

American Psychiatric Association

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MAY 4 2006

April 25, 2006

Mark B. McClellan, M.D., Ph.D., Administrator
Centers for Medicare & Medicaid Services, Room C5-25-25
Department of Health and Human Services
CMS-6272-IFC
P.O. Box 8017
Baltimore, MD 21244-8017

**RE: CMS Interim Final Rule: "Medicare Secondary Payer Amendments"
CMS-6272-IFC**

Dear Administrator McClellan:

The American Psychiatric Association (APA), the national medical specialty society representing more than 37,000 psychiatric physicians, appreciates the opportunity to submit these comments concerning Medicare Secondary Payer Amendments. This was published in the Federal Register on February 24, 2006, with the title, "Medicare Secondary Payer Amendments."¹

APA is concerned with two primary issues. One is that CMS is not providing a full regulatory process for these regulatory amendments. The other is a presumably unintended consequence of CMS' construction of regulatory amendments. That is, the potential that they could be construed in a manner that may allow Medicare beneficiaries as individuals and via businesses, through which they retain personal liability, to fall within the definition of a self-insured, primary payer. That would mean that Medicare beneficiaries and/or some types of their businesses could be potentially held legally liable for reimbursement to the Medicare Trust Fund for Medicare benefits paid to the beneficiary.

A. Waiver of Proposed Rulemaking is not Justified

APA finds it inappropriate for CMS to waive the essential step of proposed rulemaking with regard to the regulatory amendments at issue.

¹ CMS Interim Final Rule: "Medicare Secondary Payer Amendments;" CMS-6272-IFC [Federal Register February 24, 2006 (Volume 71, No. 37)].

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Considering that Section 301 of the MMA was passed on December 8, 2003, CMS did not seek to make any regulatory conforming amendments for the past nearly two and a half years since then. There would not appear to be the urgency to implement these regulatory changes that is implied by CMS' decisions to: 1) waive proposed rulemaking in this case; 2) adopt an effective date for the regulations that is the same as the comments' due date; and 3) make the regulations effective, prior to publication of a final rule. All of these elements shorten and weaken the regulatory process.

A waiver of proposed rulemaking is supposed to be used only when "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."² The only basis of "good cause" that CMS articulates to justify the waiver of proposed rulemaking is that "this interim final rule with comment period merely conforms part 411 and Section 489.20(i)(2(ii) to changes affected by section 301 of the MMA."³

CMS' desire to conform regulatory language to a statutory amendment over two years after it passed does not justify eliminating proposed rulemaking, nor does it render a "notice-and-comment procedure" "impracticable, unnecessary, or contrary to the public interest." If CMS did not believe that there was substantial meaning to these regulatory amendments, there would be little point in promulgating them. Insofar as they are meaningful, the public deserves to have access to a full regulatory process. CMS has not set forth any reason why doing so would be "impracticable, unnecessary, or contrary to the public interest."

B. CMS' Adoption of Comment Due Date as Effective Date for Regulations is Inappropriate and Renders Comments Moot

CMS states that the effective date for the regulations subject to the interim final rule is to be April 25, 2006, which is the same date as the comments to this interim final rule are due.⁴ CMS specifically included a 60-day comment period with respect to this interim final rule, which has value only to the extent of CMS' intent to be responsive to the substance of the comments. APA notes also that this published notice of an interim final rule is not the legal equivalent of a published notice of a final rule. Yet, CMS has prematurely adopted an effective date for the regulations, as though the rule were final. This would appear to skip over another step in the regulatory process, in addition to the proposed rulemaking step that CMS has waived.

² CMS Interim Final Rule: "Medicare Secondary Payer Amendments;" CMS-6272-IFC [Federal Register February 24, 2006 (Volume 71, No. 37)], at 9466.

³ CMS Interim Final Rule: "Medicare Secondary Payer Amendments;" CMS-6272-IFC [Federal Register February 24, 2006 (Volume 71, No. 37)], at 9466.

⁴ CMS Interim Final Rule: "Medicare Secondary Payer Amendments;" CMS-6272-IFC [Federal Register February 24, 2006 (Volume 71, No. 37)], at 9466.



The purpose of soliciting public comments on the interim final rule is obviated, if CMS does not intend to consider the comments seriously and incorporate them into the process of developing a final rule. There is already substantial truncation of the usual rulemaking process by CMS's decision to eliminate the proposed rulemaking stage of the process. This truncation should not be intensified by making the comment period *pro forma* and without meaning.

CMS effectively pre-empts consideration of the comments' substance and renders them moot by adopting an effective date that is the same as the comments' due date. APA strongly urges CMS to adopt an effective date for the amended regulations that is the same as or subsequent to the date CMS publishes notice of a final rule on these regulations.

C. Medicare Beneficiaries' Potential for Personal Liability as Primary Payers

Contrary to CMS' assertion that the interim final rule merely conforms to MMA amendment Section 301, it goes further. For instance, CMS amends Section 411.20 to remove "definitions of 'third party payer' and 'third party payment'" from Section 411.21 "Definitions."⁵ CMS also adds definitions under Sections 411.20 and 411.21 for "primary payer" and "primary payment" that are not in Section 301. CMS also expands Section 301's meaning by which an "entity" would be considered to have a "self-insured plan" by specifying in Section 411.50 that a "self-insured plan means *an individual, or a private or governmental entity*" (italics provided).⁶

Section 301 concerned the Secretary's authority to make conditional (reimburseable) Medicare payments to beneficiaries when third-party entities that constitute "primary plans" do not or are not expected to pay beneficiaries promptly. This Section 301 language understandably prevents beneficiaries from being paid twice (by a primary plan and Medicare) for items or services for which the primary plan was legally responsible. It essentially clarified that Medicare was to be a secondary payer and could take reimbursement action against primary plans, under certain conditions.

Definitions for "third-party payer" and "third-party payment" under Section 411.21 and elsewhere in the relevant regulations clearly refer to third-party entities that are neither Medicare beneficiaries, nor the Medicare program itself. Thus, CMS is removing and modifying existing language about third-party repayment liability that inherently excluded Medicare beneficiaries from being liable, either as individuals or by

⁵ 42 C.F.R., Section 411.21:

"*Prompt or promptly*, when used in connection with third party payments, except as provided in §411.50, for payments by liability insurers, means payment within 120 days after receipt of the claim. . . .

"*Third party payer* means an insurance policy, plan, or program that is primary to Medicare.

"*Third party payment* means payment by a third party payer for services that are also covered under Medicare."

⁶ CMS Interim Final Rule: "Medicare Secondary Payer Amendments," CMS-6272-IFC [Federal Register February 24, 2006 (Volume 71, No. 37)], at 9470.



virtue of owning businesses where they remain personally liable, such as sole proprietorships.

Section 301(b) allows the federal government to recover payment made to Medicare beneficiaries from primary plans, including self-insured plans. CMS' language removes references to third-party payers and includes definitions under Sections 411.21 and 411.50 that define a "self-insured plan" as being a "primary payer." Rather than just conforming to Section 301, these definitions go beyond it. Per Section 411.50, CMS' definition for a "self-insured plan" now includes an "individual" that "carries its own risk instead of taking out insurance with a carrier."⁷ That language could conceivably be construed to mean that the Medicare beneficiary (an "individual" "who carries its own risk") has a "self-insured plan." This could present the undoubtedly unintended situation where a person who receives Medicare benefits could be pressured to repay those benefits, due to status as a self-insured plan that is a primary payer. Rather than open the door to the possibility of that untoward argument being used to the disadvantage of a Medicare beneficiary, the language could be constructed in such a way as to avoid it altogether.

Section 411.50 also defines a "self-insured plan" as "(a)n entity that engages in a business, trade, or profession is deemed to have a self-insured plan for purposes of liability insurance if it carries its own risk (whether by a failure to obtain insurance, or otherwise) in whole or in part." This definition would not only include a legally separate business entity owned by a Medicare beneficiary, it would encompass business entities such as a sole proprietorship and partnership, through which the beneficiary retains personal legal liability and where the beneficiary is either uninsured or under-insured.⁸

⁷ CMS Interim Final Rule: "Medicare Secondary Payer Amendments;" CMS-6272-IFC [Federal Register February 24, 2006 (Volume 71, No. 37)], at 9470.

⁸ U.S. Small Business Administration website: "SELECTING THE LEGAL STRUCTURE FOR YOUR BUSINESS;" <http://www.sba.gov/library/pubs/mp-25.pdf>
Retrieved April 24, 2006:

"In a sole proprietorship, the business and the owner are one and the same. There is no separate legal entity and thus no separate legal "person." This means that as a sole proprietor you will have unlimited personal responsibility for your business's liabilities."
page 3.

"A general partnership has characteristics of both a separate legal entity and a group of individuals. For example, it can own property and conduct business as a separate legal entity. However, the general partners are "jointly and severally" liable for the partnership; i.e., all of the partners are liable together and each general partner is individually liable for all of the obligations of the partnership. . . Limited partners do not have personal liability for the business of the partnership. Limited partners are at risk only to the extent of their previously agreed-upon contributions to the partnership." page 6.

"The most important reason for you to consider incorporating your business is because a corporation is its own legal "person," separate from its owners. This means, among other things, that creditors of the corporation may look only to the corporation and the business assets for payment." page 9.



The Medicare beneficiary's business could be construed as having a self-insured plan obligated to repay benefits, but the beneficiary would still be personally liable, in effect.

D. Conditional Payment and Mental Capacity

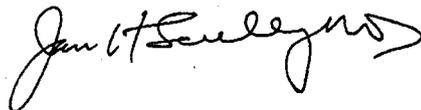
The language referring to conditional payment is inconsistent. Conditional payment is discretionary, where a beneficiary "because of physical or mental *capacity* failed to file a proper claim" (Section 411.45, Workers' Compensation cases) or "because of physical or mental *incapacity* failed to meet a claim-filing requirement" (Section 411.53, no-fault cases). These should both read either *capacity* or *incapacity* for the sake of consistency of application and evidentiary requirements. Also, CMS has not defined in the interim final rule what a beneficiary must do, if anything, to establish such *capacity* or *incapacity*. It would be clarifying for beneficiaries to know what the requirements are, in this regard.

Conclusion

CMS undoubtedly did not intend that the consequence of its regulatory amendments could be to incur personal liability for Medicare beneficiaries or certain types of their businesses to repay Medicare benefits they received. APA strongly recommends that CMS revise the language of these regulatory amendments to ensure that they cannot be construed in that manner. It should be clear that no Medicare beneficiary is to be construed as a primary plan, primary payer, self-insured plan, or otherwise as having personal liability deriving either from the beneficiary's status as an individual or through a beneficiary's business that is not a separate and distinct legal entity.

APA also strongly urges CMS to follow the customary regulatory process with regard to these regulatory changes. APA recommends that CMS re-characterize and re-publish the interim final rule as a proposed rule with appropriate time for public comments. AAP also urges CMS to adopt an effective date for the revised regulations that is on or after the date of Federal Register publication of a final rule, not prior to its promulgation.

Thank you for your consideration of these comments.



James H. Scully Jr., M.D.
Medical Director & C.E.O., American Psychiatric Association

Refer to: BCB14

MAR 29 2006

MAY 4 2006

The Honorable Peter J. Visclosky
Member, U.S. House of Representatives
701 East 83rd Avenue, Suite 9
Merrillville, IN 46410

Dear Mr. Visclosky:

Re: George Patrick

This is in reply to your correspondence dated March 6, 2006 concerning Mr. George Patrick's inquiry to your office. Mr. Patrick is under the impression that the Centers for Medicare & Medicaid Services' (CMS') Interim Final Rule, CMS-6272-IFC, will: 1) allow CMS to refrain from making conditional payments where there is no anticipation of prompt reimbursement; 2) will broaden the recovery scope for reimbursement when conditional payments are made; and 3) cause enormous consequences for injured employees who are already affected by the lag time that occurs in the Workers' Compensation review process at CMS.

We have forwarded a copy of Mr. Patrick's comments to the address identified in CMS-6272-IFC. As this is a formal process, his comments, along with all other submitted comments, will be addressed by CMS and published in the Final Rule.

Should you have any questions regarding this matter, your staff may contact Nancy Zahn, Health Insurance Specialist, at 312-353-0592.

Sincerely,



Opal Nealy
Associate Regional Administrator
Division of Medicare Financial Management

PETER J. VISCLOSKY
1ST DISTRICT, INDIANA

COMMITTEE ON APPROPRIATIONS
SUBCOMMITTEES:
DEFENSE
ENERGY AND WATER DEVELOPMENT
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0019

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March 6, 2006

Dr. Mark B. McClellan
Administrator
Centers for Medicare and Medicaid Services
314G Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, D.C. 20201

03-20-2006 P01:22

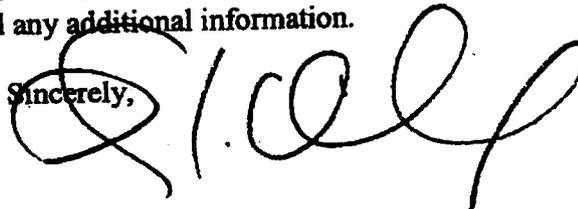
Dear Administrator McClellan:

I write on behalf of Mr. George Patrick, a resident of Indiana's First Congressional District.

Mr. Patrick has contacted me to express his concerns regarding a proposed rule by the Centers for Medicare and Medicaid Services (CMS), identified as CMS-6272-IFC. Mr. Patrick is concerned that the regulatory change will allow CMS to refrain from making conditional payments where there is no anticipation of prompt reimbursement, while broadening the recovery scope for reimbursement when conditional payments are made. He has expressed concern that the consequences of this change would be enormous for injured employees in the State of Indiana. He also expressed concern with the lag time that occurs in the Worker's Compensation review process at CMS. Enclosed, please find a copy of the proposed rule to which Mr. Patrick has expressed his opposition. I would appreciate your addressing his concerns and making them part of the official comments you receive for the proposed regulation.

Thank you in advance for your serious consideration of this matter. Do not hesitate to let me know if you have any questions or need any additional information.

Sincerely,



Peter J. Visclosky
Member of Congress

PJV:ms
Enclosure

From: George Patrick [mailto:george@georgepatrick.com]
Sent: Wednesday, March 01, 2006 3:45 PM
To: Lopez, Mark
Subject: CMS & Work Comp & Lake County problems

Dear Mark:

Please give this a quick review and get back to me with your thoughts on if Pete would be willing to help us in opposing this proposed rule.

I would be having Eric Oxfeld contact you all if you think that we can count Pete's support. As I read it CMS is going to broaden its recovery scope for reimbursement when they do make conditional payments and at the same time refrain from making conditional payments where there is no anticipation of reimbursement "promptly."

The consequences are enormous if that is the case for injured employees in the State of Indiana and Lake County. CMS is already killing us with the delay in the review of the Worker's Compensation resolutions. Please let me know how you read this proposal and Pete's possible support.

Also available in html format at:
<http://www.webgate3.access.gpo.gov/cgi-bin/waisgate.cgi?WALSdocID=15332810149+6+0+0&WALSaction=retrieve>

Many Thanks for your time and thoughts.

George

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3/1/2006

ADDENDUM F.—REVISED SINGLE DRUG CATEGORY LIST—Continued

HICPCS	Long description	Weight
J8390	Vinorelbine tartrate, per 10 mg	0.00111035
J8395	Injection, fulvestrant, 25 mg	0.00126670
J9600	Porfimer sodium, 75 mg	0.00000030
Q3025	Injection, interferon BETA-1A, 11 mcg for intramuscular use	0.00078263

IV. Waiver of Proposed Rulemaking and Delay in Effective Date

We ordinarily publish a notice of proposed rulemaking in the Federal Register to provide a period for public comment before the provisions of a rule take effect in accordance with section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 553(h)). However, we can waive the notice and comment procedures if the Secretary finds, for good cause, that the notice and comment process is impracticable, unnecessary or contrary to the public interest, and incorporates a statement of the finding and the reasons therefore in the rule. We can also waive the 30-day delay in effective date under the APA (5 U.S.C. 553(d)) when there is good cause to do so and we publish in the rule an explanation of our good cause.

This correcting amendment addresses technical errors and omissions made in FR Doc. 05-22160, entitled "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B," which appeared in the Federal Register on November 21, 2005 (70 FR 70116) and was made effective January 1, 2006. The provisions of this final rule with comment period have been previously subjected to notice and comment procedures. These corrections are consistent with the discussion and text and do not make substantive changes to the CY 2006 published rule. As such, this correcting amendment is intended to ensure the CY 2006 final rule with comment accurately reflects the policy adopted. Therefore, we find that undertaking further notice and comment procedures to incorporate these corrections into the final rule with comment is unnecessary and contrary to the public interest.

For the same reasons, we are also waiving the 30-day delay in effective date for this correcting amendment. We believe that it is in the public interest to ensure that the CY 2006 final rule with comment accurately states our policy on physician fee schedule and other Part B payment policies, and provisions related to the competitive

acquisition program of outpatient drugs and biologicals under Part B. Therefore, delaying the effective date of these corrections beyond the January 1, 2006 effective date of the final rule with comment period would be contrary to the public interest. In so doing, we find good cause to waive the 30-day delay in the effective date.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)
Dated: February 7, 2006.

Ann C. Agnew,
Executive Secretary to the Department.
[FR Doc. 06-1711 Filed 2-23-06; 8:45 am]
BILLING CODE 4120-01-L

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 411 and 489

[CMS-6272-IFC]

RIN 0939-AN27

Medicare Program; Medicare Secondary Payer Amendments

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

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period implements amendments to the Medicare Secondary Payer (MSP) provisions under Title III of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The MMA amendments clarify the MSP provisions regarding the obligations of primary plans and primary payers, the nature of the insurance arrangements subject to the MSP rules, the circumstances under which Medicare may make conditional payments, and the obligations of primary payers to reimburse Medicare.

DATES: Effective date: These regulations are effective on April 25, 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 April 25, 2006.

ADDRESSES: In commenting, please refer to file code CMS-6272-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-6272-IFC, g1P.O. Box 8017, Baltimore, MD 21244-8017.

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-6272-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: Suzanne Ripley, (410) 788-0970.

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-6272-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 be also 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 indicate the caption "Background" at the beginning of your comment.]

Beginning in 1980, the Congress enacted a series of amendments to section 1862(b) of the Social Security Act (the Act) (hereafter referred to as the Medicare Secondary Payer (MSP) provisions) to protect the financial integrity of the Medicare program by making Medicare a secondary payer, rather than a primary payer of health care services, when certain types of

other health care coverage are available. (Workers' compensation had already been primary to Medicare since the implementation of the original Medicare statute.) In enacting the MSP provisions, the Congress intended that the MSP provisions be construed to make Medicare a secondary payer to the maximum extent possible. These statutory provisions are set forth in regulations at 42 CFR part 411, Exclusions From Medicare and Limitations on Medicare Payment.

II. MMA Amendments to the Medicare Secondary Payer (MSP) Provisions

[If you choose to comment on issues in this section, please indicate the caption "MMA Amendments to the Medicare Secondary Payer Provisions" at the beginning of your comment.]

The Congress later became aware that various parties were pressing several interpretations of the MSP provisions that would, if ultimately accepted, severely limit the applicability of the MSP provisions at considerable expense to the Medicare program. Many of these interpretations were presented in the context of Federal court litigation over the meaning of various MSP provisions. The Congress rejected these attempts to incorrectly limit the application and scope of the MSP statute. The Congress passed section 301 under Title III of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) on December 8, 2003 to clarify its original intent regarding the MSP provisions under section 1862(b) of the Act, thereby indicating that these interpretations were incorrect and that the Secretary's interpretations were accurate. These clarifications are effective as if enacted on the date of the original legislation.

Section 301(a) of the MMA amends section 1862(b)(2)(A)(ii) of the Act to remove the term "promptly." This amendment establishes that various parties were incorrect in their interpretation that section 1862(b)(2)(A)(ii) of the Act applied only if the workers' compensation law or plan, liability insurance, or no-fault insurance has paid or could reasonably be expected to pay for services "promptly." This amendment also adds language at section 1862(b)(2)(B) of the Act to clarify that the Secretary may make payment subject to reimbursement if the workers' compensation law or plan, liability insurance, or no-fault insurance has not paid or could not reasonably be expected to pay for services "promptly."

Section 301(b)(1) of the MMA amends section 1862(b)(2)(A) of the Act to

clarify the application of the term "self-insured plan." It establishes that "an entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance, or otherwise) in whole or in part."

Section 301(b)(2)(A) of the MMA amends section 1862(b)(2)(B) of the Act to specify that a primary plan, and an entity that receives payment from a primary plan, shall reimburse the appropriate Trust Fund for any payment that the Secretary makes with respect to an item or service if it is demonstrated that the primary plan has or had a responsibility to make payment with respect to the item or service. It adds language establishing that a primary plan's responsibility for this payment "may be demonstrated by a judgment, a payment conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan's insured, or by other means."

Section 301(b)(3) of the MMA amends section 1862(b)(2) of the Act to further delineate those entities (that is, "primary payers") from which the United States may seek reimbursement. It amends language specifying that the United States may bring an action against "all entities that are or were required or responsible (directly, as an insurer or self-insurer, as a third-party administrator, as an employer that sponsors or contributes to a group health plan, or large group health plan, or otherwise) to make payment with respect to the same item or service (or any portion thereof) under a primary plan." This amendment specifies that the United States may recover double damages against these entities. Also, it amends language clarifying that the United States may recover payment from "any entity that has received payment from a primary plan or from the proceeds of a primary plan's payment to any entity."

Under section 301(d) of the MMA, these provisions are effective as if enacted on the date of the original legislation to reflect the original MSP provisions and Congressional intent at issue. As we discuss in more detail below, this interim final rule with comment period amends 42 CFR part 411 and § 489.20(i)(2)(ii) of our regulations to implement these MSP provisions.

III. Provisions of This Interim Final Rule With Comment Period

[If you choose to comment on issues in this section, please indicate the caption "Provisions of This Interim Final Rule with Comment Period" at the beginning of your comment.]

As is the case with group health plan and large group health plan insurance, Medicare may not make payment if payment with respect to the same item or service has been made or can reasonably be expected to be made under workers' compensation, no-fault, or liability insurance. However, Medicare may make a payment conditioned on reimbursement when the workers' compensation, no-fault, or liability insurance (including a self-insured plan) plan has not made or cannot reasonably be expected to make payment with respect to such item or service promptly. In accordance with section 301(a) of the MMA, we are removing the word "promptly" from § 411.20(a)(2), § 411.40(b)(1)(i), and § 411.50(c)(1) and (c)(2) to clarify that these Medicare payments are conditional and must be reimbursed whenever a primary payer's responsibility to make payment is demonstrated.

At § 411.21, we are removing the definitions for "third party payer" and "third party payment" and replacing them with definitions for "primary payer" and "primary payment." We are also providing a definition for "primary plan." We are making these changes to conform to the statutory language under the MMA. Consistent with these changes, we are making nomenclature changes to replace the terms "third party payer," "third party payment," and "third party plan" with "primary payer," "primary payment," or "primary plan," respectively under part 411 throughout subparts B through H. At § 411.33(f)(4), we are replacing the term "third party" with "primary payer." We are also amending § 489.20(i)(2)(ii) to replace "third party payment" with "primary payment."

In this interim final rule with comment period, we are also adding language to the definition of "self-insured" plan in § 411.50(b) in accordance with section 301(b)(1) of the MMA. We are clarifying that an entity that engages in a business, trade, or profession is deemed to have a "self-insured" plan for liability insurance if it carries its own risk, in whole or in part. Any such entity's self-insured status may be demonstrated, among other ways, by the failure to obtain insurance.

In accordance with section 301(b)(2)(A) of the MMA, we are adding

a new § 411.22 to clarify that a primary payer, and an entity that receives payment from a primary payer, become obligated to reimburse CMS if and when it is demonstrated that the primary payer has or had primary payment responsibility. This responsibility may be demonstrated by a judgment, a payment conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items and services included in a claim against the primary payer, or by other means, including but not limited to a settlement, award, or contractual obligation. This means that a primary payer may not extinguish its obligations under the MSP provisions by paying the wrong party—for example, by paying the Medicare beneficiary or the provider when it should have reimbursed the Medicare program. Primary payers are expected to reimburse CMS when it is demonstrated that they have or had payment responsibility.

In accordance with section 301(b)(3) of the MMA, the definition of "primary payer" in § 411.21, the new § 411.22, and the revised § 411.24(e) also clarify that the Medicare program may seek reimbursement from a primary payer, or any or all the entities responsible or required to make payment as a primary payer. With respect to debts where a group health plan or large group health plan is the primary plan, the amendments make clear that all employers that sponsor or contribute to the group health plan or large group health plan are primary payers required to reimburse Medicare regardless of whether the group health plan or large group health plan was an insured plan (that is, the employer or other plan sponsor purchased insurance) or was self-insured by the employer or other plan sponsor. Medicare may also seek reimbursement from any entity that has received payment from a primary payer. Entities that receive payment include, but are not limited to beneficiaries, attorneys, and providers or suppliers (including physicians).

Furthermore, in this interim final rule with comment period, we are revising § 411.24(e) by adding language pertaining to Medicare's authority to recover conditional payments. Specifically, in accordance with section 301(b)(3) of the MMA, we specify at § 411.24(e) that CMS has a direct right of action to recover from any primary payer. We are making a technical revision at § 411.24(f)(2) to replace the words "is primary" with "is a primary plan."

Consistent with section 301(b)(2)(A) of the MMA, this interim rule with comment period clarifies at § 411.24(i)(1) that, like liability insurance and disputed claims under group health plans and no-fault insurance, workers' compensation insurance and plans must also reimburse Medicare, although it paid some other entity, if it knew or should have known that the claimant was a Medicare beneficiary. Where Medicare has already recovered payment from the entity, reimbursement to Medicare by the workers' compensation insurance or plan is not required. However, nothing in this interim final rule with comment period will be construed to require us to first pursue the entity which receives payment before it can pursue the primary payer. Also consistent with section 301(b)(2)(A) of the MMA, we are adding language to § 411.45, § 411.52, and § 411.53 to specify that any conditional payment that Medicare makes is based upon the recovery rules under subpart B of part 411. In addition, at § 411.52, we clarify the basis for which Medicare makes payment in liability cases. We are revising § 411.53 by removing the terms "or the provider or supplier," in the existing paragraph (a) to clarify that it is the beneficiary's responsibility to file a claim for no-fault benefits.

III. 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.

IV. Waiver of Proposed Rulemaking

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 notice and comment rulemaking

because this interim final rule with comment period merely conforms part 411 and § 489.20(i)(2)(ii) of the regulations to statutory changes affected by section 301 of the MMA. Therefore, we find good cause to waive the notice of proposed rulemaking and to issue this final rule on an interim basis. We are providing a 60-day public comment period.

V. 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.

VI. Regulatory Impact Statement

[If you choose to comment on issues in this section please indicate the caption "Regulatory Impact" at the beginning of your comment.]

We have examined the impacts of this interim final rule with comment period 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). We have determined that the effect of this interim final rule with comment period on the economy and the Medicare program is not economically significant, since it merely clarifies certain MSP provisions to reflect original congressional intent and ratifies the manner in which we have implemented/administered the MSP provisions. If the technical and clarifying amendments had not been enacted, "savings" reflected in the table below would have been lost and Medicare expenditures would have increased.

The table reflects the potential impact of a Fifth Circuit Court decision that held that the MSP liability provision did not apply when there was no liability insurance purchased or no formal plan of self-insurance recognized under the

Internal Revenue Code. This placed a small portion of future MSP liability savings at risk. It was assumed that over time, some U.S. Circuit Courts could have reached a similar conclusion so that the potential losses of future MSP liability savings would increase slowly over time in addition to the projected growth of Medicare benefits. It was further assumed that some individuals who repaid Medicare before 2003 would sue for refunds and that favorable decisions would be rendered in some, but not all, cases. It was also assumed that the refunds of past MSP liability savings would peak about 2007. Lastly, it was assumed that MSP liability collections represent approximately 70 percent Part A claims payments and 30 percent Part B claims payments (which are based on historic MSP liability savings).

**MEDICARE SAVINGS RETAINED
[ROUNDED TO THE NEAREST \$10 MILLION]**

	Part A	Part B	Total
2003	0	0	0
2004	10	0	10
2005	10	0	10
2006	10	0	10
2007	20	0	20
2008	10	0	10
2009	20	0	20
2010	20	10	30
2011	20	10	30
2012	20	10	30
2013	20	10	30
2014	20	10	30
2015	20	10	30

Therefore, this interim final rule with comment period is not a major rule as defined in Title 5, United States Code, section 804(2) and is not an economically significant rule under Executive Order 12866.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. 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 have determined and we certify that this interim final rule with comment period will not have a significant economic impact on a substantial number of small entities because there is and will be no change in the administration of the MSP provisions. Therefore, we are not preparing an analysis for the RFA.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule or notice having the effect of 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 Core-Based Statistical Area and has fewer than 100 beds. We have determined that this interim final rule with comment period will not have a significant effect on the operations of a substantial number of small rural hospitals because there is and will be no change in the administration of the MSP provisions. Therefore, we are not preparing an analysis for section 1102(b) of the Act.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule or notice having the effect of a rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately \$120 million. This interim final rule with comment period has no consequential effect on State, local, or tribal governments or on the private sector because there is and will be no change in the administration of the MSP provisions.

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 411

Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 1. The authority citation for part 411 continues to read as follows:

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

§ 411.20 [Amended]

■ 2. Section 411.20 is amended by removing the word "promptly" in paragraph (a)(2) introductory text.
■ 3. Section 411.21 is amended by adding definitions of "primary payer," "primary payment," and "primary plan" and removing the definitions of "third party payer" and "third party payment" to read as follows:

§ 411.21 Definitions.

Primary payer means, when used in the context in which Medicare is the secondary payer, any entity that is or was required or responsible to make payment with respect to an item or service (or any portion thereof) under a primary plan. These entities include, but are not limited to, insurers or self-insurers, third party administrators, and all employers that sponsor or contribute to group health plans or large group health plans.

Primary payment means, when used in the context in which Medicare is the secondary payer, payment by a primary payer for services that are also covered under Medicare.

Primary plan means, when used in the context in which Medicare is the secondary payer, a group health plan or large group health plan, a workers' compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan), or no-fault insurance.

■ 4. A new § 411.22 is added to read as follows:

§ 411.22 Reimbursement obligations of primary payers and entities that received payment from primary payers.

(a) A primary payer, and an entity that receives payment from a primary payer, must reimburse CMS for any payment if it is demonstrated that the primary payer has or had a responsibility to make payment.

(b) A primary payer's responsibility for payment may be demonstrated by—

- (1) A judgment;
- (2) A payment conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services

included in a claim against the primary payer or the primary payer's insured; or
(3) By other means, including but not limited to a settlement, award, or contractual obligation.

§ 411.24 [Amended]

■ 5. Section 411.24 is amended by—
■ A. Revising paragraph (e).
■ B. Removing the words "is primary" and adding in its place the phrase "is a primary plan" in paragraph (f)(2).
■ C. Adding ", workers' compensation insurance or plan," after "group health plans" and before "and" in paragraph (i)(1).

Revisions for paragraph (e) read as follows:

§ 411.24 Recovery of conditional payments.

(e) *Recovery from primary payers.* CMS has a direct right of action to recover from any primary payer.

■ 6. Section 411.33(f)(4) introductory text is revised to read as follows:

§ 411.33 Amount of Medicare secondary payment.

(f) *Examples:* * * *
(4) A hospital furnished 5 days of inpatient care in 1987 to a Medicare beneficiary. The provider's charges for Medicare-covered services were \$4,000 and the gross amount payable was \$3,500. The provider agreed to accept \$3,000 from the primary payer as payment in full. The primary payer paid \$2,900 due to a deductible requirement under the primary plan. Medicare considers the amount the provider is obligated to accept as full payment (\$3,000) to be the provider charges. The Medicare secondary payment is the lowest of the following:

§ 411.40 [Amended]

■ 7. Section 411.40 is amended by removing the word "promptly" in paragraph (b)(1)(i).
■ 8. Section 411.45 is revised to read as follows:

§ 411.45 Basis for conditional Medicare payment in workers' compensation cases.

(a) A conditional Medicare payment may be made under either of the following circumstances:
(1) The beneficiary has filed a proper claim for workers' compensation benefits, but the intermediary or carrier determines that the workers' compensation carrier will not pay promptly. This includes cases in which a workers' compensation carrier has denied a claim.

(2) The beneficiary, because of physical or mental capacity, failed to file a proper claim.

(b) Any conditional payment that CMS makes is conditioned on reimbursement to CMS in accordance with subpart B of this part.

§ 411.50 [Amended]

■ 9. Section 411.50 is amended by—
■ A. Revising the definition of "self-insured plan" in paragraph (b).
■ B. Removing the word "promptly" in paragraphs (c)(1) and (c)(2).
■ The revision reads as follows:

§ 411.50 General provisions.

(b) *Definitions.*

Self-insured plan means a plan under which an individual, or a private or governmental entity, carries its own risk instead of taking out insurance with a carrier. This term includes a plan of an individual or other entity engaged in a business, trade, or profession, a plan of a non-profit organization such as a social, fraternal, labor, educational, religious, or professional organization, and the plan established by the Federal government to pay liability claims under the Federal Tort Claims Act. An entity that engages in a business, trade, or profession is deemed to have a self-insured plan for purposes of liability insurance if it carries its own risk (whether by a failure to obtain insurance, or otherwise) in whole or in part.

■ 10. Section 411.52 is revised to read as follows:

§ 411.52 Basis for conditional Medicare payment in liability cases.

(a) A conditional Medicare payment may be made in liability cases under either of the following circumstances:
(1) The beneficiary has filed a proper claim for liability insurance benefits but the intermediary or carrier determines that the liability insurer will not pay promptly for any reason other than the circumstances described in § 411.32(a)(1). This includes cases in which the liability insurance carrier has denied the claim.
(2) The beneficiary has not filed a claim for liability insurance benefits.
(b) Any conditional payment that CMS makes is conditioned on reimbursement to CMS in accordance with subpart B of this part.

■ 11. Section 411.53 is revised to read as follows:

§ 411.53 Basis for conditional Medicare payment in no-fault cases.

(a) A conditional Medicare payment may be made in no-fault cases under either of the following circumstances:

(1) The beneficiary has filed a proper claim for no-fault insurance benefits but the intermediary or carrier determines that the no-fault insurer will not pay promptly for any reason other than the circumstances described in § 411.32(a)(1). This includes cases in which the no-fault insurance carrier has denied the claim.

(2) The beneficiary, because of physical or mental incapacity, failed to meet a claim-filing requirement stipulated in the policy.

(b) Any conditional payment that CMS makes is conditioned on reimbursement to CMS in accordance with subpart B of this part.

PART 411—[NOMENCLATURE CHANGE]

■ 12. In part 411, revise all references to "third party payer" to read "primary payer"; revise all references to "third party payment" to read "primary payment"; and revise all references to "third party plan" to read "primary plan".

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

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

Authority: Secs. 1102 and 1871 of the Social Security Act.

§ 489.20 [Amended]

■ 2. Section § 489.20(i)(2)(ii) introductory text is amended by removing the words "third party payment" and adding in its place the words "primary payment".

(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: November 14, 2005.

Michael O. Leavitt,
Secretary, Department of Health and Human Services.

[FR Doc. 06-1712 Filed 2-23-06; 8:45 am]

BILLING CODE 4120-01-2

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 648**

[Docket No. 051128313-6029-02; I.D. 111705C]

RIN 0648-AT20

Fisheries of the Northeastern United States; Atlantic Bluefish Fisheries; 2006 Atlantic Bluefish Specifications; Quota Adjustment; 2006 Research Set-Aside Project

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

ACTION: Final rule; final specifications for the 2006 Atlantic bluefish fishery.

SUMMARY: NMFS issues 2006 specifications for the Atlantic bluefish fishery, including state-by-state commercial quotas, a recreational harvest limit, and recreational possession limits for Atlantic bluefish off the east coast of the United States. The intent of these specifications is to establish the allowable 2006 harvest levels and possession limits to attain the target fishing mortality rate (F), consistent with the stock rebuilding program in Amendment 1 to the Atlantic Bluefish Fishery Management Plan (FMP). This action will publish final specifications that are modified from those contained in the proposed rule.

DATES: This rule is effective March 27, 2006, through December 31, 2006.

ADDRESSES: Copies of the specifications document, including the Environmental Assessment (EA) and the Initial Regulatory Flexibility Analysis (IRFA) are available from Daniel Furlong, Executive Director, Mid-Atlantic Fishery Management Council, Room 2115, Federal Building, 300 South Street, Dover, DE 19901 6790. The specifications document is also accessible via the Internet at <http://www.nmfs.gov>.

The Final Regulatory Flexibility Analysis (FRFA) consists of the IRFA, public comments and responses contained in this final rule, and a summary of impacts and alternatives contained in this final rule.

The small entity compliance guide is available from Patricia A. Kurkul, Regional Administrator, Northeast Regional Office, National Marine Fisheries Service, One Blackburn Drive, Gloucester, MA 01930 2298.

The Northeast Fisheries Science Center 41st Stock Assessment Review Committee (SARC) Panelist Reports are available at: <http://www.nefsc.noaa.gov/nefsc/saw/saw41/>.

FOR FURTHER INFORMATION CONTACT: Bonnie Van Pelt, Fishery Policy Analyst, (978) 281-9244.

SUPPLEMENTARY INFORMATION:**Background**

The regulations implementing the Atlantic Bluefish Fishery Management Plan (FMP) appear at 50 CFR part 648, subparts A and J. Regulations requiring annual specifications are found at 50 CFR 648.160. The management unit for bluefish (*Pomatomus saltatrix*) is U.S. waters of the western Atlantic Ocean.

The FMP requires that the Mid-Atlantic Fishery Management Council (Council) recommend, on an annual basis, total allowable landings (TAL) for the fishery, consisting of a commercial quota and recreational harvest limit.

The annual review process for bluefish requires that the Council's Bluefish Monitoring Committee (Monitoring Committee) review and make recommendations based on the best available data including, but not limited to, commercial and recreational catch/landing statistics, current estimates of fishing mortality, stock abundance, discards for the recreational fishery, and juvenile recruitment. Based on the recommendations of the Monitoring Committee, the Council makes a recommendation to NMFS. This FMP is a joint plan with the Atlantic States Marine Fisheries Commission (Commission); therefore, the Commission meets during the annual specification process to adopt complementary measures.

The Council's recommendations must include supporting documentation concerning the environmental, economic, and social impacts of the recommendations. NMFS is responsible for reviewing these recommendations to ensure they achieve the FMP objectives, and may modify them if they do not. NMFS then publishes proposed specifications in the Federal Register. After considering public comment, NMFS publishes final specifications in the Federal Register.

In July 2005, the Monitoring Committee accepted the most recent bluefish stock assessment as the basis for its specification recommendations to the Council. In August 2005, the Council approved the Monitoring Committee's recommendations and the Commission's Bluefish Board (Board) adopted complementary management measures.