

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 whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2010, that threshold is approximately \$135 million. This rule will not have consequential effect on State, local, or tribal governments 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 Executive Order 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 in 42 CFR Part 447**

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, 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 447—PAYMENT FOR SERVICES**

■ 1. The authority citation for part 447 continues to read as follows:

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

**Subpart I—Payment for Drugs**

■ 2. Section 447.502 is amended by removing the definition of “multiple source drug.”

**§ 447.504 [Removed and reserved]**

■ 3. Section 447.504 is removed and reserved.

■ 4. Section 447.510 is amended by—

- A. Republishing paragraph (a) introductory text.
- B. Revising paragraphs (a)(1), (c)(2)(i), and (d)(2).

The revisions read as follows:

**§ 447.510 Requirements for manufacturers.**

(a) *Quarterly reports.* A manufacturer must report product and pricing

information for covered outpatient drugs to CMS not later than 30 days after the end of the rebate period. The quarterly pricing report must include:

(1) AMP, calculated in accordance with section 1927(k)(1) of the Social Security Act.

\* \* \* \* \*

(c) \* \* \*

(2) \* \* \*

(i) A manufacturer’s recalculation of the base date AMP must only reflect the revisions to AMP as provided for in section 1927(k)(1) of the Social Security Act.

\* \* \* \* \*

(d) \* \* \*

(2) *Calculation of monthly AMP.* Monthly AMP should be calculated based on section 1927(k)(1) of the Social Security Act, except the period covered should be based on monthly, as opposed to quarterly AMP sales.

\* \* \* \* \*

- 5. Section 447.512 is amended by—
  - A. Removing and reserving paragraph (a).
  - B. Revising the introductory text of paragraph (b).
  - C. Revising paragraph (c).
- The revisions read as follows:

**§ 447.512 Drugs: Aggregate upper limits of payment.**

(a) [Reserved]

(b) *Other drugs.* The agency payments for brand name drugs certified in accordance with paragraph (c) of this section and drugs other than multiple source drugs for which a specific limit has been established must not exceed, in the aggregate, payments levels that the agency has determined by applying the lower of the—

\* \* \* \* \*

(c) *Certification of brand name drugs.*

(1) The upper limit for payment for multiple source drugs for which a specific limit has been established does not apply if a physician certifies in his or her own handwriting (or by an electronic alternative means approved by the Secretary) that a specific brand is medically necessary for a particular recipient.

(2) The agency must decide what certification form and procedure are used.

(3) A check-off box on a form is not acceptable but a notation like “brand necessary” is allowable.

(4) The agency may allow providers to keep the certification forms if the forms will be available for inspection by the agency or HHS.

**§ 447.514 [Removed and reserved]**

■ 6. Section 447.514 is removed and reserved.

■ 7. Section 447.518 is amended by revising paragraphs (b)(1)(i) and (b)(2) to read as follows:

**§ 447.518 State plan requirements, findings and assurances.**

\* \* \* \* \*

(b) \* \* \*

(1) \* \* \*

(i) In the aggregate, its Medicaid expenditures for multiple source drugs are in accordance with the established upper limits.

\* \* \* \* \*

(2) *Assurances.* The agency must make assurances satisfactory to CMS that the requirements set forth in § 447.512 of this subpart concerning upper limits and in paragraph (b)(1) of this section concerning agency findings are met.

\* \* \* \* \*

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

Dated: October 20, 2010.

**Donald M. Berwick,**  
*Administrator, Centers for Medicare & Medicaid Services.*

Approved: November 3, 2010.

**Kathleen Sebelius,**  
*Secretary.*

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**DEPARTMENT OF COMMERCE**

**National Oceanic and Atmospheric Administration**

**50 CFR Part 679**

[Docket No. 0910131363–0087–02]

**RIN 0648–XA038**

**Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod in the Bering Sea and Aleutian Islands Management Area**

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

**ACTION:** Temporary rule; closure.

**SUMMARY:** NMFS is prohibiting retention of Pacific cod in the Bering Sea and Aleutian Islands Management Area (BSAI) by vessels participating in the Amendment 80 limited access fisheries. This action is necessary to prevent exceeding the 2010 total allowable catch (TAC) of Pacific cod in the BSAI.

**DATES:** Effective 1200 hrs, Alaska local time (A.l.t.), November 9, 2010, through 2400 hrs, A.l.t., December 31, 2010.

**FOR FURTHER INFORMATION CONTACT:**

Steve Whitney, 907-586-7269.

**SUPPLEMENTARY INFORMATION:**

NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management 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 2010 Pacific cod TAC allocated to the Amendment 80 limited access sector in the BSAI is 3,319 metric tons as established by the final 2010 and 2011 harvest specifications for groundfish in the BSAI (75 FR 11778, March 12, 2010).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2010 TAC of Pacific cod in the BSAI allocated to the Amendment 80 limited access sector has been reached. Therefore, in accordance with § 679.21(b), NMFS is requiring that Pacific cod caught in the BSAI be treated as prohibited species by vessels participating in the Amendment 80 limited access fisheries.

**Classification**

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay prohibiting the retention of Pacific cod by Amendment 80 limited access vessels in the BSAI. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of November 8, 2010.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and § 679.21 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 9, 2010.

**Brian Parker,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 2010-28672 Filed 11-9-10; 4:15 pm]

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**DEPARTMENT OF COMMERCE****National Oceanic and Atmospheric Administration****50 CFR Part 679**

[Docket No. 0910131363-0087-02]

**RIN 0648-XA032**

**Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Ocean Perch by Vessels in the Amendment 80 Limited Access Fishery in the Central Aleutian District of the Bering Sea and Aleutian Islands Management Area**

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

**ACTION:** Temporary rule; closure.

**SUMMARY:** NMFS is prohibiting directed fishing for Pacific ocean perch by vessels participating in the Amendment 80 limited access fishery in the Central Aleutian District of the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the 2010 Pacific ocean perch total allowable catch specified for vessels participating in the Amendment 80 limited access fishery in the Central Aleutian District of the BSAI.

**DATES:** Effective 1200 hrs, Alaska local time (A.l.t.), November 10, 2010, through 2400 hrs, A.l.t., December 31, 2010.

**FOR FURTHER INFORMATION CONTACT:**

Steve Whitney, 907-586-7269.

**SUPPLEMENTARY INFORMATION:** NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management 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 2010 Pacific ocean perch TAC specified for vessels participating in the Amendment 80 limited access fishery in

the Central Aleutian District of the BSAI is 1,796 metric tons (mt) as established by the final 2010 and 2011 harvest specifications for groundfish in the BSAI (75 FR 11778, March 12, 2010).

In accordance with § 679.20(d)(1)(i), the Regional Administrator has determined that the 2010 Pacific ocean perch TAC specified for vessels participating in the Amendment 80 limited access fishery in the Central Aleutian District of the BSAI will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 1,786 mt and is setting aside the remaining 10 mt as incidental catch to support other groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific ocean perch by vessels participating in the Amendment 80 limited access fishery in the Central Aleutian District of the BSAI.

After the effective date of this closure the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

**Classification**

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA, (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of Pacific ocean perch by vessels participating in the Amendment 80 limited access fishery in the Central Aleutian District of the BSAI. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of November 8, 2010.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

**Authority:** 16 U.S.C. 1801 *et seq.*