immediately follow the subheading: ''[Bullet] side effects occur. You may report side effects to FDA at 1–800–FDA–1088.'' The telephone number must appear in a minimum 6–point bold letter height or type size.

* * * * *

PART 208—MEDICATION GUIDES FOR PRESCRIPTION DRUG PRODUCTS

■ 3. The authority citation for 21 CFR part 208 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360, 371, 374; 42 U.S.C. 262.

■ 4. Amend § 208.20 by adding paragraph (b)(7)(iii) to read as follows:

§ 208.20 Content and format of a Medication Guide.

* * * * *

(b) * * *

(7) * * *

(iii) For drug products approved under section 505 of the act, the following verbatim statement: ''Call your doctor for medical advice about side effects. You may report side effects to FDA at 1–800–FDA–1088.''

* * * * *

■ 5. Add part 209 to read as follows:

PART 209—REQUIREMENT FOR AUTHORIZED DISPENSERS AND PHARMACIES TO DISTRIBUTE A SIDE EFFECTS STATEMENT

Subpart A—General Provisions

Subpart B—Requirements

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 371; 42 U.S.C. 241.

Subpart A—General Provisions

§ 209.1 Scope and purpose.

(a) This part sets forth requirements for human prescription drug products approved under section 505 of the Federal Food, Drug, and Cosmetic Act and dispensed by authorized dispensers and pharmacies to consumers. This part requires distribution of a side effects statement and applies to new and refill prescriptions. This part is not intended to apply to authorized dispensers dispensing or administering prescription drug products to inpatients in a hospital or health care facility under an order of a licensed practitioner, or as part of supervised home health care.

(b) The purpose of providing the side effects statement is to enable consumers to report side effects of prescription drug products to FDA.

§ 209.2 Definitions.

For the purposes of this part, the following definitions apply:

Act means the Federal Food, Drug, and Cosmetic Act (sections 201–907 (21 U.S.C. 301–397)).

Authorized dispenser means an individual licensed, registered, or otherwise permitted by the jurisdiction in which the individual practices to provide drug products on prescription in the course of professional practice.

Consumer medication information means written information voluntarily provided to consumers by dispensing pharmacists as part of patient medication counseling activities.

Medication Guide means FDA-approved patient labeling conforming to the specifications set forth in part 208 of this chapter and other applicable regulations.

Pharmacy includes, but is not limited to, a retail, mail order, Internet, hospital, university, or clinic pharmacy, or a public health agency, regularly and lawfully engaged in dispensing prescription drugs.

Side effects statement means the following verbatim statement: ''Call your doctor for medical advice about side effects. You may report side effects to FDA at 1–800–FDA–1088.''

Subpart B—Requirements

§ 209.10 Content and format of the side effects statement.

(a) *Content.* The side effects statement provided with each prescription drug product approved under section 505 of the act must read: ''Call your doctor for medical advice about side effects. You may report side effects to FDA at 1–800–FDA–1088.''

(b) *Format.* The side effects statement must be in a single, clear, easy-to-read type style. The letter height or type size used for the side effects statement in accordance with paragraphs (b)(1) and (b)(2) of § 209.11 must be no smaller than 6 points (1 point = 0.0138 inch). The letter height or type size for the side effects statement under paragraphs (b)(3), (b)(4), and (b)(5) of § 209.11 must be no smaller than 10 points.

§ 209.11 Dispensing and distributing the side effects statement.

(a) Each authorized dispenser or pharmacy must distribute the side effects statement with each prescription drug product approved under section 505 of the act and dispensed. The side effects statement must be distributed with new and refill prescriptions.

(b) An authorized dispenser or pharmacy must choose one or more of the following options to distribute the side effects statement:

(1) Distribute the side effects statement on a sticker attached to the unit package, vial, or container of the drug product;

(2) Distribute the side effects statement on a preprinted pharmacy prescription vial cap;

(3) Distribute the side effects statement on a separate sheet of paper;

(4) Distribute the side effects statement in consumer medication information; or

(5) Distribute the appropriate FDA-approved Medication Guide that contains the side effects statement.

Dated: December 21, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–25426 Filed 1–2–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS–1385–F2]

RIN 0938–AO65

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Delay of the Date of Applicability of the Revised Anti-Markup Provisions for Certain Services Furnished in Certain Locations (§ 414.50)

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

ACTION: Final rule.

SUMMARY: This final rule delays until January 1, 2009 the applicability of the anti-markup provisions in § 414.50, as revised at 72 FR 66222, except with respect to the technical component of a purchased diagnostic test and with respect to any anatomic pathology diagnostic testing services furnished in space that: Is utilized by a physician group practice as a ''centralized building'' (as defined at § 411.351 of this chapter) for purposes of complying with the physician self-referral rules; and does not qualify as a ''same building'' under § 411.355(b)(2)(i) of this chapter.

DATES: The provisions of this final rule are effective January 1, 2008. However,

the date of applicability of the provisions of § 414.50, as revised at 72 FR 66222, with respect to certain services furnished in certain locations, as described herein, are delayed until January 1, 2009.

FOR FURTHER INFORMATION CONTACT: Donald Romano, (410) 786–1401.

SUPPLEMENTARY INFORMATION:

I. Background

The final rule with comment period, entitled ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions,'' that appeared in the November 27, 2007 **Federal Register** (72 FR 66222), amended the anti-markup provisions for certain diagnostic tests in § 414.50.

II. Provisions of the Final Regulations

As amended, the anti-markup provisions in § 414.50 will apply to the technical and professional components of diagnostic tests covered under section 1861(s)(3) of the Social Security Act (the Act) and paid for under part 414 (other than clinical diagnostic laboratory tests paid under section 1833(a)(2)(D) of the Act, which are subject to the special billing rules set forth in section 1833(h)(5)(A) of the Act). If a physician or other supplier bills for the technical component or professional component of a diagnostic test that was ordered by the physician or other supplier (or ordered by a party related to such physician or other supplier through common ownership or control) and the diagnostic test is either purchased from an outside supplier or performed at a site other than the office of the billing physician or other supplier, the payment to the billing physician or other supplier (less the applicable deductibles and coinsurance paid by the beneficiary or on behalf of the beneficiary) for the technical component or professional component of the diagnostic test may not exceed the lowest of the following amounts:

- The performing supplier's net charge to the billing physician or other supplier.
- The billing physician or other supplier's actual charge.
- The fee schedule amount for the test that would be allowed if the performing supplier billed directly.

In revised § 414.50(a)(2)(iii), we define the ''office of the billing physician or other supplier'' as medical office space where the physician or other supplier regularly furnishes patient care. With respect to a billing physician or other supplier that is a physician organization (as defined at § 411.351 of this chapter), the ''office of the billing physician or other supplier'' is space in which the physician organization provides substantially the full range of patient care services that the physician organization provides generally.

Subsequent to the publication of the final rule with comment period, we received informal comments from various stakeholders who allege that the application of the rule is unclear with respect to whether certain types of space arrangements meet the definition of the ''office of the billing physician or other supplier.'' Further, some of these stakeholders assert that patient access may be significantly disrupted due to the alleged inability of physician groups to render services in a cost-effective manner if medical office space that satisfies the ''same building'' test in § 411.355(b)(2)(i) of this chapter for purposes of the physician self-referral rules in Part 411, Subpart J of this chapter and other medical office space in which patients are seen and that complies with the physician self-referral rules are subject to the anti-markup provisions in revised § 414.50. That is, physician groups allege that, in situations in which they are subject to the anti-markup provisions and are limited to billing Medicare for the amount of the net charge imposed by the performing supplier, because they will not be able to realize a profit and will not be able to recoup their overhead costs, they will not be able to continue to provide diagnostic testing services to the same extent that they are currently providing such services.

We are concerned that the definition of ''office of the billing physician or other supplier'' may not be entirely clear and could have unintended consequences. Accordingly, in order for us to study the issues further, we are delaying until January 1, 2009, the applicability of the revised anti-markup provisions in § 414.50, except for anatomic pathology diagnostic testing services furnished in space that: (1) Is utilized by a physician group practice as a ''centralized building'' (as defined at § 411.351 of this chapter) for purposes of complying with the physician self-referral rules; and (2) does not qualify as a ''same building'' under § 411.355(b)(2)(i) of this chapter. During the next 12 months, we plan to issue clarifying guidance as to what constitutes the ''office of the billing physician or other supplier'' or propose additional rulemaking, or both. Because anatomic pathology diagnostic testing arrangements precipitated our proposal for revision of the anti-markup provisions and remain our core concern, we are not delaying the date of applicability with respect to anatomic pathology diagnostic testing services furnished in space that: (1) Is utilized by a physician group practice as a ''centralized building'' (as defined at § 411.351 of this chapter) for purposes of complying with the physician self-referral rules; and (2) does not qualify as a ''same building'' under § 411.355(b)(2)(i) of this chapter. In addition, we are not delaying the applicability of the revised anti-markup rule with respect to the technical component of any purchased diagnostic test. The anti-markup prohibition with respect to the technical component of purchased diagnostic tests is longstanding and was incorporated into the expanded and revised provision of § 414.50. Accordingly, it will remain applicable to the technical component of any purchased diagnostic test.

III. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking and invite public comment on the proposed rule. The notice and comment rulemaking procedure is not required, however, if the rule is interpretive or procedural in nature, and it may be waived if there is good cause that it is impracticable, unnecessary, or contrary to the public interest and we incorporate in the rule a statement of such a finding and the reasons supporting that finding. Likewise, we ordinarily provide for a delayed effective date of a final rule, but we are not required to do so if the rule is procedural or interpretive. Where a delayed effective date is required, this requirement may be waived for good cause. We set forth below our finding of good cause for the waiver of notice and comment rulemaking and the waiver of a delayed effective date.

Our implementation of this action without opportunity for public comment and without a delayed effective date is based on the good cause exceptions in 5 U.S.C. 553(b)(3)(B) and (d), respectively. We find that seeking public comment on this action is impracticable and contrary to the public interest. We are implementing this delay of effective date as a result of our review of the informal comments on the final rule with comment period from various stakeholders. As discussed above, we understand from those comments that patient access for common diagnostic tests may be significantly disrupted

unless we delay the effective date of revised § 414.50 with respect to anatomic pathology diagnostic testing services furnished in space that: (1) Is utilized by a physician group practice as a ''centralized building'' (as defined at § 411.351 of this chapter) for purposes of complying with the physician self-referral rules; and (2) does not qualify as a ''same building'' under § 411.355(b)(2)(i) of this chapter. Likewise, if we do not make this final rule effective upon publication, patient care may be significantly disrupted during the interim period between the issuance of the rule and a delayed effective date.

IV. 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 (44 U.S.C. 35).

V. Regulatory Impact Statement

We do not believe that this delay in the date of applicability will result in any significant economic impact on any small entity. Until January 1, 2009, the majority of billing suppliers affected by the revised § 414.50 do not have to comply with the revised requirements in § 414.50.

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

Dated: December 18, 2007.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: December 27, 2007.

Michael O. Leavitt,

Secretary.

[FR Doc. 07–6280 Filed 12–28–07; 1:17 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 600 and 622

[Docket No. 070518142–7238–02]

RIN 0648–AV45

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Gulf of Mexico Vermilion Snapper Fishery Management Measures

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

ACTION: Final rule.

SUMMARY: NMFS issues this final rule to implement a regulatory amendment to the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (FMP) prepared by the Gulf of Mexico Fishery Management Council (Council). This final rule reduces the minimum size limit for vermilion snapper to 10 inches (25.4 cm) total length (TL), eliminates the 10–fish recreational bag limit for vermilion snapper within the existing 20–fish aggregate reef fish bag limit, and eliminates the 40-day commercial closed season for vermilion snapper (from April 22 through May 31 each year). NMFS is also implementing through this rule clarifications for the Gulf of Mexico red snapper individual fishing quota (IFQ) program, as well as non-substantive changes to codified text, including removing obsolete language regarding the use of fish traps in the Gulf of Mexico, removing outdated and redundant language, revising phone numbers and an outdated definition, and revising incorrect references. The intended effects of this final rule are to help achieve optimum yield (OY) by reducing vermilion snapper harvest limitations consistent with the findings of the recent stock assessment and to clarify and update existing regulations.

DATES: This rule is effective February 4, 2008, except for the amendments to§ 622.16(c)(3)(i) and (ii) which are effective January 3, 2008 and the amendment to § 622.39(b)(1)(x) which is effective February 4, 2008 through March 28, 2008.

ADDRESSES: Copies of the final regulatory flexibility analysis (FRFA) may be obtained from Sarah DeVido, NMFS, Southeast Regional Office, 263 13th Avenue South, St. Petersburg, FL 33701; telephone 727–824–5305; fax 727–824–5308; email *sarah.devido@noaa.gov*.

FOR FURTHER INFORMATION CONTACT: Sarah DeVido, telephone 727–824–5305; fax 727–824–5308; e-mail *sarah.devido@noaa.gov*.

SUPPLEMENTARY INFORMATION: The reef fish fishery of the Gulf of Mexico is managed under the FMP. The FMP was prepared by the Council and is implemented through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

In accordance with the FMP's framework procedure, the Council recommended, and NMFS published, a proposed rule to implement the regulatory amendment and requested public comment through May 14, 2007 (72 FR 20980, April 27, 2007). The rationale for the measures contained in the regulatory amendment, is provided in the preamble to the proposed rule and the responses to comment below and is not repeated here. A summary of the public comments received by NMFS on the proposed rule and NMFS' responses are provided below.

Comments and Responses

A total of 83 individuals submitted comments during the comment period on the proposed rule to reduce the size limit, relax the recreational bag limit, and remove a commercial closure. Of these, 68 of the commenters expressed support for one, two or all three of the proposed actions, and did not express any specific objections. The remaining 15 commenters opposed one or more of the proposed actions.

Comment 1: The regulations for vermilion snapper should remain as they are. Of special concern is the proposal to remove the 10–fish bag limit restriction. Such an action is not in line with a conservation-oriented approach to recreational fishing. The upcoming reductions in bag limits for red snapper and gray triggerfish may cause an effort shift to vermilion snapper, which could lead to increased harvests of this species. Optimistic assumptions regarding current low fishing mortality should not be relied upon. Effort shifts could substantially increase fishing mortality, and the regulations would have to be revised to ensure the vermilion snapper stock does not become overfished or undergo overfishing.

Response: Fishery stocks should be managed conservatively, with a goal of achieving optimum yield (OY) from the fishery. The 2006 stock assessment for vermilion snapper incorporated new