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

Subpart F—Conditions of Participation: Critical Access Hospitals (CAHs)

■ 16. Section 485.623 is amended as follows:

■ A. Paragraph (d)(7)(iii) is revised.

■ B. Paragraph (d)(7)(iv) is amended by removing the last sentence.

■ C. Paragraph (d)(7)(iv) is further amended by removing the period at the end of the paragraph and adding in its place ''; and''.

■ D. Paragraph (d)(7)(v) is added.

The revisions read as follows:

§ 485.623 Condition of participation: Physical plant and environment.

* * * * *

(d) * * *

(7) * * *

(iii) The dispensers are installed in a manner that adequately protects against inappropriate access;

* * * * *

(v) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

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

Dated: February 8, 2006.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: May 31, 2006.

Michael O. Leavitt,

Secretary.

[FR Doc. 06–7885 Filed 9–21–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405 and 491

[CMS–1910–IFC]

RIN 0938–AJ17

Medicare Program; Rural Health Clinics: Amendments to Participation Requirements and Payment Provisions; and Establishment of a Quality Assessment and Performance Improvement Program; Suspension of Effectiveness

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period; partial suspension of effectiveness.

SUMMARY: This interim final rule with comment period revises the rural health clinic (RHC) regulations to revert to those provisions set forth in regulations before publication of the December 24, 2003 RHC final rule. That final rule implemented certain provisions of the Balanced Budget Act (BBA) of 1997 to establish a process and criteria for disqualifying from the RHC program clinics that no longer meet basic location requirements (rural and medically underserved), and to require RHCs to establish quality assessment and performance improvement programs. That rule also prohibited ''commingling'' (the use of the space, professional staff, equipment, and other resources) of an RHC with another entity. [In addition, it addressed comments on the February 28, 2000 proposed rule. Since the publication of the RHC final rule exceeded the 3-year timeline for finalizing proposed rules set by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, we are suspending the effectiveness of the current provisions by removing the RHC provisions set forth in the December 2003 final rule and reverting to those RHC provisions previously in effect.] We intend to reissue new proposed and final RHC rules to reinstate the current provisions. However, these revisions do not impact the effectiveness of the self-implementing provisions of the BBA or any provisions we had previously implemented or enforced through program memoranda.

DATES: *Effective date:* These regulations are effective on September 22, 2006.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on November 21, 2006.

ADDRESSES: In commenting, please refer to file code CMS–1910–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/eRulemaking.* Click on the link ''Submit electronic comments on CMS regulations with an open comment period.'' (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1910–IFC, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1910–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or

courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: John Warren, (410) 786–3633.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–1910–IFC and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.cms.hhs.gov/eRulemaking.* Click on the link ''Electronic Comments on CMS Regulations'' on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

[If you choose to comment on issues in this section, please include the caption ''BACKGROUND'' at the beginning of your comments.]

A. Changes Based on Legislation

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, Pub. L. 108–173) was enacted on December 8, 2003. Section 902 of MMA of 2003 amended section 1871(a) of the Act and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA also states that the timelines for these regulations may vary but shall not exceed 3 years after publication of the preceding proposed or interim final regulation except under exceptional circumstances. A notice implementing this provision was published in the **Federal Register** on December 30, 2004 (69 FR 78442).

On February 28, 2000, we published a proposed rule in the **Federal Register** (65 FR 10450) to revise certification and payment requirements for RHCs, as required by section 4205 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33, enacted on August 5, 1997). On December 24, 2003, we published a final rule in the **Federal Register** (68 FR 74792) to finalize that proposed rule. Because we published the proposed rule on February 2000 and the final rule on December 2003 (more than 3 years following the publication of the proposed rule), we will be issuing, through separate rulemaking, a new proposed rule and subsequently, a new final rule. However, before we publish those two rules, we are publishing this interim final rule to suspend the implementation of the current provisions by revising our regulations to remove those provisions and to reinstate the provisions previously in effect before the December 2003 final rule was published. The changes are necessary to avoid any confusion regarding the effectiveness of the provisions of the RHC final rule. We intend to publish a new proposed rule, which would propose to re-adopt many of the provisions set forth under the December 2003 final rule, followed by a new final rule informed by public comment.

B. State Survey Agency Directors Letter

To provide clarification regarding provisions set forth in the December 2003 final rule (effective date of rule: February 23, 2004), we issued a letter to State Survey Agency Directors in August 2004. We specified in the letter that we have not yet implemented certain changes to the RHC provisions set forth in the December 2003 final rule. We instructed State Agencies, until further notice, not to take any action to disqualify currently approved Medicare participating RHCs that no longer meet basic location requirements. We added that initial RHC applicants must meet existing rural and shortage area location requirements.

In addition, we stated that the Quality Assessment and Performance Improvement (QAPI) program requirements were not yet mandatory. However, we added that because a QAPI program as specified in the December 2003 final rule will exceed the current program evaluation requirement, any RHC that has implemented the QAPI program as specified should be considered to be in compliance with the existing Program Evaluation requirements.

II. Provisions of the Interim Final Rule

[If you choose to comment on issues in this section, please include the caption ''Suspension of Regulatory Provisions'' at the beginning of your comments.]

This interim final rule with comment period makes changes to the RHC-related provisions under parts 405 and 491 of our regulations. This interim final rule revises those provisions set forth in the December 2003 final rule to remove the current RHC provisions and to reinstate policy previously in effect. This rule will not affect the provisions that are self-implementing under the BBA or any provisions that we have already enforced through program memoranda. We intend to publish a new proposed rule, which would propose to re-adopt many of the provisions set forth under the December 2003 final rule, followed by a new final rule informed by public comment.

The suspension of the December 2003 final RHC rule will remain in effect until we set forth provisions under the new RHC final rule. The new proposed and final rules will identify any changes to the RHC provisions set forth in the December 2003 final rule. The suspension clarifies that we will not implement several of the RHC provisions until we publish a new proposed and final RHC rule.

Regulatory Revisions

Below we describe the revisions that we are making to our current regulations. Unless otherwise noted, we are removing the current RHC provisions as set forth under the December 2003 rule and replacing them with those in effect before the provisions of the December 2003 final rule became effective. As we describe under section III of this interim final rule, specific provisions will remain in effect and will not be affected by regulatory revisions set forth by this rule.

- Section 405.2401 Scope and Definitions.

Under paragraph (b) of this section, we revised the definition of RHCs. We are removing the provisions that prohibit the sharing of professional staff, space, supplies, records, and other resources with another Medicare and Medicaid entity and provisions discussing how to handle related costs.

- Section 405.2410 Application of Part B Deductible and Coinsurance.

Paragraphs (a) and (b) of this section describe the responsibilities regarding

payment of the deductible and coinsurance under Part B.

We are revising paragraph (a) of this section to describe how we apply the Medicare Part B deductible. We are revising paragraph (b) of this section to revert to the language that was codified in the CFR before publication of the December 2003 final rule.

• Section 405.2462 Payment for Rural Health Clinic Services and Federally Qualified Health Clinic Services. *Hospital-Based RHCs Payment Limit.* These provisions are BBA provisions relating to the payment limit for hospital-based RHCs. We are revising this section to revert to previous policy regarding payment to provider-based RHCs and FQHCs.

• Section 491.2 Definitions.

We are revising this section to revert to the ''Definitions'' section that was codified in the CFR before publication of the December 2003 final rule. In the definition of ''nurse practitioner,'' we note that the effective date referenced in paragraph (3) of the definition would revert to the original effective date of the subpart (July 1, 1978), not the effective date of this interim final rule. In addition, we are temporarily correcting the two incorrect cross-references in this section. In the definition of ''Nurse practitioner,'' we are correcting the cross reference in paragraph (3) of that definition to read ''paragraph (2) of this definition.'' In the definition of ''Physician assistant,'' we are correcting the cross reference in paragraph (3) of that definition to read ''paragraph (2) of this definition.''

• Section 491.3 RHC Procedures.

Provisions under paragraph (a) of this section describe our general procedures for approving or disapproving an RHC's request to participate in Medicare.

We are removing the provisions under paragraph (b)(1) of this section that describe the current shortage area requirements for participating RHCs and applicants; paragraphs (b)(2) and (b)(3) of this section describe the procedures that RHCs must follow that have outdated shortage area designations; and paragraph (c) under this section describes procedures that the RHC may follow to request an exception from disqualification when failing to meet the rural or shortage area definition. We are not currently enforcing the policies described under these paragraphs but we may reinstate the policy in a future final rule.

• Section 491.5 Location of Clinic.

We are revising paragraph (b) of this section that describes the exceptions to disqualification of an approved RHC located in an area that no longer meets the definition of a shortage or rural area.

We are also revising paragraph (d), which sets forth the criteria for designation of shortage areas, to revert to the paragraph (d) that was codified before publication of the December 2003 final rule.

We are re-inserting paragraph (e), which describes a medically underserved population, to revert to the paragraph (e) that was codified before publication of the December 2003 final rule.

We are re-inserting paragraph (f), which sets forth requirements specific to FQHCs, to revert to the paragraph (f) that was codified before publication of the December 2003 final rule.

• Section 491.8 Staffing and Staff Responsibilities.

Set forth under the December 2003 final rule, at paragraph (a)(6) of this section, we made an update to reflect a previous legislative change to the amount of time non-physicians must be available to furnish services at the clinic and a technical correction to add ''certified nurse midwife'' (CNM) to the list of health care providers that are available to furnish patient care at least 50 percent of the time that the RHC operates. We clarified through manual instructions that the list of qualified RHC non-physician practitioners includes certified nurse midwives, but this clarification had not been codified in regulations.

We are revising paragraph (a)(6) to reinstate our previous requirement, which does not include ''CNM'' in the list of nonphysician providers and requires that providers be available at least ''60 percent'' of the time that the RHC operates.

We are removing the requirements under paragraph (d) of this section that relate to waivers of RHC staffing requirements. Although we are changing the nonphysician staffing requirement and removing the RHC staffing waiver provision from our regulations, we are enforcing these statutory requirements through program manuals and memoranda. In other words, we will continue to require nonphysicians to be available 50 percent of the time and issue waivers only to currently participating RHCs.

• Section 491.11 Quality assessment and performance improvement (QAPI).

We are revising this section to replace the current QAPI conditions for certification for RHCs with our previous program evaluation condition for certification.

III. Provisions That Will Remain in Effect (Refer to Provisions Under December 2003 Final Rule)

[If you choose to comment on issues in this section, please include the caption ''Provisions that Will Remain in Effect'' at the beginning of your comments.]

Specific requirements under the BBA are either considered self-implementing or have been implemented and enforced through our program memoranda. These provisions will not be affected by this interim final rule with comment period and will remain in effect. These provisions are described below:

• Section 405.2462 Payment for Rural Health Clinic Services and Federally Qualified Health Clinic Services. *Hospital-Based RHCs Payment Limit.* The BBA provisions relating to the payment limit for hospital-based RHCs (section 4205(a) of the BBA, amending section 1833(f) of the Act) are not self-implementing but were implemented and enforced through a program memorandum in 1998.

• Section 491.3 RHC Procedures.

The provisions under paragraph (b)(1) of this section state that both ''participating'' RHCs and ''applicants'' must be located in a current shortage area, which is based on section 4205(d)(1) of the BBA, amending section 1861(aa)(2)(A) of the Act. Although the revision relating to RHC applicants was implemented in a memorandum to our regional offices on February 6, 1998, the enforcement of the 3-year provision on ''participating'' RHCs would have been implemented through the RHC final rule. This provision could not be properly enforced until the process and criteria for granting exceptions from RHC disqualification are in place. Consequently, the 3-year provision as it pertains to ''participating'' RHCs will not be enforced, and the public will have another opportunity to comment on this provision and the new regulatory policies established under the December 2003 final RHC rule. The provision relating to applicants will remain in effect.

• Section 491.8 Staffing and Staff Responsibilities.

At paragraph (a)(6) of this section, we made an update to reflect a previous legislative change (section 6213(a) of OBRA 1989 amended the staffing requirements for an RHC) to the amount of time non-physicians must be available to furnish services at the clinic and a technical correction to add ''certified nurse midwife'' to the list of health care providers that are available to furnish patient care at least 50 percent of the time that the RHC

operates. We clarified through manual instructions that the list of qualified RHC non-physician practitioners includes certified nurse midwives, but this clarification was never codified in regulations. The requirements under paragraph (d) of this section regarding waivers of RHC staffing requirements (BBA-related), which we consider self-implementing, were enforced through program memoranda.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Waiver of Proposed Rulemaking and Delayed Effective Date

[If you choose to comment on issues in this section, please include the caption ''Waiver'' at the beginning of your comments.]

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

We find it unnecessary to undertake proposed rulemaking because this interim final rule with comment period does not make new policy but simply reinstates policy previously in effect relating to RHCs. This policy was in effect before the December 2003 rule became effective and has been subjected to public comments. Moreover, because the 2003 rule was rendered ineffective by operation of law, we can exercise no discretion regarding this matter and must reinstate the regulation exactly as it existed before December 24, 2003. We intend to publish a new proposed rule for RHCs that will be subject to proposed rulemaking followed by a new final rule to reinstate our current RHC policy with any necessary changes.

Further, we believe a delayed effective date is unnecessary because this interim final rule with comment period provides additional clarification to the RHC industry. This rule clarifies that any RHC provisions that have already been implemented or enforced will remain in effect and will not be impacted by the regulatory provisions that we are revising in this interim final rule. Allowing this rule to take effect immediately provides needed guidance and avoids any additional confusion experienced following the publication of the December 2003 final rule. Therefore, we find good cause to waive notice-and-comment procedures, as well as the 30-day delay in effective date.

VI. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

VII. Regulatory Impact Statement

[If you choose to comment on issues in this section, please include the caption ''Regulatory Impact Statement'' at the beginning of your comments.]

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule because it suspends enforcement of RHC participation requirements.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined that this rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $120 million. This rule will have no consequential effect on the governments mentioned or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

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

List of Subjects

42 CFR Part 405

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

42 CFR Part 491

Grant programs—Health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements, and Rural areas.

■ For the reasons set forth in the preamble, the Centers for Medicare &

Medicaid services amends 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Subpart X—Rural Health Clinic and Federally Qualified Health Center Services

■ 1. The authority citation for part 405, continues to read as follows:

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

■ 2. In § 405.2401, in paragraph (b), revise the definition of ''rural health clinic'' to read as follows:

§ 405.2401 Scope and definitions.

* * * * *

(b) *Definitions.*

* * * * *

Rural health clinic means a facility that:

(1) Has been determined by the Secretary to meet the requirements of section 1861(aa)(2) of the Act and part 491 of this chapter; and

(2) Has filed an agreement with the Secretary in order to provide rural health clinic services under Medicare. (See § 405.2402.)

* * * * *

■ 3. Revise § 405.2410 to read as follows:

§ 405.2410 Application of Part B deductible and coinsurance.

(a) *Application of deductible.* (1) Medicare payment for rural health clinic services begins only after the beneficiary has incurred the deductible.

(2) Medicare payment for services covered under the Federally qualified health center benefit is not subject to the usual Part B deductible.

(b) *Application of coinsurance.* (1) The beneficiary is responsible for a coinsurance amount which cannot exceed 20 percent of the clinic's reasonable customary charge for the covered service; and

(2)(i) The beneficiary's deductible and coinsurance liability, with respect to any one item or service furnished by the rural health clinic, may not exceed a reasonable amount customarily charged by the clinic for that particular item or service.

(ii) For any one item or service furnished by a Federally qualified health center, the coinsurance liability may not exceed 20 percent of a reasonable amount customarily charged by the center for that particular item or service.

■ 4. Revise § 405.2462 to read as follows:

§ 405.2462 Payment for rural health clinic and Federally qualified health center services.

(a) *Payment to provider-based rural health clinics and Federally qualified health centers.* A rural health clinic or Federally qualified health center is paid in accordance with parts 405 and 413 of this subchapter, as applicable, if—

(1) The clinic or center is an integral and subordinate part of a hospital, skilled nursing facility or home health agency participating in Medicare (that is, a provider of services); and

(2) The clinic or center is operated with other departments of the provider under common licensure, governance and professional supervision.

(b) *Payment to independent rural health clinics and freestanding Federally qualified health centers.* (1) All other clinics and centers will be paid on the basis of an all-inclusive rate for each beneficiary visit for covered services. This rate will be determined by the intermediary, in accordance with this subpart and general instructions issued by CMS.

(2) The amount payable by the intermediary for a visit will be determined in accordance with paragraphs (b)(3) and (4) of this section.

(3) *Federally qualified health centers.* For Federally qualified health center visits, Medicare will pay 80 percent of the all-inclusive rate since no deductible is applicable to Federally qualified health center services.

(4) *Rural health clinics.* (i) If the deductible has been fully met by the beneficiary prior to the rural health clinic visit, Medicare pays 80 percent of the all-inclusive rate.

(ii) If the deductible has not been fully met by the beneficiary before the visit, and the amount of the clinic's reasonable customary charge for the services that is applied to the deductible is—

(A) Less than the all-inclusive rate, the amount applied to the deductible will be subtracted from the all-inclusive rate and 80 percent of the remainder, if any, will be paid to the clinic;

(B) Equal to or exceeds the all-inclusive rate, no payment will be made to the clinic.

(5) To receive payment, the clinic or center must follow the payment procedures specified in § 410.165 of this chapter.

(6) Payment for treatment of mental psychoneurotic or personality disorders is subject to the limitations on payment in § 410.155(c).

PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

■ 1. The authority citation for part 491 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302); and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

■ 2. Revise § 491.2 to read as follows:

§ 491.2 Definitions.

As used in this subpart, unless the context indicates otherwise:

Direct services means services provided by the clinic's staff.

FQHC means an entity as defined in § 405.2401(b).

Nurse practitioner means a registered professional nurse who is currently licensed to practice in the State, who meets the State's requirements governing the qualifications of nurse practitioners, and who meets one of the following conditions:

(1) Is currently certified as a primary care nurse practitioner by the American Nurses' Association or by the National Board of Pediatric Nurse Practitioners and Associates; or

(2) Has satisfactorily completed a formal 1 academic year educational program that:

(i) Prepares registered nurses to perform an expanded role in the delivery of primary care;

(ii) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and

(iii) Awards a degree, diploma, or certificate to persons who successfully complete the program; or

(3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements of paragraph (2) of this definition, and has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding the effective date of this subpart.

Physician means a doctor of medicine or osteopathy legally authorized to practice medicine or surgery in the State.

Physician assistant means a person who meets the applicable State requirements governing the qualifications for assistants to primary care physicians, and who meets at least one of the following conditions:

(1) Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians; or

(2) Has satisfactorily completed a program for preparing physician's assistants that:

(i) Was at least 1 academic year in length;

(ii) Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and

(iii) Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation; or

(3) Has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements of paragraph (2) of this definition and assisted primary care physicians for a total of 12 months during the 18-month period that ended on December 31, 1986.

Rural area means an area that is not delineated as an urbanized area by the Bureau of the Census.

Rural health clinic or clinic means a clinic that is located in a rural area designated as a shortage area, is not a rehabilitation agency or a facility primarily for the care and treatment of mental diseases, and meets all other requirements of this subpart.

Shortage area means a defined geographic area designated by the Department as having either a shortage of personal health services (under section 1302(7) of the Public Health Service Act) or a shortage of primary medical care manpower (under section 332 of that Act).

Secretary means the Secretary of Health and Human Services, or any official to whom he has delegated the pertinent authority.

■ 3. Revise § 491.3 as follows:

§ 491.3 Certification procedures.

A rural health clinic will be certified for participation in Medicare in accordance with subpart S of 42 CFR part 405. The Secretary will notify the State Medicaid agency whenever he has certified or denied certification under Medicare for a prospective rural health clinic in that State. A clinic certified under Medicare will be deemed to meet the standards for certification under Medicaid.

■ 4. In § 491.5, revise paragraphs (b) and (d) and add paragraphs (e) and (f) to read as follows:

§ 491.5 Location of clinic.

* * * * *

(b) *Exceptions.* (1) CMS does not disqualify an RHC approved under this subpart if the area in which it is located subsequently fails to meet the definition of a rural, shortage area.

(2) A private, nonprofit facility that meets all other conditions of this subpart except for location in a shortage area will be certified if, on July 1, 1977, it was operating in a rural area that is determined by the Secretary (on the basis of the ratio of primary care physicians to the general population) to have an insufficient supply of physicians to meet the needs of the area served.

(3) Determinations on these exceptions will be made by the Secretary upon application by the facility.

* * * * *

(d) *Criteria for designation of shortage areas.* (1) The criteria for determination of shortage of personal health services (under section 1302(7) of the Public Health Services Act), are:

(i) The ratio of primary care physicians practicing within the area to the resident population;

(ii) The infant mortality rate;

(iii) The percent of the population 65 years of age or older; and

(iv) The percent of the population with a family income below the poverty level.

(2) The criteria for determination of shortage of primary medical care manpower (under section 332(a)(1)(A) of the Public Health Services Act) are:

(i) The area served is a rational area for the delivery of primary medical care services;

(ii) The ratio of primary care physicians practicing within the area to the resident population; and

(iii) The primary medical care manpower in contiguous areas is overutilized, excessively distant, or inaccessible to the population in this area.

(e) *Medically underserved population.* A medically underserved population includes the following:

(1) A population of an urban or rural area that is designated by PHS as having a shortage of personal health services.

(2) A population group that is designated by PHS as having a shortage of personal health services.

(f) *Requirements specific to FQHCs.* An FQHC approved for participation in Medicare must meet one of the following criteria:

(1) Furnish services to a medically underserved population.

(2) Be located in a medically underserved area, as demonstrated by an application approved by PHS.

■ 5. Amend § 491.8 by—

■ A. Revising paragraph (a).

■ B. Removing paragraph (d).

The revisions read as follows:

§ 491.8 Staffing and staff responsibilities.

(a) *Staffing.* (1) The clinic or center has a health care staff that includes one or more physicians. Rural health clinic staffs must also include one or more physician's assistants or nurse practitioners.

(2) The physician member of the staff may be the owner of the rural health clinic, an employee of the clinic or center, or under agreement with the clinic or center to carry out the responsibilities required under this section.

(3) The physician assistant, nurse practitioner, nurse-midwife, clinical social worker, or clinical psychologist member of the staff may be the owner or an employee of the clinic or center, or may furnish services under contract to the center.

(4) The staff may also include ancillary personnel who are supervised by the professional staff.

(5) The staff is sufficient to provide the services essential to the operation of the clinic or center.

(6) A physician, nurse practitioner, physician assistant, nurse-midwife, clinical social worker, or clinical psychologist is available to furnish patient care services at all times the clinic or center operates. In addition, for rural health clinics, a nurse practitioner or a physician assistant is available to furnish patient care services at least 60 percent of the time the clinic operates.

* * * * *

■ 6. Revise § 491.11 to read as follows:

§ 491.11 Program evaluation.

(a) The clinic or center carries out, or arranges for, an annual evaluation of its total program.

(b) The evaluation includes review of:

(1) The utilization of clinic or center services, including at least the number of patients served and the volume of services;

(2) A representative sample of both active and closed clinical records; and

(3) The clinic's or center's health care policies.

(c) The purpose of the evaluation is to determine whether:

(1) The utilization of services was appropriate;

(2) The established policies were followed; and

(3) Any changes are needed.

(d) The clinic or center staff considers the findings of the evaluation and takes corrective action if necessary.

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

Dated: March 30, 2006.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: June 12, 2006.

Michael O. Leavitt,

Secretary.

[FR Doc. 06–7886 Filed 9–21–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 40

[Docket OST–2006–24112]

RIN 2105–AD57

Procedures for Transportation Workplace Drug and Alcohol Testing Programs: Corrections to the Federal Register

AGENCY: Office of the Secretary, DOT.

ACTION: Final rule; correction.

SUMMARY: The Department of Transportation published in the **Federal Register** of August 23, 2006, a final rule (effective September 22, 2006) which added state-licensed or certified marriage and family therapists to the list of credentialed professionals eligible to serve as substance abuse professionals under subpart O of 49 CFR part 40. The final rule also made a series of technical amendments to its drug and alcohol testing procedural rule. This notice corrects a misspelling in the final rule and adds text that was discussed in the preamble but omitted in the rule text.

DATES: This correction is effective September 22, 2006.

FOR FURTHER INFORMATION CONTACT: Bohdan Baczara, Office of Drug and Alcohol Policy and Compliance, 400 Seventh Street, SW., Washington, DC 20590; 202–366–3784 (voice), 202–366–3897 (fax), or *bohdan.baczara@dot.gov* (e-mail).

SUPPLEMENTARY INFORMATION: The Office of Drug & Alcohol Policy & Compliance published a final rule in the **Federal Register** (71 FR 49382). In this rule, there was a typographical error and an omission of text. This notice will correct these oversights.

■ In rule FR Doc. E6–13956 published on August 23, 2006 (71 FR 49382) make the following corrections.

§ 40.3 [Corrected]

■ 1. On page 49384, in the second column, third line, replace the word ''Material'' with ''Materials''.

§ 40.281 [Corrected]

■ 2. On page 49384, in the third column, add a new instruction 10a following the amendment to § 40.281 to read as follows:

■ ''10a. Section 40.281 is further amended in the introductory text after the word 'drug' by adding the text 'and alcohol'.''

Dated: September 14, 2006.

Jim L. Swart,

Acting Director, Office of Drug and Alcohol Policy and Compliance, United States Department of Transportation.

[FR Doc. E6–15617 Filed 9–21–06; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 060216045–6045–01; I.D. 091806A]

Fisheries of the Exclusive Economic Zone Off Alaska; Adjustment of Pacific Cod Total Allowable Catch Amount in the Bering Sea and Aleutian Islands

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

ACTION: Temporary rule; inseason adjustment; request for comments.

SUMMARY: NMFS is adjusting the 2006 Pacific cod total allowable catch (TAC) amount in the Bering Sea and Aleutian Islands Management Area (BSAI). This action is necessary to allow harvest of Pacific cod that will not be harvested under the State of Alaska's guideline harvest level (GHL) for the Aleutian Islands subarea state waters Pacific cod fishery. This action is consistent with the goals and objectives of the Fishery Management Plan for Groundfish of the BSAI (FMP).

DATES: Effective September 19, 2006, through 2400 hrs, Alaska local time (A.l.t.), December 31, 2007.

Comments must be received at the following address no later than 4:30 p.m., A.l.t., October 4, 2006.

ADDRESSES: Send comments to Sue Salveson, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region, NMFS, Attn: Ellen Walsh. Comments may be submitted by:

- Mail to: P.O. Box 21668, Juneau, AK 99802;
- Hand delivery to the Federal Building, 709 West 9th Street, Room 420A, Juneau, Alaska;
- FAX to 907–586–7557;
- E-mail to *statepcodrelb@noaa.gov* and include in the subject line of the e-mail comment the document identifier: statepcodrelb (E-mail comments, with or without attachments, are limited to 5 megabytes); or
- Webform at the Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions at that site for submitting comments.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI according to the FMP prepared by the North Pacific Fishery Management Council (Council) under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2006 and 2007 final harvest specifications for groundfish in the BSAI (71 FR 10894, March 3, 2006) established the 2006 and 2007 Pacific cod acceptable biological catches (ABC) as 194,000 metric tons (mt) and 148,000 mt, respectively. The TACs were set equal to the ABCs for Pacific cod in the BSAI. On March 14, 2006, NMFS reduced the Pacific cod TAC in the BSAI after the Alaska Department of Fish and Game (ADF&G) announced by emergency regulation a Pacific cod GHL, west of 170 degrees west longitude in the Aleutian Islands subarea, equal to three percent of the Pacific cod ABC in the BSAI (71 FR 13777, March 17, 2006).

On August 28, 2006, ADF&G announced the closure of the 2006 state waters Pacific cod fishery, west of 170 degrees west longitude in the Aleutian Islands subarea, effective 11:59 a.m. A.l.t., September 1, 2006. As of September 1, 2006, the Administrator, Alaska Region, NMFS, (Regional Administrator) has determined that ADF&G is making available 1,588 mt of unharvested Pacific cod from the Aleutian Islands state waters Pacific cod fishery to the federal Pacific cod fisheries. As a result, the Regional Administrator has determined, using the best scientific information available, that the current 2006 TAC is incorrectly specified because the transfer of unharvested state waters GHL in the Aleutian Islands subarea to the federally managed fisheries requires an increase to the 2006 TAC of Pacific cod in the BSAI. This action will not exceed the