposed rule.

A final rule identified as HSQ–156–F, published on November 10, 1994 (at 59 FR 56116) implemented the OBRA '87 amendments. That rule—

- Establishes a revised enforcement system that detects and responds to noncompliance with any of the requirements, as opposed to the previous system which provided for adverse action only when the noncompliance was with level A requirements;
- Establishes the concept of ''substantial compliance'' as the criterion that SNFs and NFs must meet in order to participate in Medicare and Medicaid, and defines the term;
- Provides for termination of any SNF or NF that does not achieve substantial compliance within 6 months from the date of survey; and
- Removes references to ''level A and level B'' requirements.

Regarding the issue of allowing participation by an SNF or NF that has minor deficiencies, we believe that it is impractical and unrealistic to require perfect compliance. In fact, in 1992, only 7.3 percent of all SNFs and NFs surveyed were deficiency-free. Under the previous enforcement system defined by ''level A'' and ''level B'' requirements, most of the facilities that were experiencing only minor problems could continue to participate because the system allowed for some noncompliance at the lower or ''B'' level. That is no longer the case. By vastly increasing the number of statutory requirements that SNFs and NFs must meet, and by requiring us to do away with the hierarchy of requirements, Congress made it far more difficult for the facilities to qualify for program participation. We do not believe that Congress intended to write into law a set of requirements that would preclude almost all SNFs and NFs from participating in Medicare and Medicaid. Therefore, we have defined ''substantial compliance'' as a degree of compliance such that any existing deficiencies have not caused actual harm and do not create the potential for more than minimal harm to a resident. This definition is consistent with the statutory focus on resident outcomes as opposed to procedural requirements that do not always accurately measure whether quality care is being furnished. Although an SNF or NF that falls short of total compliance may escape imposition of a remedy, it still has a duty to provide, to each resident, care that enhances the chances of positive outcomes and avoids negative outcomes. If a single resident experiences any harm, the facility has not satisfied its statutory obligations. Given the statute's focus on each resident's right to receive quality care, and the facility's obligation to provide it, we could not adopt a less rigorous standard of compliance. (The preamble to HSQ–156–F contained a more detailed discussion of the background and rationale for the ''substantial compliance'' concept.)

However, precisely because the new standard is more stringent than its predecessor, it follows that once an SNF or NF achieves ''substantial compliance'', it has demonstrated its capacity for participation in the programs. Thus, if the survey finds that the facility is in ''substantial compliance'', the provider agreement is effective on the date the survey is completed. If we require the SNF or NF to submit a plan of correction for whatever requirements it does not fully meet, that does not delay the effective date of the agreement. If the facility needs a waiver, current practice remains unchanged, and the effective date is delayed until we receive an approvable waiver request.

2. Appeals and Payment

Comment: One commenter expressed the opinion that the proposed rule would not change the basic procedures for determining effective date, but merely add an appeal mechanism. The commenter understood the appeals provisions to mean that—

- Payment to a new provider would continue during the pendency of an appeal; and
- If the hearing decision changed the effective date, payments would be effective as of the new date.

Response: We agree that the procedures for determining effective date remain essentially unchanged except for the new ''substantial compliance'' concept for SNFs and NFs. For other providers, the rule continues to be that the effective date is the earlier of the date on which the provider meets all requirements or the date on which it meets all condition level requirements (or conditions for coverage in the case of suppliers) and has an acceptable plan of correction for standard level

deficiencies or an approvable waiver request, or both.

To preclude any confusion concerning the determination of effective date when it is related to a plan of correction or waiver request, we revised the rule to state that the effective date of the agreement or approval is the date that the State or HCFA receives (as opposed to the date the facility submits) the acceptable plan or approvable waiver request.

The commenter is correct in interpreting that payment would be made, during pendency of the appeal, for services furnished on or after the effective date of the agreement or approval; and would be adjusted to the new effective date determined by the hearing decision.

3. Effective Date When Facility Is Accredited Before It Seeks Participation

Comment: Two commenters were concerned about how the proposed rule would be applied when a facility had already been accredited by an accrediting organization. The proposed rule would not allow the provider to enter into a retroactive agreement so that it could receive payment for services furnished after accreditation but before it sought participation in Medicare or Medicaid. The commenters stated that this situation commonly arises when a provider that has been surveyed and found to be in compliance with Federal requirements—

- Is participating in its own State's Medicaid program and provides services to a Medicaid recipient from another State; or
- Is not participating in Medicaid but provides services to a Medicaid recipient before learning of the individual's Medicaid status.

Response: We consider the concerns to be justified. Accordingly, we have revised § 431.108 (content previously contained in § 442.13) and § 489.13 to provide that an agreement or approval may be made retroactive for a provider or supplier that—

- Has been deemed to meet all applicable Federal requirements on the basis of accreditation by an accrediting organization whose program had HCFA approval at the time the organization surveyed and accredited the provider or supplier; and
- Meets all applicable State licensure and Life Safety Code requirements.

Specifically, the final rule provides that the effective date of an agreement or approval can be made retroactive for up to one year to encompass dates on which the provider or supplier furnished covered services to a beneficiary or recipient. However, the retroactive effective date may not be before the earlier of—

- The date on which HCFA approves the accrediting organization's program; and
- The date of accreditation.

We already have several regulations that provide for payment in special situations:

§ 431.52—for Medicaid services furnished out of State.

Part 424 and §§ 440.170(e) and 482.2—for emergency care furnished by nonparticipating hospitals.

We believe that additional flexibility in determining effective dates of agreements and approvals will further ensure that all eligible providers and suppliers receive payment. The one-year period for retroactivity is consistent with Medicare and Medicaid regulations which generally require that claims be submitted for payment within one year from the date of service.

4. Applicability of the Rule

Comment: Two commenters questioned whether physicians in private practice and other non-institutional providers of Medicaid services would be subject to the regulation since, according to § 440.3, the effective date provisions apply to all types of Medicaid providers. One of the commenters disagreed with the provisions governing deemed status if they are to be applied to Medicaid private non-institutional providers.

Response: In response to these comments, § 431.108(a)(2) (for Medicaid) and § 489.13(a) (for Medicare) specify that the rules for determining effective date apply only to providers and suppliers that are subject to survey and certification by HCFA or the State survey agency, or have deemed status on the basis of accreditation by an accrediting organization whose program has HCFA approval. (Section 440.3 of the proposed rule cited § 442.13 for the effective date rules. In this final regulation, we have moved those rules to the new § 431.108 of subpart C because that is the subpart that pertains to Medicaid provider agreements.)

5. Regulatory Impact Statement

Comment: One commenter noted that the impact statement in the proposed rule did not explain why the Secretary certified that the rule would not have a significant impact on a substantial number of small entities. The commenter requested that the final rule include a comprehensive regulatory impact analysis.

Response: A regulatory impact *analysis* is required when a rule *would have* a significant impact. It has been determined that the effect of this rule on small entities is negligible because, in practice, we have for the most part determined effective dates of provider agreements and supplier approvals using the policies and procedures that were not until now incorporated in the regulations. Therefore, since the procedures for determining effective dates generally do not change, the impact on providers and suppliers is inconsequential and thus forms the basis for certifying that this rule will not have a significant economic impact. Since there is no significant impact, a regulatory impact analysis is not required.

Although this rule makes only minimal changes in the way effective dates are determined, it does add an appeals mechanism. We do not anticipate a significant increase in the number of requests for hearings for two reasons:

First, the current Federal regulations provide appeal rights for a prospective provider or supplier who is denied participation in the Medicare program. (State regulations may provide a similar appeals mechanism for Medicaid denials.) A determination to deny a prospective provider's or prospective supplier's request for participation in Medicare is usually based on the entity's lack of compliance with our requirements for participation. Effective date hearings would, for the most part, focus on the same noncompliance issues. Appeals from effective date determinations will probably arise when an entity disagrees with the date that HCFA or the State determines that noncompliance was corrected. We do not anticipate that entities will appeal both an initial denial and a subsequent effective date determination.

Second, the right to appeal an effective date determination, while not previously codified, had already been confirmed by court decisions. Since the effective date of participation is usually determined only once, at the time of the initial survey (the exception being ICFs/MR which have time-limited agreements), and since entities are already appealing these decisions, we do not anticipate that codification of the appeal rights will cause any great increase in the number of hearing requests.

Further, we have no reason to anticipate that publication of this rule will cause an increase in the number of small entities that request agreements or approvals for participation in Medicare, or Medicaid, or both. Neither do we have any basis for estimating how many prospective providers or suppliers will

make such requests after this rule is published.

6. Part Title

Comment: One commenter suggested that we change the title of part 442 from ''Standards for Payment to Nursing Facilities and Intermediate Care Facilities for the Mentally Retarded'' to ''Standards for Payment to Nursing Facilities and Intermediate Care Facilities for Persons with Mental Retardation''.

Response: We agree that it would be preferable to have a title that recognizes the person first and the disability second, as opposed to referring directly to the disability. However, section 1905(d) of the statute identifies these institutions as ''intermediate care facilities for the mentally retarded''. We believe that retention of that language is the best way to preclude any possible misunderstanding.

7. Miscellaneous Comments

Comment: We received favorable comments on two provisions of the proposed rule—

- Having the State survey agency recommend the effective date when it has conducted the survey.
- Precluding appeals based on the contention that a survey should have been conducted earlier than it was.

Response: We appreciate the commenter's support and believe that these two provisions will contribute to smooth implementation of the rules.

D. Provisions of the Final Rule

In summary, this final rule—

- Makes clear that the rules for determination of the effective date of a provider agreement or supplier approval apply to all providers and suppliers that are subject to survey and certification by HCFA, or the State survey agency, or have deemed status on the basis of accreditation;
- Provides that the State agency that conducts the survey makes recommendations concerning the effective date;
- Reflects statutory changes under which the basis for determining effective date for SNFs and NFs is different from the basis used in connection with other providers and with suppliers;
- Sets forth the circumstances under which effective dates may be made retroactive;
- Makes existing Medicare appeals procedures available, and requires Medicaid agencies to make their existing appeals procedures available, for effective date determinations.
- Specifies that, for laboratories, Medicaid agreements and Medicare approvals are effective only while the laboratory has in effect a valid CLIA certificate issued under part 493 of the HCFA rules, and only for the specialty and subspecialty tests it is authorized to perform; and
- Sets forth the effective date rules that apply to Medicare provider agreements with community mental health centers (CMHCs) and Federally qualified health centers (FQHCs). The effective date rule for Medicaid agreements with FQHCs will be issued as part of a separate regulation. (CMHCs do not participate in the Medicaid program.)

We are also taking advantage of this opportunity to clarify policy on termination of provider agreements, as set forth in § 489.53. Specifically, this final rule amends that section to revise the paragraph (b) heading and restore language that was inadvertently changed by HSQ–156–F, Survey, Certification, and Enforcement for Skilled Nursing Facilities and Nursing Facilities (59 FR 56116 of November 10, 1994).

The 1994 final rule, in revising § 489.53, inadvertently expanded an exception by making the 2-day notice applicable to ''a provider or supplier'', instead of only to a skilled nursing facility (SNF). This rule revises § 489.53(c)(2) to restore the previous language: ''For an SNF with deficiencies that pose immediate jeopardy to the health or safety of its residents, HCFA gives notice at least 2 days before the effective date of termination of the provider agreement.'' (The correctly limited rule for nursing facilities is set forth in § 488.402(f)(3) of the HCFA rules.)

We would also correct a technical error—the retention of ''; and'' at the end of § 489.11(c)(2) when paragraph (c)(3) of that section was removed.

Collection of Information Requirements

This rule contains no new information collection requirements subject to review by the Office of Management and Budget under the Paperwork Reduction Act.

Regulatory Impact Statement

Consistent with the Regulatory Flexibility Act (RFA) and section 1102(b) of the Social Security Act, we prepare a regulatory impact analysis for each rule, unless we can certify that the rule will not have a significant economic impact on a substantial number of small entities, or a significant impact on the operation of a substantial number of small rural hospitals.

The RFA defines *small entity* as a small business, a nonprofit enterprise, or a governmental jurisdiction (such as a county, city, or township) with a population of less than 50,000. We also consider all providers and suppliers of services to be small entities. For purposes of section 1102(b) of the Act, we define *small rural hospital* as a hospital that has fewer than 50 beds, and is not located in a metropolitan statistical area.

This rule makes minimal changes in the procedures for determining the effective date of a provider agreement or a supplier approval, and makes existing appeals procedures available to entities that are dissatisfied with any effective date determination. It has been determined that the effect of these changes on small entities is negligible because, in practice, we have for the most part determined effective dates of agreements and approvals using the policies and procedures that had not until now been incorporated in our regulations. The important aspect of this rule is that it is essentially a matter of codification, of inclusion of those practices in the CFR.

In addition, we do not anticipate that codification of the right to appeal effective date determinations will lead to a significant increase in the number of hearing requests for several reasons.

First, current Federal regulations provide appeal rights for a prospective provider or supplier who is denied participation in the Medicare program. (State regulations may provide a similar appeals mechanism for Medicaid denials). Denial of participation is usually based on the prospective provider's or prospective supplier's lack of compliance with our requirements. Effective date hearings would, for the most part, focus on the same noncompliance issues. Appeals from effective date determinations will probably arise when the entity disagrees with the date that HCFA or the State determines that the noncompliance was corrected. We do not believe that entities will appeal both an initial denial and a subsequent effective date determination.

Second, the right to appeal an effective date determination, while not previously codified, had been confirmed by court decisions. Since entities are currently appealing these decisions, and since the effective date of participation is usually determined only once, at the time of the initial survey (the exception being ICFs/MR which have time-limited agreements) we do not anticipate a large increase in the number of hearing requests.

It is clear that, since the procedures for determining and appealing effective date determinations generally will not

change as a result of publishing this rule, the criteria for requiring a regulatory impact analysis are not met. Accordingly, we have not prepared a regulatory impact analysis because we have determined and the Secretary certifies that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operation of a substantial number of small rural hospitals.

We have no reason to anticipate that this rule will cause an increase in the number of small entities that request agreements or approvals for participation in Medicare or Medicaid or both. Neither do we have any basis for estimating how many will make such requests after the effective date of this rule.

We have reviewed this rule and determined that, under the provisions of Public Law 104–121, it is not a major rule.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 431

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

42 CFR Part 442

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

42 CFR Part 488

Health facilities, Survey and certification, Forms and guidelines.

42 CFR Part 489

Health facilities, Medicare.

42 CFR Part 498

Administrative practice and procedure, Appeals, Medicare, Practitioners, providers, and suppliers.

42 CFR Chapter IV is amended as set forth below.

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

A. Part 431 is amended as set forth below.

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

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

2. Subpart C is amended to add new § 431.108 to read as follows:

§ 431.108 Effective date of provider agreements.

(a) *Applicability*—(1) *General rule.* Except as provided in paragraph (a)(2) of this section, this section applies to Medicaid provider agreements with entities that, as a basis for participation in Medicaid—

(i) Are subject to survey and certification by HCFA or the State survey agency; or

(ii) Are deemed to meet Federal requirements on the basis of accreditation by an accrediting organization whose program has HCFA approval at the time of accreditation survey and accreditation decision.

(2) *Exception.* A Medicaid provider agreement with a laboratory is effective only while the laboratory has in effect a valid CLIA certificate issued under part 493 of this chapter, and only for the specialty and subspecialty tests it is authorized to perform.

(b) *All requirements are met on the date of survey.* The agreement is effective on the date the onsite survey (including the Life Safety Code survey if applicable) is completed, if on that date the provider meets—

(1) All applicable Federal requirements as set forth in this chapter; and

(2) Any other requirements imposed by the State for participation in the Medicaid program. (If the provider has a time-limited agreement, the new agreement is effective on the day following expiration of the current agreement.)

(c) *All requirements are not met on the date of survey.* If on the date the survey is completed the provider fails to meet any of the requirements specified in paragraph (b) of this section, the following rules apply:

(1) An NF provider agreement is effective on the date on which—

(i) The NF is found to be in substantial compliance as defined in § 488.301 of this chapter; and

(ii) HCFA or the State survey agency receives from the NF, if applicable, an approvable waiver request.

(2) For an agreement with any other provider, the effective date is the earlier of the following:

(i) The date on which the provider meets all requirements.

(ii) The date on which a provider is found to meet all conditions of participation but has lower level deficiencies, and HCFA or the State survey agency receives from the provider an acceptable plan of correction for the lower level deficiencies, or an approvable waiver request, or both. (The date of receipt is the effective date of the agreement, regardless of when HCFA approves the plan of correction or waiver request, or both.)

(d) *Accredited provider requests participation in the Medicaid program.*—(1) *General rule.* If a provider is currently accredited by a national accrediting organization whose program had HCFA approval at the time of accreditation survey and accreditation decision, and on the basis of accreditation, HCFA has deemed the provider to meet Federal requirements, the effective date depends on whether the provider is subject to requirements in addition to those included in the accrediting organization's approved program.

(i) *Provider subject to additional requirements.* For a provider that is subject to additional requirements, Federal or State, or both, the effective date is the date on which the provider meets all requirements, including the additional requirements.

(ii) *Provider not subject to additional requirements.* For a provider that is not subject to additional requirements, the effective date is the date of the provider's initial request for participation if on that date the provider met all Federal requirements.

(2) *Special rule: Retroactive effective date.* If the provider meets the requirements of paragraphs (d)(1) and (d)(1)(i) or (d)(1)(ii) of this section, the effective date may be retroactive for up to one year, to encompass dates on which the provider furnished, to a Medicaid recipient, covered services for which it has not been paid.

3. Section 431.151(a) is amended to republish the introductory text and add a paragraph (a)(3), to read as follows:

§ 431.151 Scope and applicability.

(a) *General rules.* This subpart sets forth the appeals procedures that a State must make available as follows:

* * * * *

(3) To an NF or ICF/MR that is dissatisfied with a determination as to the effective date of its provider agreement.

* * * * *

4. Section 431.153 is amended to republish the introductory text of paragraph (b) and add a paragraph (b)(5), to read as follows:

§ 431.153 Evidentiary hearing.

* * * * *

(b) *Limit on grounds for appeal.* The following are not subject to appeal:

* * * * *

(5) A State survey agency's decision as to when to conduct an initial survey of a prospective provider.

* * * * *

§ 431.610 [Amended]

5. In § 431.610, the following changes are made:

a. In paragraph (e)(1), ''if'' is removed and ''whether'' is inserted in its place.

b. In paragraph (e)(2), the period is removed and ''; and'' is added in its place.

c. A new paragraph (e)(3) is added, to read as set forth below:

§ 431.610 Relations with standard-setting and survey agencies.

* * * * *

(e) *Designation of survey agency.*

* * *

(3) The agency designated in paragraph (e)(1) of this section makes recommendations regarding the effective dates of provider agreements, as determined under § 431.108.

* * * * *

PART 442—STANDARDS FOR PAYMENT TO NURSING FACILITIES AND INTERMEDIATE CARE FACILITIES FOR THE MENTALLY RETARDED

B. Part 442 is amended as set forth below.

1. The heading for part 442 is revised to read as set forth above.

2. The authority citation for part 442 continues to read as follows:

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

3. Section 442.13 is revised to read as follows:

§ 442.13 Effective date of provider agreement.

The effective date of a provider agreement with an NF or ICF/MR is determined in accordance with the rules set forth in § 431.108.

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

C. Part 488 is amended as set forth below.

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

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. Section 488.11 is revised to read as follows:

§ 488.11 State survey agency functions.

State and local agencies that have agreements under section 1864(a) of the Act perform the following functions:

(a) Survey and make recommendations regarding the issues listed in § 488.10.

(b) Conduct validation surveys of accredited facilities as provided in § 488.7.

(c) Perform other surveys and carry out other appropriate activities and certify their findings to HCFA.

(d) Make recommendations regarding the effective dates of provider agreements and supplier approvals in accordance with § 489.13 of this chapter.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

D. Part 489 is amended as set forth below.

1. The authority citation for part 489 continues to read as follows:

Authority: Secs. 1102, and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. In § 489.1, a new paragraph (d) is added, to read as follows:

§ 489.1 Statutory basis.

* * * * *

(d) Although section 1866 of the Act speaks only to providers and provider agreements, the effective date rules in this part are made applicable also to the approval of suppliers that meet the requirements specified in § 489.13.

3. § 489.13 is revised to read as follows:

§ 489.13 Effective date of agreement or approval.

(a) *Applicability*—(1) *General rule.* Except as provided in paragraph (a)(2) of this section, this section applies to Medicare provider agreements with, and supplier approval of, entities that, as a basis for participation in Medicare—

(i) Are subject to survey and certification by HCFA or the State survey agency; or

(ii) Are deemed to meet Federal requirements on the basis of accreditation by an accrediting organization whose program has HCFA approval at the time of accreditation survey and accreditation decision.

(2) *Exceptions.* (i) For an agreement with a community mental health center (CMHC) or a Federally qualified health center (FQHC), the effective date is the date on which HCFA accepts a signed agreement which assures that the CMHC or FQHC meets all Federal requirements.

(ii) A Medicare supplier approval of a laboratory is effective only while the laboratory has in effect a valid CLIA certificate issued under part 493 of this chapter, and only for the specialty and subspecialty tests it is authorized to perform.

(b) *All Federal requirements are met on the date of survey.* The agreement or approval is effective on the date the survey (including the Life Safety Code survey, if applicable) is completed, if on that date the provider or supplier meets all applicable Federal requirements as set forth in this chapter. (If the agreement or approval is time-limited, the new agreement or approval is effective on the day following expiration of the current agreement or approval.)

(c) *All Federal requirements are not met on the date of survey.* If on the date the survey is completed the provider or supplier fails to meet any of the requirements specified in paragraph (b) of this section, the following rules apply:

(1) For an agreement with an SNF, the effective date is the date on which—

(i) The SNF is in substantial compliance (as defined in § 488.301 of this chapter) with the requirements for participation; and

(ii) HCFA or the State survey agency receives from the SNF, if applicable, an approvable waiver request.

(2) For an agreement with, or an approval of, any other provider or supplier, (except those specified in paragraph (a)(2) of this section), the effective date is the earlier of the following:

(i) The date on which the provider or supplier meets all requirements.

(ii) The date on which a provider or supplier is found to meet all conditions of participation or coverage, but has lower level deficiencies, and HCFA or the State survey agency receives an acceptable plan of correction for the lower level deficiencies, or an approvable waiver request, or both. (The date of receipt is the effective date regardless of when HCFA approves the plan of correction or the waiver request, or both.)

(d) *Accredited provider or supplier requests participation in the Medicare program*—(1) *General rule.* If the provider or supplier is currently accredited by a national accrediting organization whose program had HCFA approval at the time of accreditation survey and accreditation decision, and on the basis of accreditation, HCFA has deemed the provider or supplier to meet Federal requirements, the effective date depends on whether the provider or supplier is subject to requirements in addition to those included in the accrediting organization's approved program.

(i) *Provider or supplier subject to additional requirements.* If the provider or supplier is subject to additional requirements, the effective date of the agreement or approval is the date on which the provider or supplier meets all requirements, including the additional requirements.

(ii) *Provider or supplier not subject to additional requirements.* For a provider or supplier that is not subject to additional requirements, the effective date is the date of the provider's or supplier's initial request for participation if on that date the provider or supplier met all Federal requirements.

(2) *Special rule: Retroactive effective date.* If a provider or supplier meets the requirements of paragraphs (d)(1) and (d)(1)(i) or (d)(1)(ii) of this section, the effective date may be retroactive for up to one year to encompass dates on which the provider or supplier furnished, to a Medicare beneficiary, covered services for which it has not been paid.

4. Section 489.53 is amended to revise the heading of paragraph (b) and paragraphs (c)(1) and (c)(2) to read as follows:

§ 489.53 Termination by HCFA.

* * * * *

(b) *Termination of agreements with certain hospitals.* * * *

(c) *Notice of termination*—(1) *Timing: Basic rule.* Except as provided in paragraph (c)(2) of this section, HCFA gives the provider notice of termination at least 15 days before the effective date of termination of the provider agreement.

(2) *Timing exceptions: Immediate jeopardy situations*—(i) *Hospital with emergency department.* If HCFA finds that a hospital with an emergency department is in violation of § 489.24, paragraphs (a) through (e), and HCFA determines that the violation poses immediate jeopardy to the health or safety of individuals who present themselves to the hospital for emergency services, HCFA—

(A) Gives the hospital a preliminary notice indicating that its provider agreement will be terminated in 23 days if it does not correct the identified deficiencies or refute the finding; and

(B) Gives a final notice of termination, and concurrent notice to the public, at least 2 , but not more than 4, days before the effective date of termination of the provider agreement.

(ii) *Skilled nursing facilities (SNFs).* For an SNF with deficiencies that pose immediate jeopardy to the health or safety of residents, HCFA gives notice at least 2 days before the effective date of termination of the provider agreement.

* * * * *

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF CERTAIN ICFs/MR AND CERTAIN NFs IN THE MEDICAID PROGRAM

E. Part 498 is amended as set forth below.

1. The authority citation for part 498 continues to read as follows:

Authority: Secs. 1102, and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. Section 498.3 is amended to revise paragraph (a), republish the introductory text of paragraph (b) and add a paragraph (b)(14), revise the introductory text of paragraph (d) and add new paragraphs (d)(14) and (d)(15), to read as follows:

§ 498.3 Scope and applicability.

(a) *Scope.* This part sets forth procedures for reviewing initial determinations that HCFA makes with respect to the matters specified in paragraph (b) of this section, and that the OIG makes with respect to the matters specified in paragraph (c) of this section. It also specifies, in paragraph (d) of this section, administrative actions that are not subject to appeal under this part.

(b) *Initial determinations by HCFA.* HCFA makes initial determinations with respect to the following matters:

* * * * *

(14) The effective date of a Medicare provider agreement or supplier approval.

* * * * *

(d) *Administrative actions that are not initial determinations.* Administrative actions that are not initial determination (and therefore not subject to appeal under this part) include but are not limited to the following:

* * * * *

(14) The choice of alternative sanction or remedy to be imposed on a provider or supplier.

(15) A decision by the State survey agency as to when to conduct an initial survey of a prospective provider or supplier.

* * * * *

F. Technical correction.

§ 489.1 [Amended]

In § 489.11(c), the following changes are made:

a. At the end of paragraph (c)(1), the word ''and'' is added.

b. At the end of paragraph (c)(2), ''; and'' is removed and a period is inserted in its place.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93.774, Medicare—Supplementary Medical Insurance; and Program No. 93.778, Medical Assistance.)

Dated: September 20, 1996.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: December 27, 1996.

Donna E. Shalala,

Secretary.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 222 and 227

[Docket No. 960730210–7193–02; I.D. 050294D]

RIN 0648–XX65

Endangered and Threatened Species: Listing of Several Evolutionary Significant Units (ESUs) of West Coast Steelhead

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

ACTION: Final rule.

SUMMARY: On August 9, 1996, NMFS completed a comprehensive status review of west coast steelhead (*Oncorhynchus mykiss*, or *O. mykiss*) populations in Washington, Oregon, Idaho, and California, and identified 15 Evolutionarily Significant Units (ESUs) within this range. NMFS is now issuing a final rule to list two ESUs as endangered and three ESUs as threatened under the Endangered Species Act (ESA). The endangered steelhead ESUs are located in California (Southern California) and Washington (Upper Columbia River). The threatened steelhead ESUs are located in California (Central California Coast and South-Central California Coast) and Idaho, Washington, and Oregon (Snake River Basin). For the endangered ESUs, section 9(a) prohibitions will be effective 60 days from the publication of this final rule. For the threatened ESUs, NMFS will issue shortly protective regulations under section 4(d) of the ESA, which will apply section 9(a) prohibitions with certain exceptions.

NMFS has examined the relationship between hatchery and natural populations of steelhead in these ESUs, and has assessed whether any hatchery