

bioequivalent drugs is unavailable. However, such reporting would clearly be in their interest. 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 the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals. Small rural hospitals would be affected only to the extent that no FDA-approved, therapeutically and bioequivalent drug is available in that State for a particular outpatient drug provided through their outpatient pharmacies. As discussed above for pharmacies, States may choose to change reimbursement for drugs that are not multiple source drugs within the State, but this change is expected to increase reimbursement.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending on State, local, or tribal governments in the aggregate, or by the private sector, in any 1 year of \$100 million in 1995, updated annually for inflation. In 2008, that threshold is approximately \$130 million. This final rule does not contain any mandates that will impose spending costs on State, local, or tribal governments in the aggregate, or by the private sector, of \$130 million.

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. This regulation will impose only a very small burden, if any, on States. When a pharmacy has notified a State that a drug on the CMS FUL list may not be available as a multiple source drug in that State, the State should determine whether the pharmacy's assertion of lack of general availability in the State is valid. The State, however, has no obligation to make an independent assessment of drug availability in the absence of such notification by a pharmacy. This final rule will only revise payment rates in those rare cases

in which a particular FDA-approved therapeutically, pharmaceutically, and bioequivalent drug is not generally available to the public through retail pharmacies in a particular State and, as a result, only one therapeutically, and bioequivalent drug product is generally available to the public through those pharmacies. In this circumstance, a State would need to confirm the information received from its pharmacies regarding drug availability. This would impose only a small burden on States. State systems are designed to allow for payment changes as a routine matter and to change the composition of the FUL groups or delete FUL groups. Since this regulation does not impose any significant 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 Sections 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, is confirming the interim rule published on March 14, 2008 (73 FR 13785) as final with the following changes:

PART 447—PAYMENTS 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).

■ 2. Section 447.502 the definition of “Multiple source drug” is amended by revising paragraph (3)(i) to read as follows:

§ 447.502 Definitions.

* * * * *

Multiple source drug * * *

* * * * *

(3) * * *

(i) A drug product is considered sold or marketed in a State if it appears in a published national listing of average wholesale prices, selected by the Secretary, provided that the listed product is generally available to the public through retail pharmacies in that State.

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

Dated: August 20, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: August 21, 2008.

Michael O. Leavitt,

Secretary.

[FR Doc. E8–23653 Filed 10–6–08; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 070817467–8554–02]

RIN 0648–XK82

Magnuson-Stevens Fishery Conservation and Management Act Provisions; Fisheries of the Northeastern United States; Atlantic Sea Scallop Fishery; Closure of the Limited Access General Category Scallop Fishery to Individual Fishing Quota Scallop Vessels

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS announces that the Limited Access General Category (LAGC) Scallop Fishery will close to individual fishing quota (IFQ) scallop vessels until it re-opens on December 1, 2008, under current regulations. This action is based on the determination that the third quarter scallop total allowable catch (TAC) for LAGC IFQ scallop vessels (including vessels issued an IFQ letter of authorization (LOA) to fish under appeal), is projected to be landed. This action is being taken to prevent IFQ scallop vessels from exceeding the 2008 third quarter TAC, in accordance with the regulations implementing Amendment 11 to the Atlantic Sea Scallop Fishery Management Plan (FMP), enacted by Framework 19 to the FMP, and the Magnuson-Stevens Fishery Conservation and Management Act.

DATES: The closure of the LAGC fishery to all IFQ scallop vessels is effective 0001 hr local time, October 5, 2008, through November 30, 2008.

FOR FURTHER INFORMATION CONTACT: Christopher Biegel, Fishery Management Specialist, (978) 281–9112, fax (978) 281–9135.

SUPPLEMENTARY INFORMATION: Regulations governing fishing activity in

the LAGC fishery are found at §§ 648.59 and 648.60. Regulations specifically governing IFQ scallop vessel operations in the LAGC fishery are specified at § 648.53(a)(8)(iii). These regulations authorize vessels issued a valid IFQ scallop permit to fish in the LAGC fishery under specific conditions, including a TAC. The TACs were established by the final rule that implemented Framework 19 to the FMP (73 FR 30790 May 29, 2008) and included a TAC of 623,747 lb (282,927 kg) that may be landed by IFQ vessels during the third quarter of the 2008 fishing year. The regulations at § 648.53(a)(8)(iii) require the LAGC fishery to be closed to IFQ vessels once the Northeast Regional Administrator has determined that the TAC is projected to be landed.

Based on dealer reporting and vessel pre-landing reports through Vessel Monitoring Systems (VMS), a projection concluded that, given current activity levels by IFQ scallop vessels in the area, 623,747 lb (282,927 kg) will have been landed on October 4, 2008. Therefore, in accordance with the regulations at § 648.53(a)(8)(iii), the LAGC scallop fishery is closed to all general IFQ vessels as of 0001 hr local time, October 5, 2008. IFQ scallop vessels are not allowed to fish for, possess, or retain scallops, or declare, or initiate, a scallop trip following this closure for the remainder of the 2008 third quarter, ending on November 30, 2008. This closure is in effect for the remainder of the third quarter of the 2008 scallop fishing year under current regulations. The LAGC scallop fishery is scheduled to re-open to IFQ scallop vessels on December 1, 2008.

Classification

This action is required by 50 CFR part 648 and is exempt from review under Executive Order 12866.

This action closes the LAGC scallop fishery to all IFQ scallop vessels until December 1, 2008, under current regulations. The regulations at § 648.53(a)(8)(iii) require such action to ensure that IFQ scallop vessels do not exceed the 2008 third quarter TAC. The LAGC scallop fishery opened for the third quarter of the 2008 fishing year at 0001 hours on September 1, 2008. Data indicating the IFQ scallop fleet has landed all of the 2008 third quarter TAC have only recently become available. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause pursuant to 5 U.S.C. 553(b)(B) to waive prior notice and the opportunity for public comment because it would be contrary to the public interest. If

implementation of this closure is delayed to solicit prior public comment, the quota for this quarter will be exceeded, thereby undermining the conservation objectives of the FMP. Also, if the magnitude of any overage is significant, it would warrant a decrease in the fourth quarter quota. This would have a negative economic impact on vessels that fish seasonally in that period. The AA further finds, pursuant to 5 U.S.C. 553(d)(3), good cause to waive the thirty (30) day delayed effectiveness period for the reasons stated above.

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

Dated: October 2, 2008.

Emily H. Menashes,

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

[FR Doc. E8-23708 Filed 10-2-08; 4:15 pm]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 010319075-1217-02]

RIN 0648-XK42

Magnuson-Stevens Fishery Conservation and Management Act Provisions; Fisheries of the Northeastern United States; Tilefish Fishery

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

ACTION: Temporary rule, tilefish commercial quota adjustment.

SUMMARY: NMFS announces that the Administrator, Northeast Region, NMFS (Regional Administrator), has determined that the quota for the tilefish Full-time Tier 2 permit category has been exceeded for fishing year (FY) 2008, requiring an adjustment of the Full-time Tier 2 permit category quota for FY 2009. This action complies with the Fishery Management Plan for the Tilefish Fishery (FMP) and is intended to continue the rebuilding program in the FMP by taking into account previous overages of the tilefish quota.

DATES: Effective November 1, 2008, through October 31, 2009.

FOR FURTHER INFORMATION CONTACT: Timothy A. Cardiasmenos, Fishery Policy Analyst, (978) 281-9204.

SUPPLEMENTARY INFORMATION:

Background

The regulations at 50 CFR 648.290(c) state that any overages of the quota for any tilefish limited access category that occur in a given fishing year will be subtracted from the quota for that category in the following fishing year. This same section also states that, if the tilefish harvest attributed to the open access Incidental permit category exceeds 5 percent of the total allowable landings (TAL) for a given fishing year, the trip limit for the Incidental category may be reduced the following year. In both of these instances, § 648.290(c) specifies that, if an adjustment is required, a notification of adjustment of the quota will be published in the **Federal Register**.

The tilefish TAL for FY 2009 remains unchanged from previous years at 1.995 million lb (905 mt). The FMP dictates that the TAL be divided between the three limited access tilefish permit categories after the TAL is reduced by 5 percent to account for incidental tilefish landings (open-access Incidental permit category) as follows: Sixty-six percent (1,250,865 lb (567,383 kg)) to Full-time Tier 1; 15 percent (284,288 lb (128,951 kg)) to Full-time Tier 2; and 19 percent (360,098 lb (163,338 kg)) to Part-time vessels.

Based upon vessel reports and other information available, FY 2008 tilefish landings for limited access Full-time Tier 2 permit category were 291,620 lb (132,277 kg), resulting in an overage of 7,332 lb (3,326 kg). This overage amount is being deducted from the FY 2009 Full-time Tier 2 permit category quota through this action, which results in an adjusted quota of 276,956 lb (125,625 kg) for this category in FY 2009. Adjustments to the remaining permit categories are not needed at this time, and the FY 2009 quotas for these categories therefore, remain status quo, including the Incidental trip limit for tilefish for FY 2009, which will remain at its default value of 300 lb (136 kg). If final landings data for 2008 indicate that an adjustment of the quota for any of the other permit categories is necessary, a notification of the adjustment will be published in the **Federal Register**.

The FY 2009 tilefish Full-time Tier 2 permit category quota, the FY 2008 tilefish Full-time Tier 2 permit category landings, and the resulting overage of the FY 2008 tilefish Full-time Tier 2 permit category quota are presented in Table 1. The resulting adjusted FY 2009 tilefish Full-time Tier 2 permit category commercial quota is presented in Table 2.