

(B) *Decision not to seek prior determination or negative determination does not impact the right to obtain services, seek reimbursement, or appeal rights.* Nothing in this paragraph will be construed as affecting the right of an individual who—

(1) Decides not to seek a prior determination under this paragraph with respect to physicians' services; or

(2) Seeks such a determination and has received a determination described in paragraph (d)(5)(ii)(A)(2) of this section, from receiving (and submitting a claim for) those physicians' services and from obtaining administrative or judicial review respecting that claim under the other applicable provisions of this part 405 subpart I of this chapter. Failure to seek a prior determination under this paragraph with respect to physicians' services will not be taken into account in that administrative or judicial review.

(C) *No prior determination after receipt of services.* Once an individual is provided physicians' services, there will be no prior determination under this paragraph with respect to those physicians' services.

Editorial Note: This document was received at the Office of the Federal Register on February 11, 2008.

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

Dated: May 31, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: October 30, 2007.

Michael O. Leavitt,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 411 and 489

[CMS–6272–F]

RIN 0938–AN27

Medicare Program; Medicare Secondary Payer (MSP) Amendments

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

ACTION: Final rule.

SUMMARY: On February 24, 2006, we published an interim final rule with

comment period in the **Federal Register** that implemented 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 clarified 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.

In this final rule, we are finalizing several clarifications made to the MSP provisions. In addition, we are responding to public comments on the February 24, 2006 interim final rule with comment period that pertain to these MSP provisions.

DATES: *Effective Date:* These regulations are effective on March 24, 2008.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory Background

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.

On December 8, 2003, the Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 (Pub. L. 108–173). The Congress passed section 301 under Title III of the MMA to address several interpretations of the MSP provisions being pressed by various parties that would, if ultimately accepted, severely limit the applicability of the MSP provisions at considerable expense to the Medicare program. As discussed in the February 24, 2006 interim final rule with comment period (71 FR 9466) 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.

In the MMA, the Congress clarified 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 were effective as if enacted on the date of the original legislation.

Section 301(a) of the MMA amended 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 added language to 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 amended 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 amended 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 added 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 amended 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 amended 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 specified that the United States may recover double damages against these entities. Also, it amended 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. This final rule amends 42 CFR part 411 and § 489.20(i)(2)(ii) of our regulations to implement these MSP provisions.

B. Requirements for Issuance of Regulations

Section 902 of the MMA amended section 1871(a) of the Act and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA also states that the timelines for these regulations may vary but shall not exceed 3 years after publication of the preceding proposed or interim final regulation except under exceptional circumstances.

This final rule finalizes provisions set forth in the February 2006 interim final regulations. In addition, this final rule has been published within the 3-year time limit imposed by section 902 of the MMA. Therefore, we believe that the final rule is in accordance with the Congress’ intent to ensure timely publication of final regulations.

II. Provisions of the Interim Final Regulations

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 plan (including a self-insured plan) has not made or cannot reasonably be expected to make payment with respect to this item or service promptly. As discussed in the February 2006 interim final rule, in accordance with section 301(a) of the MMA, we removed 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.

In § 411.21, we removed the definitions for “third party payer” and “third party payment” and replaced them with definitions for “primary payer” and “primary payment.” We also provided a definition for “primary plan.” We made these changes to conform to the statutory language under the MMA. Consistent with these changes, we made 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. In § 411.33(f)(4), we replaced the term “third party” with “primary payer.” We also amended § 489.20(i)(2)(ii) to replace “third party payment” with “primary payment.”

In the February 2006 interim final rule with comment period, we also added language to the definition of “self-insured” plan in § 411.50(b) in accordance with section 301(b)(1) of the MMA. We clarified 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 added 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, in § 411.21, § 411.22, and § 411.24(e) also clarified 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 the February 2006 interim final rule with comment period, we revised § 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 specified at § 411.24(e) that CMS has a direct right of action to recover from any primary payer. We made 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, the February 2006 interim rule with comment period clarified 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 the February 2006 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 added 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 clarified the basis for which Medicare makes payment in liability cases. We revised § 411.53 by removing the phrase “, 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. Analysis of and Responses to Public Comments

We received five comments from the public on the February 2006 interim final rule with comment period. The comments received and our responses to those comments are discussed below.

A. General Comments

Comment: A commenter stated that the February 2006 interim final rule with comment period would “refrain” CMS from making conditional payments where there is no anticipation of reimbursement “promptly” while broadening CMS’ recovery scope for reimbursement of conditional payments. The commenter also stated concern that the consequences of this would be enormous for injured employees in the State of Indiana.

Response: We recognize the commenter’s concerns and note that we will continue to be permitted to make conditional payments when liability insurance, no-fault insurance, or workers compensation do not pay promptly. In addition, we will continue to recover any conditional payments made. Furthermore, we will continue to not make conditional payments when the “injured employee” also has group health plan coverage that is primary to Medicare. The group health plan is expected to fulfill its responsibilities under the statute.

Comment: A commenter believes that CMS’ waiver of proposed rulemaking is not justified. The commenter stated that conforming regulatory language to statutory amendments does not justify waiving proposed rulemaking nor does it render a “notice-and-comment procedure” “impracticable, unnecessary, or contrary to the public interest.” The commenter suggested that CMS recharacterize and republish the February 2006 interim final rule with comment period as a proposed rule with appropriate time for public comments.

Response: We recognize the commenter’s concerns. However, it is unnecessary to undertake notice and comment rulemaking because we are merely conforming existing regulations to the statutory changes affected by section 301 of the MMA.

Comment: The commenter also believes that CMS’ adoption of a comment due date as the effective date for the regulation is inappropriate and renders any comments moot. The commenter suggested that CMS adopt an effective date for the revised regulations that is on or after the date of **Federal Register** publication of a final rule, not before its promulgation.

Response: In the February 2006 interim final rule (71 FR 9466), “MMA Amendments to the Medicare Secondary Payer (MSP) Provisions,” we explained that the clarifications regarding the Congress’s original intent in implementing the MSP provisions under section 1862(b) of the Social Security Act made by section 301 of the MMA were effective as if enacted on the date of the original legislation. In the February 2006 interim final rule (71 FR 9468), we explained that because the interim final rule merely conformed part 411 and § 489.20(i)(2)(ii) of the regulations to statutory changes affected by section 301 of the MMA, we found good cause to waive the notice of proposed rulemaking and issue the rule on an interim basis. We published the February 2006 interim final rule with a 60-day public comment period, providing the public adequate time to comment on the rule. In addition, there was a 60-day delay in the effective date of that rule. Although the effective date and the date of the close of the public comment period coincided, we believe the public comments are not moot because we are required to publish a subsequent final rule in which we consider and address all timely public comments on the preceding interim final rule. We have addressed the timely public comments in section III of this final rule, “Analysis of and Responses to Public Comments.” Based on our consideration of the public comments, § 411.22 and § 411.25 have been amended to further clarify the reimbursement obligations and notice requirements of primary payers. Section 411.45 has been amended to replace the word “capacity” with “incapacity” so that there is consistency between the language used in § 411.45 and § 411.53. This final rule will be effective 30 days after date of publication.

Comment: A commenter expressed the view that only beneficiaries and not beneficiaries, providers, and other entities should be responsible and have

the burden of updating the Coordination of Benefits (COB) files.

Response: This comment is outside of the scope of the February 2006 interim final rule. Please note that beneficiaries, providers, physicians, other suppliers, and other entities all have appropriate obligations to ensure our COB records are updated.

Comment: A commenter believes that the February 2006 interim final rule with comment period should require that “when a payer other than Medicare is determined to be the primary payer, the payer should be required to pay at least the Medicare payment amount for the service.” The commenter also believes that CMS should address “the undue administrative burden” created when a payer is determined to be primary and makes payment to a physician at a rate that is different than the Medicare amount that has already been paid to the physician.

Response: This comment is outside of the scope of the February 2006 interim final rule. However, we note that the MSP statute prohibits a group health plan from “taking Medicare entitlement into account” when Medicare is the secondary payer. The group health plan must make the same primary payment it makes for non-Medicare entitled individuals. We recognize the commenter’s concerns. Providers, physicians, and other suppliers are required by the MSP statute at 42 U.S.C. 1395 y(6)(b) to identify payers primary to Medicare and to bill them before billing Medicare. Regulations at § 411.24(h) require entities that receive duplicate primary payment to reimburse Medicare within 60 days. It is reasonable to expect providers, physicians, and other suppliers to reconcile payments received for services to Medicare beneficiaries and to comply with these requirements.

B. Definitions

In the February 2006 interim final rule, to conform to the statutory language under the MMA, we removed the definitions for “third party payer” and “third party payment” and replaced them with “primary payer” and “primary payment.” We also added a new definition for “primary plan.”

Comment: A commenter believes that the definition of “third party payer” and “third party payment” in the previous version of the regulation excluded the application of the MSP provisions to individuals if they are Medicare beneficiaries; are engaged in a business, trade, or profession; and are self-insured for purposes of liability insurance.

Response: The MMA clarifies that all entities (including sole proprietorships

and partnerships) that engage in a business, trade, or profession are deemed to be self-insured to the extent that they do not purchase liability insurance. This does not constitute a change in the way we have administered the MSP provisions.

In the February 2006 interim final rule, to implement the statutory amendment to section 1862(b)(2)(A) of the Act, we added language to the current definition of “self-insured plan” to read as follows: “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.”

Comment: A commenter questioned whether any individual engaged in a business trade or profession may be personally liable to the extent a claim is asserted against the individual and the claim is satisfied through a settlement, judgment, or award from the personal assets of the individual or otherwise.

Response: The commenter is correct that an individual who is engaged in a business, trade, or profession is deemed to be self-insured for purposes of the MSP liability provisions to the extent that he or she does not purchase liability insurance. An individual not engaged in a business, trade, or profession is not deemed to be self-insured.

Comment: A commenter expressed concern that the definition of self-insured plan would not only include a legally separate business entity owned by a Medicare beneficiary, but 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 underinsured. The commenter also stated that 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.

Response: The commenter is correct that an individual engaged in a

business, trade, or profession is personally liable in a liability insurance situation to the extent that he or she does not purchase liability insurance.

B. Reimbursement Obligations of Primary Payers and Entities That Received Payment From Primary Payers

In the February 2006 interim final rule, to implement one of the statutory amendments to section 1862(b)(2)(B) of the Act, we added a new § 411.22 to state that a primary payer, and an entity that receives payment from a primary payer, must reimburse us for any payment if it is demonstrated that the primary payer has or had responsibility to make payment. A primary plan’s responsibility for 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 payer or the primary payer’s insured; or by other means, including but not limited to a settlement, award, or contractual obligation.

Comment: A commenter stated that § 411.22 should clarify that “if a judgment or other legal proceeding determines that a payer (other than Medicare) is the primary payer, and the payer mistakenly reimburses the physician rather than Medicare (which has already provided reimbursement to the physician for the service), then it is the payer and/or Medicare’s responsibility to notify the physician.” The same commenter is concerned that the “double damage” language of § 411.24(c)(2) can be interpreted to apply to physicians.

Response: We disagree. It is reasonable to expect providers, physicians, and other suppliers to realize that they have received duplicate primary payments and to reimburse Medicare as required by § 411.24(h). Section 411.24(c)(2) specifically says we may “* * * recover from the primary payer * * *”. As defined in § 411.21, a “primary payer” is “* * * 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 plans.” “Physicians” in their capacity as “physicians” clearly do not fall within the definition of “primary payer.” However, a physician as an employer which sponsors or contributes to a group health plan, including a self-

insured group health plan, may be a “primary payer.”

Comment: A commenter believes that § 411.22 could be interpreted to allow Medicare to seek reimbursement from the provider first, before going to the primary payer. The commenter suggested that CMS further clarify § 411.22 by including language stating that Medicare will pursue reimbursement from the primary payer first; and that Medicare will not seek payment from providers that have not been paid by the primary payer for the claim in question.

Response: Section 1862(b)(2)(B)(iii) of the Act gives Medicare the authority to recover from the party responsible for making primary payment; any entity that has received a primary payment from Medicare and a primary plan; and from providers, physicians, and other suppliers who fail to file a proper claim. Accordingly, it would be inappropriate to limit Medicare’s recovery options.

Comment: A commenter stated that § 411.22 suggests that CMS anticipates that primary payers will reimburse Medicare immediately and directly upon a “demonstration” that a given payer has or had primary payment responsibility, thereby relieving CMS and its contractors of the requirement to issue a demand letter. The commenter asked for direction as to whom and in what form the reimbursement is to be made and, as well, the nature of the supporting information to be provided. The commenter also requested clarification as to whether entities that receive “payment from a primary payer” are required to notify Medicare of mistaken or conditional payments. Specifically, the commenter asked whether the notice requirements in § 411.25 (which states that if a primary payer learns that CMS has made a Medicare primary payment for services for which the primary payer has made or should have made primary payment, it must give notice to that effect to the Medicare intermediary or carrier that paid the claim) extend to both primary payers and entities that receive “payment from a primary payer.”

Response: We have modified § 411.22 and § 411.25 to address this comment in part. In addition, we will provide notice as to where and in what format the repayment should be made. Section 411.25 applies only to primary payers.

Comment: A commenter is questioned how a “contractual obligation” can of itself “demonstrate” an obligation to make a primary payment for a particular claim because a contractual obligation is a generic statement of responsibility applicable to all claims. The commenter believes the contract itself cannot

“demonstrate” that a particular claim meets its criteria for responsibility to make payment. The commenter stated that some other step must be taken to apply the contract terms to the facts and circumstances of a particular case, for example, analysis and conclusions evidenced by judgments, formal written settlements, awards, etc. The commenter noted that in the group health plan context, issues of primary responsibility to pay are usually not resolved by judgments, settlements, or awards, etc. The commenter requested clarification regarding how “responsibility for payment” would be demonstrated in these circumstances.

Response: A contract can establish that a primary plan is obligated to make primary payment for designated covered items and services under the plan. A primary payer has the obligation upon learning that Medicare has paid for certain items and services provided to an individual for which it has primary payment responsibility to determine if it is the proper primary payer for those items and services. This determination constitutes a demonstration of primary payment responsibility for those items and services and the consequential obligation to repay Medicare.

Comment: A commenter stated that, in the context of § 411.25, CMS has consistently taken the position that “learns” means “is, or should be, aware.” The commenter would like CMS to clarify whether the obligation to reimburse CMS arises only when responsibility to pay is “demonstrated” in accordance with the terms of § 411.22 or whether it also arises when the primary payer “learns” of the existence of a conditional payment under § 411.25. The commenter requested that CMS clarify whether the notice requirements of § 411.25 and the reimbursement requirements of § 411.22 must be satisfied at the same time or whether they are separate obligations that must be satisfied separately.

Response: Section 1862(b)(2)(B)(ii) of the Act specifically states that the obligation to repay Medicare arises when primary payment responsibility is demonstrated. Thus, the primary payer is obligated to repay Medicare whenever it learns in any manner or form that it has primary payment responsibility. We have modified § 411.22 and § 411.25 to address this comment.

C. Conditional Payments and Mental Incapacity

In the February 2006 interim final rule with comment period, we added 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.

Comment: A commenter expressed concern with the inconsistency in the language used when we state that conditional payment may be made where a beneficiary “because of physical or mental *capacity* failed to file a proper claim” (§ 411.45) or “because of physical or mental *incapacity* failed to meet a claim-filing requirement (§ 411.53). The commenter suggested that CMS use either the term “capacity” or “incapacity” for consistency of application and evidentiary requirements. The commenter also suggested that CMS define what a beneficiary must do to establish “capacity” or “incapacity.”

Response: We agree and will use the term “incapacity.” However, we do not believe it is necessary to define what a beneficiary must do to establish “incapacity.” “Incapacity” is determined on a case-specific basis. A provider, physician, or other supplier is responsible for demonstrating on a claim-specific basis that the beneficiary was physically or mentally incapable of providing the information necessary for the provider, physician, or other supplier to submit a proper claim.

IV. Provisions of the Final Regulations

For the most part, this final rule incorporates the provisions of the February 2006 interim final rule with comment period. Those provisions of this final rule that differ from the February 2006 interim final rule are as follows:

- Section 411.22 and § 411.25 have been amended to further clarify the reimbursement obligations and notice requirements of primary payers.
- Section 411.45 has been amended to replace the word “capacity” with “incapacity” so that there is consistency between the language used in § 411.45 and § 411.53.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.

- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements. Section 411.25 primary payer’s notice of primary payment responsibility.

Section 411.25(a) requires a primary payer to provide information about primary payment responsibility and the information about Medicare Secondary Payer situation to the entity or entities designated by CMS to receive the information. Primary payers must provide this information upon demonstration that CMS made a Medicare primary payment for services for which the primary payer has made or should have made primary payment. As stated earlier in the preamble of this document, a demonstration of the primary payers responsibility includes a judgment, a payment conditioned upon the recipients compromise, waiver, or release (whether or not there is a determination of admission or 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 411.25(c) states that the primary payer must provide additional information to the designated entity or entities as needed. The information may be required for the entity or entities to update CMS’ system of records.

The burden associated with the requirements in § 411.25 is the time and effort associated with a primary payer gathering and providing of information about primary payer responsibilities, Medicare secondary payer situations, and additional information used to update the CMS’ system of records. While these requirements are subject to the PRA, the associated burden is approved under OMB control number 0938–0214, with an expiration date of May 31, 2009.

As required by section 3504(h) of the Paperwork Reduction Act of 1995, we have submitted a copy of this document to the Office of Management and Budget (OMB) for its review of these information collection requirements.

VI. Regulatory Impact Statement

We have examined the impacts of this final rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the

Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We have determined that the effect of this final rule 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	Year
2003	\$0	\$0	\$0
2004	10	0	10
2005	10	0	10
2006	10	0	10

MEDICARE SAVINGS RETAINED— Continued

[Rounded to the nearest \$10 million]

Part A	Part B	Total	Year
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 final rule 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 final rule 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 final rule 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 final rule 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 final rule 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.

■ Accordingly, the interim final rule amending 42 CFR Chapter IV, which was published on February 2006 (71 FR 9466), is adopted as a final rule with the following changes:

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

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

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

■ 2. Section 411.22 is amended by adding a paragraph (c) as follows:

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

* * * * *

(c) The primary payer must make payment to either of the following:

(1) To the entity designated to receive repayments if the demonstration of primary payer responsibilities is other than receipt of a recovery demand letter from CMS or designated contractor.

(2) As directed in a recovery demand letter.

■ 3. Section 411.25 is amended by—

A. Revising the section heading.

■ B. Revising paragraphs (a) and (c).

The revisions read as follows:

§ 411.25 Primary payer's notice of primary payment responsibility.

(a) If it is demonstrated to a primary payer that CMS has made a Medicare primary payment for services for which the primary payer has made or should have made primary payment, it must provide notice about primary payment responsibility and information about the underlying MSP situation to the entity or entities designated by CMS to receive and process that information.

* * * * *

(c) The primary payer must provide additional information to the designated entity or entities as the designated entity or entities may require this information to update CMS' system of records.

§ 411.45 [Amended]

■ 4. Section 411.45(a)(2) is amended by removing the word "capacity" and adding the word "incapacity" in its place.

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

Dated: September 4, 2007.

Herb B. Kuhn,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: October 19, 2007.

Michael O. Leavitt,

Secretary.

Editorial Note: This document was received at the Office of the Federal Register on February 12, 2008.

[FR Doc. E8–2938 Filed 2–21–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Part 433**

[CMS 2275–F]

RIN 0938–AO80

Medicaid Program; Health Care-Related Taxes

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

ACTION: Final rule.

SUMMARY: This final rule revises the collection threshold under the regulatory indirect guarantee hold harmless arrangement test to reflect the provisions of the Tax Relief and Health Care Act of 2006. When determining whether there is an indirect guarantee

under the 2-prong test for portions of fiscal years beginning on or after January 1, 2008 and before October 1, 2011, the allowable amount that can be collected from a health care-related tax is reduced from 6 to 5.5 percent of net patient revenues received by the taxpayers. This final rule also clarifies the standard for determining the existence of a hold harmless arrangement under the positive correlation test, Medicaid payment test, and the guarantee test (with conforming changes to parallel provisions concerning hold harmless arrangements with respect to provider-related donations); codifies changes to permissible class of health care items or services related to managed care organizations as enacted by the Deficit Reduction Act of 2005; and, removes obsolete transition period regulatory language.

DATES: *Effective date:* This rule is effective April 22, 2008.

Compliance date: CMS will not consider a State to be out of compliance with the revision to the definition of permissible classes until October 1, 2009.

FOR FURTHER INFORMATION CONTACT: Charles Hines, (410) 786–0252 or Stuart Goldstein, (410) 786–0694.

SUPPLEMENTARY INFORMATION:**I. Background****A. General**

Title XIX of the Social Security Act (the Act) authorizes Federal grants to the States for Medicaid programs to provide medical assistance to persons with limited income and resources. While Medicaid programs are administered by the States, they are jointly financed by the Federal and State governments. The Federal government pays its share of medical assistance expenditures to the State on a quarterly basis according to a formula described in sections 1903 and 1905(b) of the Act. The amount of the Federal share of medical assistance expenditures is called Federal financial participation (FFP). The State pays its share of medical expenditures in accordance with section 1902(a)(2) of the Act.

The Medicaid Voluntary Contribution and Provider Specific Tax Amendments of 1991 (Pub. L. 102–234), enacted December 12, 1991, amended section 1903 of the Act to specify limitations on the amount of FFP available for medical assistance expenditures in a fiscal year when States receive certain funds donated from providers and revenues generated by certain health care-related taxes. We issued regulations to

implement the statutory provisions concerning provider donations and health care-related taxes in an interim final rule (with comment period) published on November 24, 1992 (57 FR 55118). A final rule was issued on August 13, 1993 (58 FR 43156). The Federal statute and implementing regulations were designed to protect Medicaid providers from being unduly burdened by health care related tax programs. Health care related tax programs that are compliant with the requirements set forth by the Congress create a significant tax burden for health care providers that do not participate in the Medicaid program or that provide limited services to Medicaid individuals.

B. Health Care-Related Taxes

Section 1903(w) of the Act requires that State health care-related taxes must be imposed on a permissible class of health care services; be broad based or apply to all providers within a class; be uniform, such that all providers within a class must be taxed at the same rate; and avoid hold harmless arrangements in which collected taxes are returned directly or indirectly to taxpayers. Section 1903(w)(3)(E) of the Act specifies that the Secretary shall approve broad based (and uniformity) waiver applications if the net impact of the health care-related tax is generally redistributive and the amount of the tax is not directly correlated to Medicaid payments. The broad based and uniformity requirements are waivable through a statistical test that measures the degree to which the Medicaid program incurs a greater tax burden than if these requirements were met. The permissible class of health care services and hold harmless requirements cannot be waived. The statute and Federal regulation identify 19 permissible classes of health care items or services that States can tax without triggering a penalty against Medicaid expenditures.

The regulatory language at 42 CFR 433.68(f) sets forth tests for determining the presence of a hold harmless arrangement that were directly based on the language contained in section 1903(w)(4) of the Act. The preamble to the 1993 regulation provided guidance and some illustrative examples of the types of health care-related tax programs that we believed would violate the hold harmless prohibitions. In a June 29, 2005 decision, however, the HHS Departmental Appeals Board (DAB), DAB No. 1981, found that these regulations did not clearly preclude certain types of arrangements that we believe to be within the scope of the