

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## SOCIAL SECURITY ADMINISTRATION

### 20 CFR Parts 404 and 416

[Docket No. SSA–2016–0015]

RIN 0960–AH92

### Evidence From Statutorily Excluded Medical Sources

AGENCY: Social Security Administration.

ACTION: Notice of proposed rulemaking (NPRM).

**SUMMARY:** In accordance with section 812 of the Bipartisan Budget Act of 2015 (BBA section 812), we propose to revise our rules to explain how we would address evidence furnished by medical sources that meet one of BBA section 812's exclusionary categories (statutorily excluded medical sources). Under this proposed rule, we would not consider evidence furnished by a statutorily excluded medical source unless we find good cause to do so. We propose several circumstances in which we would find good cause, and we also propose to require statutorily excluded medical sources to notify us of their excluded status when they furnish evidence to us. These rules would allow us to fulfill obligations that we have under the Bipartisan Budget Act of 2015 (BBA).

**DATES:** To ensure that we consider your comments, we must receive them by no later than August 9, 2016.

**ADDRESSES:** You may submit comments by any one of three methods—Internet, fax, or mail. Do not submit the same comments multiple times or by more than one method. Regardless of which method you choose, please state that your comments refer to Docket No. SSA–2016–0015 so that we may associate your comments with the correct regulation.

**Caution:** You should be careful to include in your comments only information that you wish to make publicly available. We strongly urge you not to include in your comments any personal information, such as Social

Security numbers or medical information.

1. *Internet:* We strongly recommend that you submit your comments via the Internet. Please visit the Federal eRulemaking portal at <http://www.regulations.gov>. Use the “Search” function to find docket number SSA–2016–0015. The system will issue a tracking number to confirm your submission. You will not be able to view your comment immediately because we must post each comment manually. It may take up to a week for your comment to be viewable.

2. *Fax:* Fax comments to (410) 966–2830.

3. *Mail:* Mail your comments to the Office of Regulations and Reports Clearance, Social Security Administration, 3100 West High Rise Building, 6401 Security Boulevard, Baltimore, Maryland 21235–6401.

Comments and background documents are available for public viewing on the Federal eRulemaking portal at [www.regulations.gov](http://www.regulations.gov) or in person, during regular business hours, by arranging with the contact person identified below.

**FOR FURTHER INFORMATION CONTACT:** Dan O'Brien, Office of Disability Policy, Social Security Administration, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, (410) 597–1632. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213, or TTY 1–800–325–0778, or visit our Internet site, Social Security Online, at [www.socialsecurity.gov](http://www.socialsecurity.gov).

### SUPPLEMENTARY INFORMATION:

#### I. How BBA Section 812 Affects How We Consider Evidence

We consider all evidence we receive when we determine whether an individual is blind or disabled under the Social Security Act (Act).<sup>1</sup> We define evidence as anything you or anyone else submits to us, or that we obtain, that relates to your claim.<sup>2</sup>

The BBA was enacted on November 2, 2015.<sup>3</sup> BBA section 812 amended section 223(d)(5) of the Act, 42 U.S.C. 423(d)(5), by adding a new paragraph “C.” Under this provision, when we

make a disability determination or decision, or when we conduct a continuing disability review (CDR), under titles II or XVI of the Act, we cannot consider evidence furnished by certain sources, unless we have good cause.<sup>4</sup>

Specifically, we may not consider evidence from the following medical sources:

- A medical source convicted of a felony under sections 208 or 1632 of the Act,<sup>5</sup>
- a medical source excluded from participating in any Federal health care program under section 1128 of the Act,<sup>6</sup> or
- a medical source imposed with a civil monetary penalty (CMP),

<sup>4</sup> Public Law 114–74, sec. 812, 129 Stat. 584, 602. Excluding evidence under BBA section 812 does not constitute an exclusion of a medical source from Social Security programs under section 1136 of the Act, 42 U.S.C. 1320b–6.

<sup>5</sup> 42 U.S.C. 408 and 1383a. These sections make it a felony to give false statements or omit information to cause an improper payment, convert a payment intended for someone else, provide us with false information we need for our records concerning the individual's true identity, or misuse a Social Security card or number for the purpose of obtaining or causing an increase in benefits to which the individual is not entitled or eligible.

<sup>6</sup> 42 U.S.C. 1320a–7. This section identifies four mandatory and 16 permissive bases for excluding a provider from participating in all Federal health care programs (as defined in section 1128B(f) of the Act). The four mandatory exclusions from participating in Federal health care programs are: (1) Conviction relating to patient abuse, (2) conviction relating to health care fraud, and (4) felony conviction relating to controlled substance. The 16 permissive exclusions from participating in Federal health care programs are: (1) Conviction relating to fraud, (2) conviction relating to obstruction of an investigation or audit, (3) misdemeanor conviction relating to controlled substance, (4) license revocation or suspension, (5) exclusion or suspension under federal or state health care program, (6) claims for excessive charges or unnecessary services and failure of certain organizations to furnish medically necessary services, (7) fraud, kickbacks, and other prohibited activities, (8) entities controlled by a sanctioned individual, (9) failure to disclose required information, (10) failure to supply requested information on subcontractors and suppliers, (11) failure to supply payment information, (12) failure to grant immediate access, (13) failure to take corrective action, (14) default on health education loan or scholarship obligations, (15) individuals controlling a sanctioned entity, and (16) making false statements or misrepresentation of a material fact. The Department of Health and Human Services' Office of Inspector General (HHS OIG), which administers section 1128 of the Act, may grant a waiver for all but one of these bases. A mandatory exclusion for a conviction related to patient abuse may not be waived.

<sup>1</sup> 42 U.S.C. 416(i), 42 U.S.C. 423(d), and 42 U.S.C. 1382c(a).

<sup>2</sup> 20 CFR 404.1512(b) and 416.912(b).

<sup>3</sup> Pub. L. 114–74, 129 Stat. 584.

assessment, or both, for submitting false evidence under section 1129 of the Act.<sup>7</sup> We refer to the individuals and entities that fall into one or more of these exclusionary categories as statutorily excluded medical sources.

Our Inspector General or the Secretary of Health and Human Services (HHS) will inform us about these statutorily excluded medical sources at such times and to the extent necessary for the effective implementation of this requirement.<sup>8</sup> BBA section 812 requires us to issue regulations to carry out the amendments to the Act by November 2, 2016.<sup>9</sup> BBA section 812 is effective on or after the effective date of the regulations, or by November 2, 2016, whichever is earlier.<sup>10</sup>

## II. Proposed Revisions to Our Rules

We propose to implement BBA section 812 by adding new 20 CFR 404.1503b and 416.903b to state that we will not consider evidence from a statutorily excluded medical source under section 223(d)(5)(C) of the Act, unless we find good cause. Under our proposed rules, we may find good cause to consider evidence from an excluded medical source in the following five situations:

- The evidence from the medical source consists of evidence of treatment that occurred before the date the source was convicted of a felony under section 208 or under section 1632 of the Act;
- The evidence from the medical source consists of evidence of treatment that occurred during a period in which the source was not excluded from participation in any Federal health care program under section 1128 of the Act;
- The evidence from the medical source consists of evidence of treatment that occurred before the date the source received a final decision imposing a CMP, assessment, or both, for submitting false evidence under section 1129 of the Act;
- The sole basis for the medical source's exclusion under section 223(d)(5)(C) of the Act is that the source cannot participate in any Federal health care program under section 1128 of the Act, but the Office of Inspector General of the Department of Health and Human

Services granted a waiver of the section 1128 exclusion; or

- The evidence is a laboratory finding about a physical impairment and there is no indication that the finding is unreliable.

We may find good cause to consider evidence from an excluded medical source in any of these five enumerated situations when we make a disability determination or decision or when we conduct a CDR.

The first three good cause exceptions relate to evidence that pertains to periods prior to the event that would trigger exclusion under BBA section 812, or relate to a period during which the medical source was not excluded from participating in any Federal health care program. We believe that it would be consistent with the purpose of BBA section 812 to find good cause to consider evidence furnished by a medical source of treatment that occurred: (1) Before the source is convicted of a felony under section 208 or 1632 of the Act,<sup>11</sup> (2) outside of the period the source cannot participate in Federal health care programs under section 1128 of the Act,<sup>12</sup> or (3) before the source is issued a final decision imposing a CMP, assessment, or both, for submitting false evidence under section 1129 of the Act.<sup>13</sup> We propose these good cause exceptions in order to protect the public interest. In our view, an undue hardship would be placed on our claimants, and the purposes of BBA section 812 would not be served, unless we include these exceptions. In this situation, there is little risk that the evidence would be tainted by the activity for which the source has been sanctioned or convicted, but a greater risk that we could make an incorrect determination or decision by excluding probative evidence.

Specifically, it would be against the public interest if we barred claimants from ever using evidence furnished by statutorily excluded medical sources concerning treatment that occurred prior to the period those sources qualify for a BBA section 812 exclusion. For example, there may be instances where a statutorily excluded medical source provided treatment to a claimant prior to the period the source qualified for a BBA section 812 exclusion or performed the acts that led to the exclusion. In those instances, and others, we would determine whether to consider the source's evidence concerning such treatment on a case-by-case basis. In addition, section 1128 of the Act

permits some medical sources to resume participating in Federal health care programs after a prescribed exclusion period if they successfully apply for reinstatement.<sup>14</sup> We believe it would also be against the public interest for us to place an absolute bar on claimants from ever using evidence of treatment that occurred after termination of the exclusion under section 1128 when medical sources are permitted to resume their participation in Federal health care programs. We would determine whether to consider that evidence on a case-by-case basis as well.

The fourth good cause exception aligns our rules with those of HHS and provides a consistent approach regarding evidence from affected medical sources. HHS' Office of the Inspector General (HHS OIG) may waive a medical source's exclusion<sup>15</sup> from participating in any Federal health care program for three of the four mandatory exclusions contained in section 1128 of the Act if: (1) It receives a written waiver request from the program's administrator who has determined that the exclusion will pose a hardship to any beneficiary, and (2) the medical source is the sole community physician or sole source of essential specialized services in a community.<sup>16</sup> HHS OIG may waive a medical source's exclusion for one of the permissive exclusions if it determines that imposing the exclusion would not be in the public interest.<sup>17</sup> All waivers may be rescinded if the basis for the waiver ceases to exist.<sup>18</sup> Because a waiver from HHS OIG permits an otherwise excluded medical source to participate in a Federal health care program, we may find good cause to consider evidence from such a medical source consistent with the particular terms of the waiver.

The fifth good cause exception relies on the unique nature of laboratory findings about physical impairments.<sup>19</sup> Laboratory findings about physical impairments are objective, reliable, and reproducible tests that require the least amount of subjective interpretation by a medical source. They are important to help us understand fundamental information about claimants' impairments and whether they are

<sup>74</sup> 2 U.S.C. 1320a-8. This section permits the imposition of a CMP or assessment (or both) for certain offenses. One such offense is making a false statement or representation of a material fact for us to use in determining an initial or continuing right to Social Security disability benefits.

<sup>8</sup> Section 812(a) of Public Law 114-74, 129 Stat. at 602.

<sup>9</sup> Section 812(b) of Public Law 114–74, 129 Stat. at 602.

<sup>10</sup> Section 812(c) of Public Law 114-74, 129 Stat. at 602.

<sup>11</sup> 42 U.S.C. 408 and 42 U.S.C. 1383a.

<sup>12</sup> 42 U.S.C. 1320a-7.

<sup>13</sup> 42 U.S.C. 1320a-8.

<sup>14</sup> 42 U.S.C. 1320a-7.

<sup>15</sup> 42 U.S.C. 1320a-7(c)(3)(B); 42 CFR 1001.1801.

<sup>16</sup> 42 U.S.C. 1320a-7(a), (c)(3)(B); 42 CFR 1001.1801(a). HHS OIG cannot waive an exclusion based on a conviction related to patient abuse.

<sup>17</sup> 42 U.S.C. 1320a-7(b); 42 CFR 1001.1801(c).

<sup>18</sup> 42 CFR 1001.1801(d), (e).

<sup>19</sup> Laboratory findings related to a physical impairment include chemical tests (such as blood tests), electrophysiological studies (such as electrocardiograms and electroencephalograms), pathology reports, and medical imaging (such as x-rays). See 20 CFR 404.1528(c) and 416.928(c).



and ways to minimize the burden on respondents, including the use of automated techniques or other forms of information technology. If you would like to submit comments, please send them to the following locations:

Office of Management and Budget, Attn:  
Desk Officer for SSA, Fax Number:  
202-395-6974, Email address: *OIRA\_*  
*Submission@omb.eop.gov*

Social Security Administration, Attn:  
Reports Clearance Officer, 1333  
Annex, 6401 Security Blvd.,  
Baltimore, MD 21235-0001, Fax  
Number: 410-965-6400, Email:  
*OR.Reports.Clearance@ssa.gov*

You can submit comments until August 9, 2016, which is 60 days after the publication of this notice. However, your comments will be most useful if you send them to SSA by July 11, 2016, which is 30 days after publication. To receive a copy of the OMB clearance package, contact our Reports Clearance Officer using any of the above contact methods. We prefer to receive comments by email or fax.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security—Disability Insurance; 96.002, Social Security—Retirement Insurance; and 96.004, Social Security—Survivors Insurance)

## List of Subjects

## 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors, and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

## 20 CFR Part 416

Administrative practice and procedure, Reporting and recordkeeping requirements, Supplemental Security Income (SSI).

Dated: May 27, 2016.

**Carolyn W. Colvin,**

*Acting Commissioner of Social Security.*

For the reasons set out in the preamble, we propose to amend 20 CFR part 404 subpart P and part 416 subpart I as set forth below:

**PART 404—FEDERAL OLD-AGE,  
SURVIVORS AND DISABILITY  
INSURANCE (1950- )**

### Subpart P—Determining Disability and Blindness

■ 1. The authority citation for subpart P of part 404 continues to read as follows:

**Authority:** Secs. 202, 205(a)–(b) and (d)–(h), 216(i), 221(a), (i), and (j), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a)–(b) and (d)–(h), 416(i), 421(a), (i), and (j), 422(c), 423, 425, and

902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189; sec. 202, Pub. L. 108–203, 118 Stat. 509 (42 U.S.C. 902 note).

■ 2. Add § 404.1503b to read as follows:

**§ 404.1503b Evidence from statutorily excluded medical sources.**

(a) *General.* We will not consider evidence from the following medical sources statutorily excluded under section 223(d)(5)(C) of the Social Security Act (Act), as amended, unless we find good cause under paragraph (b) of this section:

(1) Any medical source that has been convicted of a felony under section 208 or under section 1632 of the Act;

(2) Any medical source that has been excluded from participation in any Federal health care program under section 1128 of the Act; or

(3) Any medical source that has received a final decision imposing a civil monetary penalty or assessment, or both, for submitting false evidence under section 1129 of the Act.

(b) *Good cause.* We may find good cause to consider evidence from a statutorily excluded medical source under section 223(d)(5)(C) of the Act, as amended, if:

(1) The evidence from the medical source consists of evidence of treatment that occurred before the date the source was convicted of a felony under section 208 or under section 1632 of the Act;

(2) The evidence from the medical source consists of evidence of treatment that occurred during a period in which the source was not excluded from participation in any Federal health care program under section 1128 of the Act;

(3) The evidence from the medical source consists of evidence of treatment that occurred before the date the source received a final decision imposing a civil monetary penalty or assessment, or both, for submitting false evidence under section 1129 of the Act:

(4) The sole basis for the medical source's exclusion under section 223(d)(5)(C) of the Act, as amended, is that the source cannot participate in any Federal health care program under section 1128 of the Act, but the Office of Inspector General of the Department of Health and Human Services granted a waiver of the section 1128 exclusion; or

(5) The evidence is a laboratory finding about a physical impairment and there is no indication that the finding is unreliable.

(c) *Statutorily excluded medical sources' reporting requirements.* Statutorily excluded medical sources (as described in paragraph (a) of this section) must inform us in writing that they are excluded under section

223(d)(5)(C) of the Act, as amended, each time they submit evidence related to a claim for benefits under titles II or XVI of the Act. This reporting requirement applies to evidence that statutorily excluded medical sources submit to us either directly or through a representative, claimant, or other individual or entity.

(1) Statutorily excluded medical sources must provide a written statement, which contains the following information:

(i) A heading stating: “WRITTEN STATEMENT REGARDING SECTION 223(d)(5)(C) OF THE SOCIAL SECURITY ACT—DO NOT REMOVE”

(ii) The name and title of the medical source:

(iii) The applicable excluding event(s) stated in paragraphs (a)(1)–(a)(3) of this section;

(iv) The date of the medical source's felony conviction under sections 208 or 1632 of the Act, if applicable;

(v) The date of the imposition of a civil monetary penalty or assessment, or both, for the submission of false evidence, under section 1129 of the Act, if applicable; and

(vi) The basis, effective date, anticipated length of the exclusion, and whether the Office of the Inspector General of the Department of Health and Human Services waived the exclusion, if the excluding event was the medical source's exclusion from participation in any Federal health care program under section 1128 of the Act.

(2) The written statement provided by an excluded medical source may not be removed by any individual or entity prior to submitting evidence to us.

(3) We may request that the excluded medical source provide us with additional information or clarify any information submitted that bears on the medical source's exclusion(s) under section 223(d)(5)(C) of the Act, as amended.

**PART 416—SUPPLEMENTAL  
SECURITY INCOME FOR THE AGED,  
BLIND, AND DISABLED**

## Subpart I—Determining Disability and Blindness

■ 3. The authority citation for subpart I of part 416 continues to read as follows:

**Authority:** Secs. 221(m), 702(a)(5), 1611, 1614, 1619, 1631(a), (c), (d)(1), and (p), and 1633 of the Social Security Act (42 U.S.C. 421(m), 902(a)(5), 1382, 1382c, 1382h, 1383(a), (c), (d)(1), and (p), and 1383(b); secs. 4(c) and 5, 6(c)–(e), 14(a), and 15, Pub. L. 98–460, 98 Stat. 1794, 1801, 1802, and 1808 (42 U.S.C. 421 note, 423 note, and 1382h note).

■ 4. Add § 416.903b to read as follows:

**§ 416.903b Evidence from statutorily excluded medical sources.**

(a) *General.* We will not consider evidence from the following medical sources statutorily excluded under section 223(d)(5)(C) of the Social Security Act (Act), as amended, unless we find good cause under paragraph (b) of this section:

(1) Any medical source that has been convicted of a felony under section 208 or under section 1632 of the Act;

(2) Any medical source that has been excluded from participation in any Federal health care program under section 1128 of the Act; or

(3) Any medical source that has received a final decision imposing a civil monetary penalty or assessment, or both, for submitting false evidence under section 1129 of the Act.

(b) *Good cause.* We may find good cause to consider evidence from a statutorily excluded medical source under section 223(d)(5)(C) of the Act, as amended, if:

(1) The evidence from the medical source consists of evidence of treatment that occurred before the date the source was convicted of a felony under section 208 or under section 1632 of the Act;

(2) The evidence from the medical source consists of evidence of treatment that occurred during a period in which the source was not excluded from participation in any Federal health care program under section 1128 of the Act;

(3) The evidence from the medical source consists of evidence of treatment that occurred before the date the source received a final decision imposing a civil monetary penalty or assessment, or both, for submitting false evidence under section 1129 of the Act;

(4) The sole basis for the medical source's exclusion under section 223(d)(5)(C) of the Act, as amended, is that the source cannot participate in any Federal health care program under section 1128 of the Act, but the Office of Inspector General of the Department of Health and Human Services granted a waiver of the section 1128 exclusion; or

(5) The evidence is a laboratory finding about a physical impairment and there is no indication that the finding is unreliable.

(c) *Statutorily excluded medical sources' reporting requirements.* Statutorily excluded medical sources (as described in paragraph (a) of this section) must inform us in writing that they are excluded under section 223(d)(5)(C) of the Act, as amended, each time they submit evidence related to a claim for benefits under titles II or XVI of the Act. This reporting requirement applies to evidence that

statutorily excluded medical sources submit to us either directly or through a representative, claimant, or other individual or entity.

(1) Statutorily excluded medical sources must provide a written statement, which contains the following information:

(i) A heading stating: "WRITTEN STATEMENT REGARDING SECTION 223(d)(5)(C) OF THE SOCIAL SECURITY ACT—DO NOT REMOVE"

(ii) The name and title of the medical source;

(iii) The applicable excluding event(s) stated in paragraphs (a)(1)–(a)(3) of this section;

(iv) The date of the medical source's felony conviction under sections 208 or 1632 of the Act, if applicable;

(v) The date of the imposition of a civil monetary penalty or assessment, or both, for the submission of false evidence, under section 1129 of the Act, if applicable; and

(vi) The basis, effective date, anticipated length of the exclusion, and whether the Office of the Inspector General of the Department of Health and Human Services waived the exclusion, if the excluding event was the medical source's exclusion from participation in any Federal health care program under section 1128 of the Act.

(2) The written statement provided by an excluded medical source may not be removed by any individual or entity prior to submitting evidence to us.

(3) We may request that the excluded medical source provide us with additional information or clarify any information submitted that bears on the medical source's exclusion(s) under section 223(d)(5)(C) of the Act, as amended.

[FR Doc. 2016–13744 Filed 6–9–16; 8:45 am]

**BILLING CODE 4191–02–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Parts 175, 176, 177, and 178**

[Docket No. FDA–2016–F–1253]

**Breast Cancer Fund, Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, Clean Water Action, Consumer Federation of America, Earthjustice, Environmental Defense Fund, Improving Kids' Environment, Learning Disabilities Association of America, and Natural Resources Defense Council; Filing of Food Additive Petition; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of petition; correction.

**SUMMARY:** The Food and Drug Administration (FDA or we) is correcting a notice entitled "Breast Cancer Fund, Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, Clean Water Action, Consumer Federation of America, Earthjustice, Environmental Defense Fund, Improving Kids' Environment, Learning Disabilities Association of America, and Natural Resources Defense Council; Filing of Food Additive Petition" that appeared in the **Federal Register** of May 20, 2016 (81 FR 31877). The document announced that Breast Cancer Fund, Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, Clean Water Action, Consumer Federation of America, Earthjustice, Environmental Defense Fund, Improving Kids' Environment, Learning Disabilities Association of America, and Natural Resources Defense Council filed a petition proposing that we amend and/or revoke specified regulations to no longer provide for the food contact use of specified ortho-phthalates, but omitted two items. This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:** Kelly Randolph, Center for Food Safety and Applied Nutrition (HFS–275), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1188.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 2016–11866, appearing on page 31878 in the **Federal Register** of Friday, May 20, 2016, the following correction is made:

On page 31878, in the third column, under the heading "§ 175.300 *Resinous and Polymeric Coatings*," the