



This document is scheduled to be published in the Federal Register on 02/27/2015 and available online at <http://federalregister.gov/a/2015-04143>, and on FDsys.gov

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 405

[CMS-6055-F]

RIN 0938-AS03

Medicare Program; Right of Appeal for Medicare Secondary Payer Determinations Relating to Liability Insurance (Including Self-Insurance), No-Fault Insurance, and Workers' Compensation Laws and Plans

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

ACTION: Final rule.

SUMMARY: This final rule implements provisions of the Strengthening Medicare and Repaying Taxpayers Act of 2012 (SMART Act) which require us to provide a right of appeal and an appeal process for liability insurance (including self-insurance), no-fault insurance, and workers' compensation laws or plans when Medicare pursues a Medicare Secondary Payer (MSP) recovery claim directly from the liability insurance (including self-insurance), no-fault insurance, or workers' compensation law or plan.

DATES: Effective date: These regulations are effective on [Insert date 60 days after the date of publication in the **Federal Register**].

Applicability date: Applicable plans are parties to initial determinations issued on or after [Insert date 60 days after the date of publication in the **Federal Register**] where CMS pursues recovery directly from an applicable plan.

FOR FURTHER INFORMATION CONTACT:

Barbara Wright, (410) 786-4292.

Cynthia Ginsburg, (410) 786-2579.

SUPPLEMENTARY INFORMATION:

I. General Overview and Background

A. General Overview

When the Medicare program was enacted in 1965, Medicare was the primary payer for all medically necessary covered and otherwise reimbursable items and services, with the exception of those items and services covered and payable by workers' compensation. In 1980, the Congress enacted the Medicare Secondary Payer (MSP) provisions of the Social Security Act (the Act), which added section 1862(b) to the Act and established Medicare as the secondary payer to certain primary plans. Primary plan, as defined in section 1862(b)(2)(A) of the Act, means a group health plan or large group health plan, workers' compensation law or plan, automobile or liability insurance policy or plan (including self-insured plan) or no-fault insurance.

Section 1862(b)(2) of the Act, in part, prohibits Medicare from making payment where payment has been made or can reasonably be expected to be made by a primary plan. If payment has not been made or cannot reasonably be expected to be made by a primary plan, Medicare may make conditional payments with the expectation that the payments will be reimbursed to the appropriate Medicare Trust Fund. That is, Medicare may pay for medical claims with the expectation that it will be repaid if the beneficiary obtains a settlement, judgment, award, or other payment. A primary plan and any entity that receives payment from a primary plan shall reimburse the appropriate Medicare Trust Fund for Medicare's payments for items and services if it is demonstrated that such primary

plan has or had responsibility to make payment with respect to such items and services.

The responsibility for payment on the part of workers' compensation, liability insurance (including self-insurance), and no-fault insurance is generally demonstrated by a settlement, judgment, award, or other payment (including, for example, assuming ongoing responsibility for medicals (ORM)). When such occurs, the settlement, judgment, award or other payment is subject to the Act's MSP provisions because a "payment has been made" with respect to medical care of a beneficiary related to that settlement, judgment, award or other payment. Section 1862(b)(2)(B)(iv) of the Act provides the federal government subrogation rights to any right under MSP of an individual or any other entity to payment for items or services under a primary plan, to the extent Medicare payments were made for such medical items and services. Moreover, section 1862(b)(2)(B)(iii) of the Act provides the federal government a direct right of action to recover conditional payments made by Medicare. This direct right of action, which is separate and independent from Medicare's statutory subrogation rights, may be brought to recover conditional payments against any or all entities that are or were responsible for making payment for the items and services under a primary plan. Under the direct right of action, the federal government may also recover from any entity that has received payment from a primary plan or the proceeds of a primary plan's payment to any entity.

Moreover, the MSP statute requires a "demonstration of primary payment responsibility;" it does not require that CMS prove that the alleged incident or injury caused particular medical care. 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 of liability) of payment or otherwise. A settlement, judgment, award, or other payment (including, for example, an assumption of ORM) is sufficient to demonstrate primary payment responsibility for what has been claimed, released, or released in effect.

B. Background

The Strengthening Medicare and Repaying Taxpayers Act of 2012 (the SMART Act) was signed into law by President Obama on January 10, 2013, and amends the Act's MSP provisions (found at 42 U.S.C. 1395y(b)). Specifically, section 201 of the SMART Act added paragraph (viii) to section 1862(b)(2)(B) of the Act. This new clause requires Medicare to promulgate regulations establishing a right of appeal and an appeals process, with respect to any determination for which the Secretary is seeking to recover payments from an applicable plan (as defined in the MSP provisions), under which the applicable plan involved, or an attorney, agent, or third-party administrator on behalf of the applicable plan, may appeal such a determination. Further, the individual furnished such an item and/or service shall be notified of the applicable plan's intent to appeal such a determination. For purposes of this provision, the term applicable plan refers to liability insurance (including self-insurance), no-fault insurance, or a workers' compensation law or plan, as defined at section 1862(b)(8)(F) of the Act.

Currently, if an MSP recovery demand is issued to the beneficiary as the identified debtor, the beneficiary has formal administrative appeal rights and eventual judicial review as set forth in subpart I of part 405. If the recovery demand is issued to the applicable plan as the identified debtor, currently the applicable plan has no formal administrative

appeal rights or judicial review. CMS' recovery contractor addresses any dispute raised by the applicable plan, but there is no multilevel formal appeal process.

Subpart I of part 405, provides for a multilevel process including a redetermination by the contractor issuing the recovery demand, a reconsideration by a Qualified Independent Contractor (QIC), an Administrative Law Judge (ALJ) hearing, a review by the Departmental Appeals Board's (DAB) Medicare Appeals Council (MAC), and eventual judicial review, and sets forth details on the process including standing to request an appeal, filing requirements, amount in controversy requirements, and other requirements. The December 27, 2013 proposed rule (78 FR 78802) would add appeals for applicable plans where Medicare is pursuing recovery directly from the applicable plan. The debts at issue involve recovery of the same conditional payments that would be at issue if recovery were directed at the beneficiary. Given this, we believe it is appropriate to utilize the same multilevel appeals process for applicable plans.

II. Provisions of the Proposed Regulations and Analysis of and Responses to Public Comments

A. Introduction

In the December 27, 2013 **Federal Register** (78 FR 78802), we published a proposed rule that would implement section 201 of the SMART Act which required us to promulgate regulations establishing a right of appeal and an appeals process with respect to any determination for which the Secretary is seeking to recover payments from an applicable plan. Our proposals would add appeal rights for applicable plans where Medicare is pursuing recovery directly from the applicable plan utilizing the existing

appeals procedures in part 405 subpart I applicable to appeals filed by beneficiaries when Medicare seeks recovery of conditional payments directly from the beneficiary.

We received approximately 19 timely pieces of public correspondence on the December 27, 2013 proposed rule. Commenters included insurance industry associations and organizations, beneficiary and other advocacy groups, entities offering MSP compliance services, and health insurance plans. The commenters generally supported our proposals.

Because of the type of comments received, we are using the following approach to structure this section of the final rule:

- Presenting the proposed provision(s) based on topic area(s) of the public comments.
- Providing the proposed provisions for which we did not received public comments.
- Providing and responding to the public comments that do not "fit" in the topic areas noted previously. The following is a list of the regulatory provisions that would be revised or added in accordance with the December 13, 2013 proposed rule:
 - §405.900 Basis and scope
 - §405.902 Definitions
 - §405.906 Parties to the initial determinations, redeterminations, reconsiderations, hearings, and reviews
 - §405.910 Appointed representatives
 - §405.921 Notice of initial determination

- §405.924 Actions that are initial determinations
- §405.926 Actions that are not initial determinations
- Proposed §405.947 Notice to the beneficiary of applicable plan's request for a redetermination

B. Discussion of the Provisions of the Proposed Rule by Public Comment Topic

In this section of the final rule we provide a general overview and a response to the public comments received, grouped under the following topics:

- Definition of Applicable Plan
- Issues Subject to Appeal/Not Subject to Appeal
- Party Status/Who Can Appeal and When
- Use of an Attorney or Other Representative; Assignment of Appeal Rights
- Notice
- Appeal Processes/Determining the Identified Debtor
- Interest and Penalties
- Applicability of the Proposed Rule to Medicare Part C and/or Medicare Part D
- Other

1. Definition of Applicable Plan

We proposed adding the following definition for "applicable plan" in §405.902, Definitions: "*Applicable plan* means liability insurance (including self-insurance), no-fault insurance, or a workers' compensation law or plan." This is the statutory definition of "applicable plan" in section 1862(b)(8)(F) of the Act.

Comment: A commenter requested that CMS revise the definition of applicable

plan in the proposed rule to read: Applicable plan means liability insurance (including self-insurance), no-fault insurance, or a workers' compensation law or plan where payment has been made or can reasonably be expected to be made under a workmen's compensation law or plan of the United States or a state or under an automobile or liability insurance policy or plan (including a self-insured plan) or under no-fault insurance.

Response: We disagree with the recommended revision. The definition of the term "applicable plan" is the definition set forth in section 1862(b)(8) of the Act. The reference to ". . . applicable plan under [section 1862(b)(2)(A)(ii) of the Act]" (pursuant to the SMART Act and as codified now in section 1862(b)(2)(B)(viii) of the Act) is a reference to when CMS would pursue recovery with respect to liability insurance (including self-insurance), no-fault insurance, or workers' compensation law or plan recoveries where primary payment responsibility has been demonstrated, and is not a part of the definition of the term "applicable plan" itself. The term "applicable plan" as referred to in the SMART Act has a pre-existing definition in the same section of the Medicare statute (that is, in section 1862(b) of the Act). Therefore, we are finalizing the definition of the term "applicable plan" as proposed.

2. Issues Subject to Appeal/Not Subject to Appeal

In order for an action to be subject to the appeal process set forth in subpart I of 42 CFR 405, there must be an "initial determination." Section 405.924, Actions that are initial determinations, addresses actions that are initial determinations (and thus subject to appeal) for purposes of part 405 subpart I. We proposed adding paragraph (b)(15) to this section to specifically provide that where Medicare is pursuing recovery directly from an

applicable plan, there is an initial determination with respect to the amount and the existence of the recovery claim. This addition would generally parallel the existing provisions of §405.924(b)(14) addressing pursuing MSP recovery claims from a beneficiary, provider, or supplier. In addition to these changes, for consistency, we proposed a number of technical and formatting changes.

Paragraph (a) of §405.926, Actions that are not initial determinations, addresses actions that are not initial determinations (and thus not subject to appeal) for purposes of part 405 subpart I because such determinations are the sole responsibility of CMS. Generally under §405.926(k) initial determinations with respect to primary payers are not initial determinations. In conjunction with the proposed addition of §405.924(b)(15), we proposed adding an exception to §405.926(k) for initial determinations set forth in §405.924(b)(15). Additionally, we proposed to add a new paragraph §405.926(a)(3) to clarify that a determination of the debtor for a particular MSP recovery claim is not an initial determination for purposes of part 405 subpart I. Because Medicare has the right to recover conditional payments from the beneficiary, the primary payer, or any other entity that has received the proceeds from payment by the primary plan, Medicare's decision regarding who or what entity it is pursuing recovery from is not subject to appeal. We also proposed to add the word "facilitates" to the existing "sponsors or contributes to" language in §405.926(k) in recognition of our longstanding position that the concept of employer sponsorship or contribution has always included facilitation efforts. Finally, for consistency, we proposed making several technical changes.

Comment: A number of commenters believe that the issue of who or which entity

CMS pursues an MSP recovery from should be subject to appeal. Some commenters requested that CMS always pursue recovery from the beneficiary first. Others believe that if the applicable plan has paid the beneficiary, recovery should be limited to the beneficiary. A commenter stated that the parties to a settlement, judgment, award, or other payment should be allowed to designate who CMS pursues or, at least who CMS pursues first.

Response: We decline these requests. Pursuant to section 1862(b)(2)(B)(ii) of the Act and 42 CFR 411.24 of the regulations, we have the right to pursue recovery from the beneficiary, the primary payer or any other entity receiving proceeds from the payment by the primary plan. We may recover from the applicable plan even if the applicable plan has already reimbursed the beneficiary or other party. Under our existing regulations under part 405 subpart I, beneficiaries have formal appeal rights; applicable plans do not have such rights. The SMART Act's provisions codified in section 1862(b)(2)(B)(viii) of the Act require us to provide formal appeal rights and a formal appeal process for applicable plans, but these provisions do not change Medicare's underlying recovery rights.

Comment: Some commenters would like to be able to appeal who is the identified debtor in a situation where there are multiple entities which are primary payers to Medicare (a beneficiary with multiple types of coverage or multiple settlements, or both). That is, they would like to be able to appeal whether CMS recovers from "applicable plan #1" rather than "applicable plan #2" in a situation where both applicable plans are primary to Medicare.

Response: We disagree. In accordance with section 1862(b)(2)(B)(ii) of the Act

and 42 CFR 411.24 of the regulations, we have the right to pursue recovery from the beneficiary, the primary payer or any other entity receiving proceeds from the payment by the primary plan. Section 411.24(e) states that we have a direct right of action to recover from any primary payer.

Comment: A commenter requested that CMS remove any restrictions on the applicable plan, including the right to seek recovery from the beneficiary, service provider or other entity. Another commenter stated that the proposed rule did not address whether the applicable plan may seek recovery from another entity.

Response: We decline this request. The commenter is requesting that we provide a statement of the applicable plan's rights against Medicare beneficiaries, providers/suppliers, or other entities which is outside the scope of this rule.

After review and consideration of comments related to §405.924 and §405.926, we are finalizing the changes to these sections with modifications. In order to address the addition of a new paragraph (b)(15) to §405.924 via the CY 2015 Physician Fee Schedule final rule with comment period (79 FR 68001), we will need to add proposed paragraph (b)(15) as paragraph (b)(16) and make conforming cross-references changes in §405.906 and §405.926(k).

3. Party Status/Who Can Appeal and When

We proposed to add paragraph (a)(4) to §405.906, Parties to the initial determinations, redeterminations, reconsiderations, hearings, and reviews, to specify that an applicable plan is a party to an initial determination under proposed §405.924(b)(15) where Medicare is pursuing recovery directly from the applicable plan. The applicable

plan is the sole party to an initial determination when an applicable plan is a party. By "pursuing recovery directly from the applicable plan," we mean that the applicable plan would be the identified debtor, with a recovery demand letter issued to the applicable plan (or its agent or representative) requiring repayment. If or when an applicable plan receives a courtesy copy of a recovery demand letter issued to a beneficiary, this does not qualify as "pursuing recovery directly from the applicable plan" and does not confer party status on the applicable plan. Making the applicable plan the sole party to the initial determination means that the applicable plan would also be the sole party to a redetermination or subsequent level of appeal with respect to that initial determination. We are also making a technical change in the section heading for §405.906 (adding a comma before the phrase "and reviews").

Comment: Several commenters requested that (1) either the applicable plan, or the beneficiary, or both be allowed to participate in any appeal where the identified debtor is either the applicable plan or the beneficiary; (2) any appeal consolidate the appeal process and appeal rights of the applicable plan and the beneficiary; (3) either the applicable plan or the beneficiary has the right to appeal at any point prior to resolution of the appeals process or full payment (whichever occurs first); or (4) appeal rights be given to any entity potentially liable for repayment .

Response: We decline these requests. This final rule makes appeal rights available to the identified debtor, not potential identified debtors. An identified debtor and a potential identified debtor do not always have the same interests or present the same issues on appeal. For example, where a demand is issued, the identified debtor may elect

to make payment in full and not appeal, in which case furnishing appeal rights to a potential debtor is unnecessary.

If we issue a demand to an identified debtor and later determine that it is appropriate to pursue recovery of some or all of the conditional payments at issue from a different identified debtor, a new separate demand will be issued, with appeal rights appropriate to the identified debtor in the new recovery demand.

Comment: A commenter requested that the provision making the applicable plan the sole party to a recovery pursued directly from the applicable plan be modified to state that the applicable plan is the sole party unless the applicable plan has previously made payment, in which circumstance any individual or entity which accepted payment would be a party to the initial determination and subsequent actions.

Response: We decline this request. In accordance with section 1862(b)(2)(B)(ii) of the Act and 42 CFR 411.24 of the regulations, we have the right to pursue recovery from the beneficiary, the primary payer or any other entity receiving proceeds from the payment by the primary plan. We may recover from the applicable plan even if the applicable plan has already reimbursed the beneficiary or other party.

Comment: Some commenters requested that CMS always pursue recovery from the individual or entity to whom/which the applicable plan has made payment (or, at minimum, pursue recovery from that individual or entity before pursuing recovery from the applicable plan). A commenter suggested that CMS should have to inform an applicable plan regarding whether recovery had been sought from the beneficiary first.

Response: We decline these requests. The determination of who to pursue is our

sole responsibility and, consequently, is not subject to appeal (see §405.926 (a)). We have the right to pursue recovery from the primary payer, the beneficiary, or any other entity receiving proceeds from the payment by the primary plan, and we may recover from the applicable plan even if the applicable plan has already reimbursed the beneficiary or other party.

After review and consideration of all comments related to §405.906, we are finalizing the changes to this section with the modifications to the cross-references to §405.924(b)(15) noted in section II.B.2. of this final rule.

4. Use of an Attorney or Other Representative; Assignment of Appeal Rights

We proposed adding paragraph (e)(4) to §405.910, Appointed representatives, in order to provide applicable plans with the benefit of the existing rule for MSP regarding the duration of appointment for an appointed representative. We also proposed revising §405.910(i)(4) to ensure that the special provision that beneficiaries as well as their representatives must receive notices or requests in an MSP case continues to apply only to beneficiaries. For all other parties, including an applicable plan, we continue to follow the regulatory provisions in §405.910(i)(1) through (3). We did not propose any changes to §405.912 which addresses the assignment of appeal rights.

Comment: Commenters requested that applicable plans be able to appoint third parties/agents as representatives in the appeal process.

Response: Applicable plans have this ability under the existing provisions in §405.910. Section 405.910 does not limit who a party may appoint as a representative other than to state that "[a] party may not name as an appointed representative, an

individual who is disqualified, suspended or otherwise prohibited by law from acting as a representative in any proceedings before DHHS, or in entitlement appeals, before SSA."

Furthermore, we are specifying when a party appointing a representative must include the beneficiary's Medicare health insurance claim number (HICN) on the appointment of representation. We believe that it is not necessary for non-beneficiary parties to include the HICN as part of a valid appointment because an applicable plan or other non-beneficiary party seeking to appoint a representative under §405.910 is not a beneficiary, and would thus not have a beneficiary HICN to provide on an appointment of representation. Accordingly, we are amending the existing §405.910(c)(5) to state that an appointment of representation must identify the beneficiary's HICN when the beneficiary (or someone, such as an authorized representative or representative payee, acting on behalf of a beneficiary) is the party appointing a representative.

Comment: Some commenters requested that beneficiaries be able to assign their appeal rights to the applicable plan; other commenters requested that applicable plans be able to assign their appeal rights to the beneficiary.

Response: We decline these requests. Both beneficiaries and applicable plans have the option of an agreement for representation when it is mutually agreed to. However, the assignment of appeal rights is controlled by section 1869(b)(1)(C) of the Act which limits the assignment of appeal rights to assignment by a beneficiary to a provider/supplier with respect to an item or service furnished by the provider/supplier in question.

After review and consideration of comments related to §405.910, we are finalizing

the changes to this section as proposed and with the specification to paragraph (c)(5) explained previously.

5. Notice

We proposed adding a new paragraph (c) to §405.921, Notice of initial determination, to provide specific language regarding requirements for notice to an applicable plan. Proposed §405.921(c)(iv) states that in addition to other stated requirements in §405.921(c), the requisite notice must contain "any other requirements specified by CMS." We also proposed to add §405.947, Notice to the beneficiary of applicable plan's request for a redetermination, to add language satisfying the requirement at section 1862(b)(2)(B)(viii) of the Act that the beneficiary receive notice of the applicable plan's intent to appeal where Medicare is pursuing recovery from the applicable plan. As the beneficiary would not be a party to the appeal at the redetermination level or subsequent levels of appeal, we believe that a single notice at the redetermination level satisfies the intent of this provision. We also proposed that the required notice be issued by a CMS contractor in order to ensure clarity and consistency in the wording of the notice. In addition to these changes, for consistency we proposed a number of technical and formatting changes.

Comment: Several commenter stated that the requisite notice must contain "any other requirements specified by CMS" in proposed §405.921(c)(iv) is too broad and/or gives CMS too much authority.

Response: We are finalizing §405.921(c) as proposed. The proposed language in §405.921(c) is designed to set forth the minimum requirements for notice of an initial

determination. Proposed §405.921(c)(iv) simply provides flexibility for CMS to include additional information appropriate for the efficient operation of the appeals process; it does not eliminate any obligations set forth in proposed §405.921(c). Additionally, we note that the same language is a longstanding provision in §405.921(a) and (b) as well as certain other sections within part 405 subpart I regarding "notice."

Comment: Commenters presented a range of concerns regarding whether-- (1) the applicable plan should be copied on a recovery demand with the beneficiary as the identified debtor; and (2) all potential debtors should be copied on all actions (that is, recovery demands, appeal requests, all notices or decisions).

Response: Given that the proposed rule provides that the applicable plan will be the sole party to an initial determination if CMS pursues recovery directly from the applicable plan, we have determined that any notice beyond the notice we have proposed in §405.947 is unnecessary, would cause an increase in administrative costs and would cause confusion in many instances, particularly where beneficiaries would receive copies of demands issued to applicable plans.

Comment: A commenter stated that the Notice of Initial Determination sent to an applicable plan must include specific statutory authority for determinations and notification of appeal rights.

Response: It is our routine practice to include the basis for our recovery rights as well as information on applicable appeal rights in the recovery demand letter. Moreover, we believe that the commenter's concerns are adequately addressed by proposed §405.921(c)(i) and (iii) (which require the reason for the determination as well as

information on appeal rights).

Comment: A commenter requested that we apply the "mailbox rule" (also known as the "postal rule" or "deposited acceptance rule") regarding receipt of a document.

Response: We decline this request. The appeals process set forth in part 405 subpart I already has rules regarding receipt of documents for the purpose of determining the timeliness of an appeal request. See, for example, §405.942(a)(1) (date of receipt for an initial determination), §405.962(a)(1) (date of receipt for a redetermination), and §405.1002(a)(3) (date of receipt for a reconsideration).

Comment: A commenter requested that language be added to beneficiary correspondence requiring beneficiaries to cooperate with the applicable plan and CMS' contractor.

Response: Because we are not involved in the interactions between a beneficiary and an applicable plan, we are not adding the requested language.

Comment: A commenter was concerned that an applicable plan might lose its opportunity to appeal if the recovery demand to the applicable plan was addressed incorrectly.

Response: Section 405.942, §405.962, §405.1014, and §405.1102 all contain provisions for extending the time for filing for a particular level of appeal upon establishing good cause. An applicable plan, as a party, is entitled to request an extension of the filing timeframe consistent with the previously referenced sections should there be good cause to extend such timeframes.

Comment: A commenter requested that notice to the beneficiary of the applicable

plan's appeal explicitly state in plain language that the applicable plan's appeal does not affect the beneficiary (that is, that the applicable plan is the sole party to the appeal).

Response: We agree, however, the content of model notices is more appropriately included in our operational instructions for contractors. We will address this issue when we draft language for the notice CMS' contractor will issue in accordance with §405.947.

Comment: A commenter requested clarification regarding "notice" for purposes of the statute of limitations provision set forth in section 205 of the SMART Act.

Response: This comment is outside the scope of this rule.

After review and consideration of all comments regarding §405.921 and §405.947, we are finalizing these provisions as proposed with one modification. We are revising §405.947(a) to read: "A CMS contractor must send notice of the applicable plan's appeal to the beneficiary." We are eliminating the reference to "the contractor adjudicating the redetermination request" issuing the notice in order to allow for operational efficiencies, where applicable. Section 405.947(b) will continue to read: "(b) Issuance and content of the notice must comply with CMS instructions."

6. Appeal Processes/Determining the Identified Debtor

Comment: Commenters requested we clarify that initial determinations (recovery demands) involving liability insurance (including self-insurance), no-fault insurance, or workers' compensation benefits are made only after there is a settlement with a beneficiary.

Response: Recovery demands are appropriate once primary payment responsibility has been demonstrated. Primary payment responsibility can be

demonstrated based upon a settlement, judgment, award, or other payment. See section 1862(b)(2)(B)(ii) of the Act and 42 CFR 411.22 of the regulations.

Comment: A commenter indicated an understanding that issues of medical necessity, beneficiary eligibility, and payment would be decided simultaneously with issues of MSP recovery under the proposed rule.

Response: The commenter's understanding is incorrect because these issues arise at different points in time. Medicare has rules in place to permit conditional payment when a beneficiary has a pending liability insurance (including self-insurance), no-fault insurance, or workers' compensation claim. Our claims processing contractors utilize normal claims processing considerations (including medical necessity rules) in processing such claims. MSP recovery claims come into play once we have information that primary payment responsibility has been demonstrated, which often occurs after items or services have been reimbursed by Medicare.

Comment: A commenter stated that there should be a clear statement regarding the availability of judicial review for applicable plans and requested that such a statement be added in 42 CFR 405.904.

Response: We believe that this clarification is unnecessary. Section 405.904(b) already addresses nonbeneficiary appellants. Additionally, §405.1136 explains that judicial review is available as authorized by statute. (See sections 1869, 1876, and 1879(d) of the Act.)

Comment: Several commenters requested that CMS consider an appeals process other than the process in part 405 subpart I. Requests ranged from suggesting fewer levels

of appeal, using a separate team of experts, to a separate docket and group of ALJs for MSP appeals. Multiple comments noted concern with the current backlog of claims-based appeals at the ALJ level of appeal.

Response: We decline this request. The existing appeals process in 42 CFR part 405 subpart I addresses claims-based Part A and Part B MSP and non-MSP appeals for beneficiaries, providers and suppliers, including appeals of pre-pay denials as well as overpayments. The proposed rule would give party status to a new party (the applicable plan) with respect to specific initial determinations. As the existing process at 42 CFR part 405 subpart I, is currently used for Part A and Part B MSP appeals by beneficiaries, we believe it is an appropriate process for resolving similar disputes with applicable plans.

Comment: A commenter requested that CMS clarify how it determines who/which entity is the identified debtor and whether the identified debtor will generally be the beneficiary.

Response: This question is outside the scope of this rule. (See, section 1862(b)(2)(B)(ii) and (iii) of the Act as well as 42 CFR 411.24 of the regulations regarding who we may pursue for recovery.)

Comment: Several commenters questioned whether: (1) CMS could pursue concurrent claims against the beneficiary and the applicable plan; (2) a claim against a beneficiary rendered a claim against the applicable plan moot (and vice versa); and (3) a demand to the beneficiary (or to the applicable plan) rendered a subsequent claim with respect to the same matter moot against the beneficiary (or the applicable plan, as appropriate).

Response: These comments are outside the scope of this rule as they do not relate to the proposed appeal process. Please note that we will not recover twice for the same item or service. Appeal rights will be given to the beneficiary or applicable plan receiving the demand.

Comment: Commenters stated that applicable plans should have access to beneficiary medical records, including an ability to unmask data on CMS' web portal.

Response: These comments are outside the scope of this rule as they are not related to the proposed appeal process. If we pursue recovery directly from the applicable plan, the applicable plan will be provided with all information related to the demand.

7. Interest and Penalties

Comment: Several commenters requested that penalties (such as civil monetary penalties (CMPs)) and interest be tolled entirely during an appeal, during a good faith appeal, or for some set period of time during an appeal.

Response: The statutory and regulatory provisions for interest and CMPs are outside the scope of this rule. However, we note that a debtor may eliminate the possibility of interest by submitting repayment within the timeframe specified in the demand letter. Such repayment does not eliminate existing appeal rights.

8. Applicability of the Proposed Rule to Medicare Part C and Medicare Part D

Comment: Some commenters requested that the proposed rule be revised to include appeal rights for applicable plans when a Medicare Part C organization or Part D plan pursues an MSP based recovery from the applicable plan.

Response: This request is outside of the scope of this rule. The SMART Act

provision for applicable plan appeals amended only the MSP provisions for Medicare Part A and Part B (section 1862(b) of the Act).

C. Other Proposals

In this section of the final rule, we note the proposed rule included a provision for which we did not receive any public comment. We proposed to amend §405.900, Basis and scope, by revising paragraph (a) to add section 1862(b)(2)(B)(viii) of the Act as part of the statutory basis or Subpart I. Section 1862(b)(2)(B)(viii) requires an appeals process for applicable plans when Medicare pursues recovery directly from the applicable plan. We received no comments on this proposal; and therefore, are finalizing this provision without modification.

D. General and Other Comments

This section of the final rule responds to public comments that are not specific to topics described in section II.B. of this final rule.

Comment: A commenter stated that the amount in controversy requirement should be consistent with the dollar threshold provided for by the SMART Act in section 1862(b)(9) of the Act.

Response: We do not accept this recommendation as the amount in controversy jurisdictional threshold for the appeals process is unrelated to the threshold set in section 1862(b)(9) of the Act. The section 1862(b)(9) of the Act threshold is a dollar threshold regarding the size of the settlement, where, in certain situations, MSP reporting and repayment is not required. The jurisdictional amount in controversy requirements for the appeals process are already set forth in §405.1006 for ALJ hearings and judicial review.

We see no basis for changing the existing thresholds at various levels of appeal based upon the addition of an applicable plan as the party for certain appeals.

Comment: A commenter stated that the proposed rule was inconsistent with the SMART Act requirement for an 11-day web portal response timeframe for "redeterminations and discrepancy resolution."

Response: The SMART Act provisions concerning a web portal are outside the scope of this rule. Moreover, the provisions concerning the web portal discrepancy resolution process (section 1862(b)(2)(B)(vii)(IV) of the Act) specifically state that: (1) the provisions do not establish a right of appeal or set forth an appeal process; and (2) there shall be no administrative or judicial review of the Secretary's determination under section 1862(b)(2)(B)(vii)(IV) of the Act.

Comment: A commenter stated that the proposed rule should address appeals related to the determination of a proposed Workers' Compensation Medicare Set-Aside Arrangement (WCMSA) amount for future medicals.

Response: This issue is outside the scope of this rule. As stated in the preamble to the proposed rule, this issue will be addressed separately.

III. Provisions of the Final Regulations

This rule incorporates all of the provisions of the December 27, 2013 proposed rule with the following exceptions:

- In §405.910(c)(5), we are revising the language to specify when an HICN is needed.
- In §405.924, finalizing the addition of proposed paragraph (b)(15) as paragraph

(b)(16). As a result of this change, we are also making conforming changes to the cross-references to this paragraph in §§405.906(a)(4) and (c), 405.921(c)(1), and 405.926(k).

- In §405.947(a), we are removing the reference to "the contractor adjudicating the redetermination request" issuing the notice in order to allow for operational efficiencies, where applicable. Therefore, paragraph (a) will read "A CMS contractor must send notice of the applicable plan's appeal to the beneficiary."

- In §405.980, we are making a grammatical change to the section heading to match the grammatical change made to the section heading of §405.906.

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

V. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct 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 rule on the economy and the Medicare program is not economically significant. The rule provides a formal administrative appeal process for MSP recovery claims where the applicable plan is the identified debtor, as opposed to the current process which requires a CMS contractor to consider any defense submitted by an applicable plan but does not provide formal administrative appeal rights.

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 less than \$7.5 million to \$38.5 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 rule would 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. The changes would simply expand or formalize existing rights with respect to MSP recovery claims pursued directly from an applicable plan. 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 (RIA) if a rule may have a significant impact on the operations of a substantial

number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We have determined that this rule would not have a significant effect on the operations of a substantial number of small rural hospitals because it would simply expand and/or formalize existing rights with respect to MSP recovery claims pursued directly from an applicable plan. 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 whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2014, that threshold is approximately \$141 million. This rule has no consequential effect on State, local, or tribal governments or on the private sector because it would simply expand and/or formalize existing rights with respect to MSP recovery claims pursued directly from an applicable plan.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Part 405 as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

1. The authority citation for part 405 continues to read as follows:

Authority: Secs. 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

2. Amend § 405.900 by revising paragraph (a) to read as follows:

§ 405.900 Basis and scope.

(a) Statutory basis. This subpart is based on the following provisions of the Act:

- (1) Section 1869(a) through (e) and (g) of the Act.

(2) Section 1862(b)(2)(B)(viii) of the Act.

* * * * *

3. Amend § 405.902 by adding the definition "Applicable plan" in alphabetical order to read as follows:

§ 405.902 Definitions.

* * * * *

Applicable plan means liability insurance (including self-insurance), no-fault insurance, or a workers' compensation law or plan.

* * * * *

4. Amend § 405.906 by:

- A. Revising the section heading.
- B. Adding new paragraph (a)(4).
- C. Amending paragraph (c) by adding a sentence at the end of the paragraph.

The additions and revision read as follows:

§ 405.906 Parties to the initial determinations, redeterminations, reconsiderations, hearings, and reviews.

(a) * * *

(4) An applicable plan for an initial determination under § 405.924(b)(16) where Medicare is pursuing recovery directly from the applicable plan. The applicable plan is the sole party to an initial determination under § 405.924(b)(16) (that is, where Medicare is pursuing recovery directly from the applicable plan).

* * * * *

(c) * * *. This paragraph (c) does not apply to an initial determination with respect to an applicable plan under § 405.924(b)(16).

4. Amend § 405.910 by:

A. Revising paragraph (c)(5)

B. Adding paragraph (e)(4).

C. Revising paragraph (i)(4).

The revisions and addition read as follows:

§ 405.910 Appointed representatives.

* * * * *

(c) * * *

(5) Identify the beneficiary's Medicare health insurance claim number when the beneficiary is the party appointing a representative;

* * * * *

(e) * * *

(4) For an initial determination of a Medicare Secondary Payer recovery claim, an appointment signed by an applicable plan which has party status in accordance with § 405.906(a)(1)(iv) is valid from the date that appointment is signed for the duration of any subsequent appeal, unless the appointment is specifically revoked.

* * * * *

(i) * * *

(4) For initial determinations and appeals involving Medicare Secondary Payer recovery claims where the beneficiary is a party, the adjudicator sends notices and requests to both the beneficiary and the beneficiary's representative, if the beneficiary has a representative.

* * * * *

5. Amend §405.921 by:

A. In paragraph (a)(1), removing ";" and adding in its place "."

B. In paragraph (a)(2) introductory text, removing the phrase "must contain—" and adding in its place the phrase "must contain all of the following:"

C. In paragraphs (a)(2)(i) and (a)(2)(ii), removing ";" and adding in its place "."

D. In paragraph (a)(2)(iii), removing "; and" and adding in its place "."

E. Redesignating the second and third sentences of paragraph (b)(1) as paragraphs (b)(1)(i) and (ii), respectively.

F. In paragraph (b)(2) introductory text, removing the phrase "must contain:" and adding in its place the phrase "must contain all of the following:"

G. In paragraphs (b)(2)(i) through (b)(2)(iv), removing ";" and add in its place "."

H. In paragraph (b)(2)(v), removing "; and" and add in its place "."

I. Adding paragraph (c) to read as follows:

§ 405.921 Notice of initial determination.

* * * * *

(c) Notice of initial determination sent to an applicable plan — (1) Content of the notice. The notice of initial determination under § 405.924(b)(16) must contain all of the following:

(i) The reasons for the determination.

(ii) The procedures for obtaining additional information concerning the contractor's determination, such as a specific provision of the policy, manual, law or regulation used in making the determination.

(iii) Information on the right to a redetermination if the liability insurance (including self-insurance), no-fault insurance, or workers' compensation law or plan is dissatisfied with the outcome of the initial determination and instructions on how to request a redetermination.

(iv) Any other requirements specified by CMS.

(2) [Reserved]

6. Amend §405.924 by:

A. In paragraph (b) introductory text, removing the phrase "with respect to:" and add in its place the phrase "with respect to any of the following:"

B. In paragraph (b)(1) through (b)(11) removing ";" and adding in its place "."

D. In paragraph (b)(12) introductory text, removing the ":" and adding in its place "--".

C. Adding paragraph (b)(16).

The addition reads as follows:

§ 405.924 Actions that are initial determinations.

* * * * *

(b) * * *

(16) Under the Medicare Secondary Payer provisions of section 1862(b) of the Act that Medicare has a recovery claim if Medicare is pursuing recovery directly from an applicable plan. That is, there is an initial determination with respect to the amount and existence of the recovery claim.

* * * * *

7. Amend §405.926 by:

A. In the introductory text, removing the phrase "not limited to –" and adding in its place the phrase "not limited to the following:"

B. In the introductory text of paragraph (a), removing the phrase "for example –" and adding in its place the phrase "for example one of the following:"

C. In paragraphs (a)(1) and (a)(2), removing ";" and adding in its place "."

D. Adding paragraph (a)(3).

E. In paragraphs (b) through (j), removing ";" and adding in its place "."

F. Revising paragraph (k).

G. In paragraphs (l) through (q), removing ";" and adding in its place "."

H. In paragraph (r), removing "; and" and adding in its place "."

The addition and revision read as follows:

§ 405.926 Actions that are not initial determinations.

* * * * *

(a) * * *

(3) Determination under the Medicare Secondary Payer provisions of section 1862(b) of the Act of the debtor for a particular recovery claim.

* * * * *

(k) Except as specified in § 405.924(b)(16), determinations under the Medicare Secondary Payer provisions of section 1862(b) of the Act that Medicare has a recovery against an entity that was or is required or responsible (directly, as an insurer or self-insurer; as a third party administrator; as an employer that sponsors, contributes to or facilitates a group health plan or a large group health plan; or otherwise) to make payment for services or items that were already reimbursed by the Medicare program.

* * * * *

8. Add a new §405.947 to read as follows:

§405.947 Notice to the beneficiary of applicable plan's request for a redetermination.

(a) A CMS contractor must send notice of the applicable plan's appeal to the beneficiary.

(b) Issuance and content of the notice must comply with CMS instructions.

9. Amend §405.980 by revising the section heading to read as follows:

§ 405.980 Reopening of initial determinations, redeterminations, reconsiderations, hearings, and reviews.

* * * * *

CMS-6055-F

Dated: November 20, 2014.

Marilyn Tavenner,

Administrator,

Centers for Medicare & Medicaid Services.

Approved: January 15, 2015.

Sylvia M. Burwell,

Secretary,

Department of Health and Human Services.

BILLING CODE 4120-01-P

CMS-6055-F

[FR Doc. 2015-04143 Filed 02/26/2015 at 8:45 am; Publication Date: 02/27/2015]