

of the maintenance plan. Therefore, when a conformity determination is prepared which assesses conformity for the years before 2021, the 2021 MVEB and the underlying assumptions supporting it would have to be considered. Finally, 40 CFR 93.110 requires the use of the latest planning assumptions in conformity determinations. Thus, the most current motor vehicle and road dust emission factors would need to be used, and we expect the analysis would show greatly reduced PM<sub>10</sub> motor vehicle and road dust emissions from those calculated in the first maintenance plan. In view of the above, EPA is proposing to approve the 2021 PM<sub>10</sub> MVEB of 946 lbs/day.

#### V. Proposed Action

We are proposing to approve the revised Pagosa Springs PM<sub>10</sub> Maintenance Plan that was submitted to us on March 31, 2010, with one exception. We are proposing to disapprove the listing of “voluntary coal and/or wood burning curtailment” as a potential contingency measure in section 5.F.3 of the revised Pagosa Springs PM<sub>10</sub> Maintenance Plan. We are proposing to approve the remainder of the revised maintenance plan because it demonstrates maintenance through 2021 as required by CAA section 175A(b), retains the control measures from the initial PM<sub>10</sub> maintenance plan that EPA approved on June 15, 2001, and meets other CAA requirements for a section 175A maintenance plan. We are proposing to exclude from use in determining that Pagosa Springs continues to attain the 24-hour PM<sub>10</sub> NAAQS exceedances of the 24-hour PM<sub>10</sub> NAAQS that were recorded at the Pagosa Springs PM<sub>10</sub> monitor on March 22, 2009, April 3, 2009, April 5, 2010, April 28, 2010, April 29, 2010, May 11, 2010, and May 22, 2010 because they meet the criteria for exceptional events caused by high wind natural events. We are also proposing to approve the revised maintenance plan’s 2021 transportation conformity MVEB for PM<sub>10</sub> of 946 lbs/day.

#### VI. Statutory and Executive Orders Review

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7410(k), 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA’s role is to approve state choices, provided that they meet the criteria of the CAA. This proposed action merely proposes to approve state law as meeting federal requirements and does not propose to impose additional

requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a “significant regulatory action” subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 USC 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 USC 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 USC 272 note) because application of those requirements would be inconsistent with the CAA; and,
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed action does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP would not be approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

#### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile Organic Compounds.

**Authority:** 42 U.S.C. 7401 *et seq.*

Dated: December 16, 2013.

**Shaun L. McGrath,**

*Regional Administrator, Region 8.*

[FR Doc. 2013–31110 Filed 12–26–13; 8:45 am]

**BILLING CODE 6560–50–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

#### 42 CFR Part 405

[CMS–6055–P]

RIN 0938–AS03

#### Medicare Program; Right of Appeal for Medicare Secondary Payer Determination 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:** Proposed rule.

**SUMMARY:** This proposed rule would implement 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:** To be assured consideration, comments must be received at one of the addresses provided, no later than 5 p.m. on February 25, 2014.

**ADDRESSES:** In commenting, please refer to file code CMS–6055–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed).

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the “More Search Options” tab.

2. *By regular mail.* You may mail written comments to the following address only:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–6055–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-6055-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-1066 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Barbara Wright, (410) 786-4292. Cynthia Ginsburg, (410) 786-2579.

**SUPPLEMENTARY INFORMATION:**

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1850, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, please phone 1-800-743-3951.

**I. Overview and Background**

*A. 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 (hereafter referred to as "settlement"). Section 1862(b)(2)(B) of the Act provides authority for Medicare to make conditional payments and requires the primary plan, if it is responsible for the payment, to reimburse Medicare. 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 "settlements." When a "settlement" occurs, the "settlement" 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." 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.

*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 subparagraph (viii) to section 1862(b)(2)(B) of the Social Security 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. (We note that the industry has expressed interest in an appeal process for determinations regarding proposed Workers' Compensation Medicare Set-

Aside Arrangement (WCMSA) amounts. This proposed rule does not address this issue. It will be addressed separately.)

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. The regulations set forth details on the process including filing requirements, amount in controversy requirements, and other requirements, as appropriate. We propose to include appeals for applicable plans where Medicare is pursuing recovery directly from the applicable plan in this process. 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

After review of the existing regulations in subpart I of 42 CFR Part 405, we are proposing the following changes, as appropriate, in order to include the applicable plan as a party when we pursue recovery directly from the applicable plan.

We propose 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 for Subpart I. Section 1862(b)(2)(B)(viii) of the Act requires an appeals process for applicable plans when Medicare pursues recovery directly from the applicable plan.

In § 405.902, Definitions, we propose to add a definition of the term "applicable plan" for purposes of Subpart I. We would adopt the statutory definition of "applicable plan" in section 1862(b)(8)(F) of the Act, which states that an applicable plan means liability insurance (including self-

insurance), no-fault insurance, or a workers' compensation law or plan.

We propose to amend § 405.906, Parties to initial determinations, redeterminations, reconsiderations, hearings and reviews by adding § 405.906(a)(4) to include the applicable plan as a party for an initial determination where Medicare is pursuing recovery directly from the applicable plan. By "pursuing recovery directly from the applicable plan," we mean that the applicable plan would be the identified debtor, with a recovery demand letter requiring repayment issued to the applicable plan (or its agent or representative). Sending an applicable plan a courtesy copy of a recovery demand letter issued to a beneficiary does not qualify as "pursuing recovery directly from the applicable plan" and does not confer party status on the applicable plan. We are also proposing a technical change in the section heading for § 405.906 (adding a comma before the phrase "and reviews").

Based upon this proposed change to § 405.906, the applicable plan's party status would continue at subsequent levels of appeal. Consistent with section 1862(b)(2)(B)(viii) of the Act, the beneficiary, provider, and/or supplier are not considered parties to an appeal by an applicable plan. Thus, we propose to remove the beneficiary, as well as the provider or supplier, as a party at the redetermination level where Medicare is pursuing recovery directly from the applicable plan. This would also, in effect, remove the beneficiary and the provider or supplier as a party at subsequent levels of appeal where Medicare is pursuing recovery directly from the applicable plan. To implement our proposed changes, we would revise § 405.906 (a) to specify: (1) The circumstances under which an applicable plan is a party to an initial determination; and (2) when an applicable plan is a party to an initial determination, it is the sole party with respect to that determination. Finally, as providers and suppliers would specifically be excluded from party status for an initial determination with respect to an applicable plan, we would make it clear that the special rule for provider or supplier party status in § 405.906(c) does not apply to an initial determination with respect to an applicable plan.

In proposed § 405.910, Appointed representatives, we would add a new paragraph (e)(4) to provide the applicable plan with parallel rights to a beneficiary's rights or a provider or supplier's rights regarding the duration of an appointment of representation

with respect to an MSP recovery claim. We also propose to revise § 405.910(i)(4) so that the special provision that beneficiaries as well as their representatives must receive notices or requests in a MSP recovery case continues to apply only to beneficiaries. For all other parties, including an applicable plan, we would continue to follow the regulatory provisions in § 405.910(i)(1) through (3).

In § 405.921, Notice of initial determination, we propose to add a paragraph (c) to provide specific language regarding requirements for notice to an applicable plan. This language would parallel the existing language in this section regarding the notice to beneficiaries. In addition to these changes, for consistency we have made a number of technical and formatting changes.

In order for an action to be subject to the appeal process set forth in subpart I of 42 CFR Part 405, there must be an "initial determination." We propose, in § 405.924, Actions that are initial determinations, to add a new paragraph § 405.924(b)(15) providing that a determination that Medicare has a recovery claim where Medicare is pursuing recovery directly from an applicable plan is an initial determination with respect to the amount of or existence of the MSP recovery claim. This addition would generally parallel the existing provisions in § 405.924(b)(14) addressing pursuing MSP recovery claims from a beneficiary, provider or supplier. In addition to these changes, for consistency we have made a number of technical and formatting changes.

The MSP provisions in section 1862(b) of the Act establish that Medicare has a direct right of recovery against a primary payer. Currently under § 405.926(k), determinations under these provisions that Medicare has a recovery against a particular primary payer, are not initial determinations for purposes of part 405 subpart I. Consequently, although the primary payer may dispute the recovery claim where Medicare pursues recovery against the applicable plan, it has no formal appeal rights. We propose to revise § 405.926(k) by creating an exception to the broad rule in § 405.926(k) to reflect the proposed addition of § 405.924(b)(15). The proposed revision would provide an exception to § 405.926(k) where there is an initial determination under § 405.924(b)(15) (where Medicare is pursuing recovery directly from an applicable plan). We also propose to add a new § 405.926(a)(3) to clarify that Medicare's determination regarding

who/what entity it will pursue with respect to an 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 the proceeds from payment by the primary plan, Medicare's decision regarding who/what entity it is pursuing recovery from is not subject to appeal. We also propose 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 are proposing several technical changes.

We propose to add a new § 405.947, Notice to the beneficiary of an 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 directly 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 propose that the required notice be issued by the contractor adjudicating the redetermination request in order to ensure clarity and consistency in the wording of the notice.

### III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

### IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

### 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 Social Security 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 proposed rule on the economy and the Medicare program is not economically significant. The proposed rule would provide 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 \$7.0 million to \$35.5 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 proposed 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 proposed 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 603 for

proposed rules 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 proposed 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 2013, that threshold is approximately \$141 million. This proposed 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 proposes to amend 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 reads 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 as follows:

- 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)(15) 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)(15) (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)(15).

■ 4. Amend § 405.910 as follows:

- A. Adding paragraph (e)(4).
■ B. Revising paragraph (i)(4).

The addition and revision read as follows:

§ 405.910 Appointed representatives.

\* \* \* \* \*

(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 as follows:

- 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 paragraph (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)(15) 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 as follows:

- 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)(15).

The addition reads as follows:

§ 405.924 Actions that are initial determinations.

\* \* \* \* \*

(b) \* \* \*

(15) 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 as follows:

- 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)(15), 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 subpart I to read as follows:

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

(a) The contractor adjudicating the redetermination request must send notice of the applicable plan's appeal to the beneficiary.

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

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

Dated: August 29, 2013.

**Marilyn Tavenner,**

*Administrator, Centers for Medicare & Medicaid Services.*

Approved: November 12, 2013.

**Kathleen Sebelius,**

*Secretary, Department of Health and Human Services.*

[FR Doc. 2013–30661 Filed 12–26–13; 8:45 am]

BILLING CODE 4120–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of Inspector General

#### 42 CFR Part 1001

#### Solicitation of New Safe Harbors and Special Fraud Alerts

**AGENCY:** Office of Inspector General (OIG), HHS.

**ACTION:** Notice of intent to develop regulations.

**SUMMARY:** In accordance with section 205 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), this annual notice solicits proposals and recommendations for developing new and modifying existing safe harbor provisions under the Federal anti-kickback statute (section 1128B(b) of the Social Security Act), as well as developing new OIG Special Fraud Alerts.

**DATES:** To ensure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on February 25, 2014.

**ADDRESSES:** In commenting, please refer to file code OIG–122–N. Because of staff and resource limitations, we cannot accept comments by facsimile (fax) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific recommendations and proposals through the Federal eRulemaking Portal at <http://www.regulations.gov>.

2. *By regular, express, or overnight mail.* You may send written comments to the following address: Patrice Drew, Office of Inspector General, Congressional and Regulatory Affairs, Department of Health and Human Services, Attention: OIG–122–N, Room 5541C, Cohen Building, 330 Independence Avenue SW., Washington, DC 20201. Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver, by hand or courier, your written comments before the close of the comment period to Patrice Drew, Office of Inspector General, Department of Health and Human Services, Cohen Building, Room 5541C, 330 Independence Avenue SW., Washington, DC 20201. Because access to the interior of the Cohen Building is not readily available to persons without Federal Government identification, commenters are encouraged to schedule their delivery with one of our staff members at (202) 619–1368. For information on viewing public comments, please see the Supplementary Information section.

**FOR FURTHER INFORMATION CONTACT:** Patrice Drew, Congressional and Regulatory Affairs Liaison, Office of Inspector General, (202) 619–1368.

**SUPPLEMENTARY INFORMATION:**

*Submitting Comments:* We welcome comments from the public on recommendations for developing new or revised safe harbors and Special Fraud Alerts. Please assist us by referencing the file code OIG–122–N.

*Inspection of Public Comments:* All comments received before the end of the comment period are available for viewing by the public. All comments will be posted on <http://www.regulations.gov> as soon as possible after they have been received.

Comments received timely will also be available for public inspection as they are received at Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue SW., Washington, DC 20201, Monday through Friday from 9:30 a.m. to 5 p.m. To schedule an appointment to view public comments, phone (202) 619–1368.

## I. Background

### A. OIG Safe Harbor Provisions

Section 1128B(b) of the Social Security Act (the Act) (42 U.S.C. 1320a–7b(b)) provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration to induce or reward business reimbursable under the Federal health care programs. The offense is classified as a felony and is punishable by fines of up to \$25,000 and imprisonment for up to 5 years. OIG may also impose civil money penalties, in accordance with section 1128A(a)(7) of the Act (42 U.S.C. 1320a–7a(a)(7)), or exclusion from the Federal health care programs, in accordance with section 1128(b)(7) of the Act (42 U.S.C. 1320a–7(b)(7)).

Since the statute on its face is so broad, concern has been expressed for many years that some relatively innocuous commercial arrangements may be subject to criminal prosecution or administrative sanction. In response to the above concern, section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100–93 § 14, the Act, § 1128B(b), 42 U.S.C. 1320a–7b(b), specifically required the development and promulgation of regulations, the so-called “safe harbor” provisions, specifying various payment and business practices that, although potentially capable of inducing referrals of business reimbursable under the Federal health care programs, would not be treated as criminal offenses under the anti-kickback statute and would not serve as a basis for administrative sanctions. OIG safe harbor provisions have been developed “to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial and innocuous arrangements” (56 FR 35952, July 29, 1991). Health care providers and others may voluntarily seek to comply with these provisions so that they have the assurance that their business practices will not be subject to liability under the anti-kickback statute or related administrative authorities. The OIG safe harbor regulations are found at 42 CFR 1001.952.

### B. OIG Special Fraud Alerts

OIG has also periodically issued Special Fraud Alerts to give continuing guidance to health care providers with respect to practices OIG finds potentially fraudulent or abusive. The Special Fraud Alerts encourage industry compliance by giving providers guidance that can be applied to their own practices. OIG Special Fraud Alerts