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 have considered in the rule making. You should not include in your comments any personal information, such as Social Security numbers or medical information. If you submit comments that include your name and address, 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. 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, or
• a medical source excluded from participating in any Federal health care program under section 1128 of the Act, or
• a medical source imposed with a civil monetary penalty (CMP).

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. 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.


The BBA was enacted on November 2, 2015. 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. 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,
• a medical source excluded from participating in any Federal health care program under section 1128 of the Act, or
• a medical source imposed with a civil monetary penalty (CMP).

The BBA enacted on November 2, 2015. 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

1 42 U.S.C. 416(i), 42 U.S.C. 423(d), and 42 U.S.C. 1382c(a).
2 20 CFR 404.1512(b) and 416.912(b).
assessment, or both, for submitting false evidence under section 1129 of the Act. 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. BBA section 812 requires us to issue regulations to carry out the amendments to the Act by November 2, 2016. BBA section 812 is effective on or after the effective date of the regulations, or by November 2, 2016, whichever is earlier.

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 prior to the period the source qualified 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. 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 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. 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. All waivers may be rescinded if the basis for the waiver ceases to exist. 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. 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...
entitled to benefits, such as the onset date and duration of an impairment(s). If we would find that a laboratory finding about a physical impairment in a claim is not reliable, we would not apply the good cause exception.

III. Proposed Notification Process

Our long-term solution to the administration of BBA section 812 is to implement automated evidence matching within our case processing system(s) to identify excludeable evidence. As part of our efforts to comply with BBA section 812’s implementation deadline of November 2, 2016, we propose to require that statutorily excluded medical sources inform us in writing of their BBA section 812 exclusion(s) each time they submit evidence to us that relates to a claim for Social Security disability benefits or payments.

Regarding the content of the written statement, statutorily excluded medical sources would be required to include a heading that states, WRITTEN STATEMENT REGARDING SECTION 223(d)(5)(C) OF THE SOCIAL SECURITY ACT—DO NOT REMOVE.

Immediately following this heading, sources would also need to include their name, title, and the applicable event(s) that triggered their statutory exclusion. Sources convicted of a felony under section 208 or 1632 of the Act would also need to provide the date of their felony conviction. Similarly, sources imposed with a CMP, assessment, or both, for submitting false evidence under section 1129 of the Act, would need to provide the date of the final imposition of the CMP, assessment, or both. Sources that cannot participate in any Federal health care program under section 1128 of the Act would need to include the basis for their exclusion, its effective date and anticipated length, and whether HHS’ OIG waived it.

As stated above, our proposed self-reporting requirement would apply only to statutorily excluded medical sources. This requirement applies when the statutorily excluded medical source submits evidence to us directly or indirectly through a representative, claimant, or other individual or entity. We further propose to require that no individual or entity be permitted to remove a statutorily excluded medical source’s written statement of exclusion prior to submitting the source’s evidence to us. We also seek to reserve the right to request that statutorily excluded medical sources provide us with additional information or clarify any information they submit regarding their exclusion under section 223(d)(5)(C) of the Act.

If statutorily excluded medical sources do not inform us of their excluded status, we may refer the medical source to our Office of the Inspector General for any action it deems appropriate, including investigation and CMP pursuit.

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<tr>
<th>Regulation section</th>
<th>Description of public reporting requirement</th>
<th>Number of respondents (annually)</th>
<th>Frequency of response</th>
<th>Average burden per response (minutes)</th>
<th>Estimated annual burden (hours)</th>
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<td>404.1503b(c) 416.903b(c).</td>
<td>Statutorily excluded medical sources 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. The written statement must include: A heading stating that it is a written statement regarding section 223(d)(5)(C) of the Act; the name and title of the medical source; the applicable excluding event(s); the date of the medical source’s felony conviction if applicable; the date of the imposition of a civil monetary penalty or assessment, or both, for the submission of false evidence if applicable; the basis, effective date, anticipated length of the exclusion, and whether the Office of Inspector General of the Department of Health and Human Services waived the exclusion.</td>
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We submitted an Information Collection Request for clearance to OMB. We are soliciting comments on the burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity;
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.Cleared@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;

(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 was not excluded 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 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, 1382b, 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 1382b 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;

(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 before the date the source was 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.


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