

regulations should be modified, in light of Executive Order 13526 (Dec. 29, 2009).

4. Investigations With Respect to Commercial Availability of Textile Fabric and Yarn in Sub-Saharan African Countries, 19 CFR part 208. The Commission intends to review its regulations addressing investigations with respect to the commercial availability of textile fabric and yarn in Sub-Saharan African countries, to assess whether these regulations can be repealed, in light of the repeal of section 112(c)(2) of the African Growth and Opportunity Act (AGOA), which required the Commission to make determinations with respect to the commercial availability and use of regional textile fabric or yarn in lesser developed beneficiary sub-Saharan African countries in the production of apparel articles receiving U.S. preferential treatment under AGOA (see section 3(a)(2)(B) of Public Law 110–436, October 16, 2008, 122 Stat. 4980). This list is non-exhaustive and the Commission will consider whether other parts of its regulations should also be subject to review within the next two years.

VIII. Publishing the Plan Online

The Commission will publish this plan in the **Federal Register** and on the agency's Web site, at <http://www.usitc.gov>. The Web site includes a page on the Commission's Rules of Practice and Procedure, at http://www.usitc.gov/secretary/fed_reg_notices/rules/. This Rules page will include a link to the plan. Members of the public will be able to post comments about the plan via a link on the page. Commenters may also choose to file comments in paper form to the Secretary to the Commission, room 112, 500 E Street, SW., Washington, DC 20436.

By Order of the Commission.

Issued: October 18, 2011.

James Holbein,

Secretary to the Commission.

[FR Doc. 2011–27363 Filed 10–24–11; 8:45 am]

BILLING CODE 7020–02–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Docket No. SSA–2009–0039]

RIN 0960–AH04

Revised Medical Criteria for Evaluating Congenital Disorders That Affect Multiple Body Systems

AGENCY: Social Security Administration.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to revise the criteria in the Listing of Impairments (listings) that we use to evaluate cases involving impairments that affect multiple body systems in adults and children under titles II and XVI of the Social Security Act (Act). The proposed revisions reflect our program experience and address adjudicator questions we have received since we last comprehensively revised this body system in 2005. We do not expect any decisional differences due the revisions in this body system.

DATES: To ensure that your comments are considered, we must receive them by no later than December 27, 2011.

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–2009–0039 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. Visit the Federal eRulemaking portal at <http://www.regulations.gov>. Use the *Search* function to find docket number SSA–2009–0039. The system will issue you 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:** Address your comments to the Office of Regulations, Social Security Administration, 107 Altmeyer Building, 6401 Security Boulevard, Baltimore, Maryland 21235–6401.

Comments are available for public viewing on the Federal eRulemaking portal at <http://www.regulations.gov> or in person, during regular business hours, by arranging with the contact person identified below.

FOR FURTHER INFORMATION CONTACT: Cheryl Williams, Office of Medical Listings Improvement, Social Security Administration, 6401 Security Boulevard, Baltimore, Maryland 21235–

6401, (410) 965–1020. 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 <http://www.socialsecurity.gov>.

SUPPLEMENTARY INFORMATION:

Why are we proposing to revise the listings for this body system?

We last published final rules making comprehensive revisions to the multiple body systems listings on August 30, 2005.¹ These listings are scheduled to expire on October 31, 2013. However, we decided to propose these revisions now to reflect our program experience and to address adjudicator questions we have received since 2005.²

What revisions are we proposing?

Most of the proposed rules are substantively the same as the current ones. We propose to clarify and reorganize them. We also propose to revise some rules to simplify them and to revise the listings to include different methods for establishing the existence of non-mosaic Down syndrome and other congenital disorders that affect multiple body systems under the listings. We do not expect any decisional differences due the revisions in this body system.

We propose to:

- Revise the name of the body system from “Impairments That Affect Multiple Body Systems” to “Congenital Disorders That Affect Multiple Body Systems”;
- Reorganize and revise the introductory text for the adult listings (section 10.00) and the childhood listings (section 110.00);
- Revise adult listing 10.06 and childhood listing 110.06 for non-mosaic Down syndrome; and
- Make editorial changes in childhood listing 110.08 for catastrophic congenital disorders.

Why are we proposing to change the name of this body system?

We are proposing to change the name of this body system from “Impairments That Affect Multiple Body Systems” to “Congenital Disorders That Affect

¹ 70 FR 51252.

² We published an advance notice of proposed rulemaking (ANPRM) on November 10, 2009. 74 FR 57971. In the ANPRM, we invited interested people and organizations to send us written comments and suggestions about whether and how we should revise these listings. We received two comment letters. We said in the ANPRM that we would not respond to the comment letters, and this NPRM does not reflect the commenters' suggestions. You may read the comment letters at <http://www.regulations.gov> by searching under docket number SSA–2009–0039.

Multiple Body Systems” to clarify that we consider only certain congenital disorders in this body system. We evaluate other disorders that affect more than one body system under the listings that address their specific effects. We

evaluate congenital disorders with single effects under other body systems.

What changes are we proposing to the introductory text of the multiple body systems adult listings?

The following chart provides a comparison of the current introductory text for adults and the proposed introductory text:

Current introductory text	Proposed introductory text
10.00A <i>What Impairment Do We Evaluate Under This Body System?</i>	10.00A <i>Which disorder do we evaluate under this body system?</i>
10.00A1 <i>General.</i>	Revised and included in 10.00A.
10.00A2 <i>What is Down syndrome?</i>	Revised and included in 10.00B.
10.00A3 <i>What is non-mosaic Down syndrome?</i>	10.00B <i>What is non-mosaic Down syndrome?</i>
10.00A4 <i>What is mosaic Down syndrome?</i>	Revised and included in 10.00B and 10.00D.
10.00B <i>What Documentation Do We Need To Establish That You Have Non-Mosaic Down Syndrome?</i>	10.00C <i>What evidence do we need to document non-mosaic Down syndrome under 10.06?</i>
10.00B1 <i>General.</i>	Revised and included in 10.00C.
10.00B2 <i>Definitive chromosomal analysis.</i>	Revised and included in 10.00C.
10.00B3 <i>What if we do not have the results of definitive chromosomal analysis?</i>	Revised and included in 10.00C.
10.00C <i>How Do We Evaluate Other Impairments That Affect Multiple Body Systems?</i>	10.00D <i>How do we evaluate mosaic Down syndrome and other congenital disorders that affect multiple body systems?</i>
	10.00D1 <i>Mosaic Down syndrome.</i>
	10.00D2 <i>Other congenital disorders that affect multiple body systems.</i>
	10.00D3 <i>Evaluating the effects of mosaic Down syndrome or another congenital disorder under the listing.</i>
	10.00E <i>What if your disorder does not meet a listing?</i>

As the chart illustrates, we are proposing to make minor revisions to terms in the introductory text (for example, changing the word “impairment” to “disorder”) and to reorganize the information in the text. We are also proposing to make other changes that we discuss below.

In proposed section 10.00A, we explain that, although there are two forms of Down syndrome, we evaluate only the non-mosaic form under the listing. Non-mosaic Down syndrome occurs when a person has three copies of chromosome 21 in all of their cells or an extra copy of chromosome 21 attached to a different chromosome in all of their cells. Mosaic Down syndrome occurs when some cells have an extra copy of chromosome 21 and other cells are normal, with only two copies of the chromosome. The mosaic form is much less common than the non-mosaic form, and its effects are less likely to be of listing-level severity. In section 10.00D of the proposed rules, we clarify our guidance in current 10.00A4b that we will evaluate impairment(s) caused by mosaic Down syndrome in the appropriate body system, or if the disorder does not meet a listing, consider whether the impairment(s) medically equals the listings.

In proposed section 10.00B, we describe non-mosaic Down syndrome and its effects. We propose to replace the term “mental retardation” with the term “intellectual disability” to conform with recent legislation that revised

certain Federal statutes that referred to “mental retardation” to use the term “intellectual disability” instead.³

In proposed section 10.00C1, we explain that we need a copy of a laboratory report of karyotype analysis to establish that a claimant’s non-mosaic Down syndrome meets proposed listing 10.06A. Karyotype analysis clarifies whether the Down syndrome is the non-mosaic or mosaic form. The report must either be signed by a physician or, if unsigned, accompanied by a statement from a physician indicating that the person has Down syndrome.

In proposed section 10.00C1, we explain that:

- We will not purchase karyotype analysis, consistent with our longstanding policy that we will not purchase genetic testing, and
- We will not accept the fluorescence in situ hybridization (FISH) test—a screening test—and that it is not equivalent to the requirement for karyotype analysis.

Our rules require evidence from an “acceptable medical source” to establish the existence of a medically determinable impairment, and a physician is the only acceptable source for establishing that a person has Down syndrome.⁴ The physician does not

³ Rosa’s Law, Pub. L. 111–256 (Oct. 5, 2010). It also revised references from “a mentally retarded individual” to “an individual with an intellectual disability.”

⁴ We define the terms “medically determinable impairment” and “acceptable medical source” in 20 CFR 404.1508, 404.1513, 416.908, and 416.913.

need to provide any additional information to establish the existence of the disorder, as we explain in proposed section 10.00C1c.

Proposed section 10.00C2 corresponds in part to current section 10.00B3 and explains the evidence we need to establish that a claimant’s non-mosaic Down syndrome meets the criteria of proposed listing 10.06B or 10.06C.

- In proposed section 10.00C2a, we explain how we would establish that non-mosaic Down syndrome meets proposed listing 10.06B. This proposed listing covers claimants who have had definitive laboratory testing, but who have not provided us with a copy of their laboratory reports. Our current rules require detailed evidence describing a person’s physical appearance and other evidence that is “persuasive” that the claimant has non-mosaic Down syndrome. Since the great majority of people with Down syndrome have the non-mosaic form, we will no longer require the physician to describe the person’s physical features. Instead, to meet proposed listing 10.06B, a physician must report that (1) The claimant has Down syndrome that is consistent with prior karyotype analysis and (2) the claimant has the distinctive physical features of the disorder.

- In proposed section 10.00C2b, we explain a new method for establishing disability based on non-mosaic Down syndrome under proposed listing 10.06C. The proposed listing, which is also based on our adjudicative

experience, allows for a finding of disability when the claimant has not had definitive laboratory testing or we have no information about karyotype analysis results even if the person did have a test. Because we do not have definitive test results, we would require a more detailed description of the clinical features of the disorder and evidence that the claimant's functioning is consistent with a diagnosis of non-mosaic Down syndrome. The proposed provision would allow us to find that a claimant does not have non-mosaic Down syndrome if we have other evidence that is inconsistent with a diagnosis of the disorder. This provision is similar to current 10.00B3 that provides "the report must be consistent with other evidence in your case record." While we do not need to obtain additional evidence, we must consider any other evidence in the case record to

ensure that it is consistent with the diagnosis.

What changes are we proposing to the multiple body systems listings for adults?

We propose to revise current listing 10.06, *Non-mosaic Down syndrome*, to make it more specific. A claimant can demonstrate that he or she meets proposed listing 10.06 in one of three ways.

- Under proposed listing 10.06A, a claimant can demonstrate that he or she meets the listing based solely on a laboratory report of karyotype analysis that a physician signed or on a laboratory report of karyotype analysis that is not signed by a physician but is accompanied by a physician's statement that the person has Down syndrome;
- Under proposed listing 10.06B, a claimant can demonstrate that he or she meets the listing based on a physician's

statement that the claimant has Down syndrome that is consistent with prior karyotype analysis demonstrating chromosome 21 trisomy or chromosome 21 translocation and that the person has the distinctive physical features of Down syndrome; and

- Under proposed listing 10.06C, a person can meet the listing when we do not have a copy of, or information about, laboratory testing, but we have a physician's report that the person has Down syndrome with distinctive physical features and evidence that the person functions at a level consistent with non-mosaic Down syndrome.

What changes are we proposing to the introductory text of the congenital disorders listings for children?

The following chart provides a comparison of the current introductory text for children and the proposed introductory text:

Current introductory text	Proposed introductory text
110.00A <i>What Kinds of Impairments Do We Evaluate Under This Body System?</i>	110.00A <i>Which disorders do we evaluate under this body system?</i>
110.00A1 <i>General.</i>	Revised and included in 110.00A.
110.00A2 <i>What is Down syndrome?</i>	Revised and included in 110.00B.
110.00A3 <i>What is non-mosaic Down syndrome?</i>	110.00B <i>What is non-mosaic Down syndrome?</i>
110.00A4 <i>What is mosaic Down syndrome?</i>	Revised and included in 110.00F.
110.00A5 <i>What are catastrophic congenital abnormalities or diseases?</i>	Revised and included in 110.00D.
110.00B <i>What Documentation Do We Need To Establish That You Have an Impairment That Affects Multiple Body Systems?</i>	110.00C <i>What evidence do we need to document non-mosaic Down syndrome under 110.06?</i>
110.00B1 <i>General.</i>	Revised and included in 110.00C.
110.00B2 <i>Non-mosaic Down syndrome (110.06)</i>	Revised and included in 110.00C.
110.00B3 <i>Catastrophic congenital abnormalities or diseases (110.08)</i>	Revised and included in 110.00D and 110.00E.
110.00C <i>How Do We Evaluate Other Impairments That Affect Multiple Body Systems and That Do Not Meet the Criteria of the Listings in This Body System?</i>	110.00D <i>What are catastrophic congenital disorders?</i>
	110.00E <i>What evidence do we need under 110.08?</i>
	110.00F <i>How do we evaluate mosaic Down syndrome and other congenital disorders that affect multiple body systems?</i>
	110.00F1 <i>Mosaic Down syndrome.</i>
	110.00F2 <i>Other congenital disorders that affect multiple body systems.</i>
	110.00F3 <i>Evaluating the effects of mosaic Down syndrome or another congenital disorder under the listings.</i>
	110.00G <i>What if your disorder does not meet a listing?</i>

We propose to reorganize and revise the introductory text as in the adult rules. Since we are proposing the same changes in the childhood rules that correspond to the adult rules, we do not summarize them here. Proposed section 110.00C is identical to proposed section 10.00C and includes a reference to a child's "work history." We included this phrase in the child rules because the listings in part B are for people up to the age of 18, and some older adolescents have worked.

As under the current listings, the proposed childhood listings include a listing that we do not include in the adult rules—proposed listing 110.08 for

"catastrophic" congenital disorders. We propose to reorganize and clarify the introductory text that explains listing 110.08 as follows:

- In proposed section 110.00D, we briefly explain the kinds of disorders we would evaluate under proposed listing 110.08 and provide some examples of these disorders. In the current rules, we include these examples in listing 110.08. We propose to move them to the introductory text so there is no implication that the examples in current listings 110.08A and B are the sole disorders covered by these listings.

- Proposed section 110.00E corresponds to current section

110.00B3. We propose changes in this section to make it similar to proposed sections 10.00C and 110.00C for non-mosaic Down syndrome. For example, the current rule requires both a clinical description of the diagnostic physical features of the disorder and the report of the definitive laboratory study establishing the diagnosis. Since the second requirement is for a *definitive* laboratory study, we do not believe that we also need a description of the diagnostic clinical features in such cases. We believe that we can simplify the rule and make some favorable determinations more quickly.

What changes are we proposing to the congenital disorders listings for children?

We propose to revise current listing 110.06, *Non-mosaic Down syndrome*, in the same way as proposed adult listing 10.06. We would revise listings 110.08A and B by moving the examples from these current listings to proposed section 110.00D in the introductory text. We would also replace the phrase “profoundly impaired” in listing 110.08A with the phrase “very serious interference” the same phrase we use in proposed listing 110.08B. Both listings should have the same severity criterion. The criterion we propose is based on current listing 110.08B, which uses the phrase “interferes very seriously” and is a term we use in other rules. We would also clarify in proposed section 110.00D that “very seriously” has the same meaning as our definition of the term “extreme” in our rules for determining functional equivalence for children.⁵

What is our authority to make rules and set procedures for determining whether a person is disabled under the statutory definition?

The Act authorizes us to make rules and regulations and to establish necessary and appropriate procedures to implement them. Sections 205(a), 702(a)(5), and 1631(d)(1).

How long would these proposed rules be effective?

If we publish these proposed rules as final rules, they will remain in effect for 5 years after the date they become effective, unless we extend them, or revise and issue them again.

Clarity of These Proposed Rules

Executive Order 12866, as supplemented by Executive Order 13563, requires each agency to write all rules in plain language. In addition to your substantive comments on these proposed rules, we invite your comments on how to make them easier to understand.

For example:

- Would more, but shorter, sections be better?
- Are the requirements in the rules clearly stated?
- Have we organized the material to suit your needs?
- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the rules easier to understand?
- Do the rules contain technical language or jargon that is not clear?

- Would a different format make the rules easier to understand, *e.g.*, grouping and order of sections, use of headings, paragraphing?

When will we start to use these rules?

We will not use these rules until we evaluate public comments and publish final rules in the **Federal Register**. All final rules we issue include an effective date. We will continue to use our current rules until that date. If we publish final rules, we will include a summary of those relevant comments we received along with responses and an explanation of how we will apply the new rules.

Regulatory Procedures

Executive Order 12866, as Supplemented by Executive Order 13563

We have consulted with the Office of Management and Budget (OMB) and determined that this NPRM meets the criteria for a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563. Therefore, OMB reviewed it.

Regulatory Flexibility Act

We certify that this NPRM will not have a significant economic impact on a substantial number of small entities because they affect individuals only. Therefore, the Regulatory Flexibility Act, as amended, does not require us to prepare a regulatory flexibility analysis.

Paperwork Reduction Act

These rules do not create any new or affect any existing collections, and therefore, do not require Office of Management and Budget approval under the Paperwork Reduction Act.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security—Disability Insurance; 96.002, Social Security—Retirement Insurance; 96.004, Social Security—Survivors Insurance; and 96.006, Supplemental Security Income).

List of Subjects in 20 CFR Part 404

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

Michael J. Astrue,

Commissioner of Social Security.

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

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

Subpart P—[Amended]

1. The authority citation for subpart P of part 404 is revised 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. Amend appendix 1 to subpart P of part 404 by revising item 11 of the introductory text before part A of appendix 1 to read as follows:

Appendix 1 to Subpart P of Part 404—Listing of Impairments

* * * * *

11. Congenital Disorders That Affect Multiple Body Systems (10.00 and 110.00): [Insert date 5 years from the effective date of the final rules].

* * * * *

3. Amend part A of appendix 1 to subpart P of part 404 by revising the body system name for section 10.00 in the table of contents to read as follows:

* * * * *

10.00 Congenital Disorders That Affect Multiple Body Systems.

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4. Revise section 10.00 in part A of appendix 1 to subpart P of part 404 to read as follows:

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Part A

* * * * *

10.00 Congenital Disorders That Affect Multiple Body Systems

A. *Which disorder do we evaluate under this body system?* Although Down syndrome exists in non-mosaic and mosaic forms, we evaluate only non-mosaic Down syndrome under this body system.

B. *What is non-mosaic Down syndrome?* Non-mosaic Down syndrome is a genetic disorder. Most people with non-mosaic Down syndrome have three copies of chromosome 21 in all of their cells (chromosome 21 trisomy); some have an extra copy of chromosome 21 attached to a different chromosome in all of their cells (chromosome 21 translocation). Virtually all people with non-mosaic Down syndrome have characteristic facial or other physical features, delayed physical development, and intellectual disability. People with non-mosaic Down syndrome may also have congenital heart disease, impaired vision, hearing problems, and other disorders. We evaluate non-mosaic Down syndrome under 10.06. If you have non-mosaic Down syndrome documented as described in 10.00C, we consider you disabled from birth.

⁵ See 20 CFR 416.926a(e)(3).

C. What evidence do we need to document non-mosaic Down syndrome under 10.06?

1. Under 10.06A, we will find you disabled based on laboratory findings.

a. To find that your disorder meets 10.06A, we need a copy of the laboratory report of karyotype analysis, which is the definitive test to establish non-mosaic Down syndrome. We will not purchase karyotype analysis. We will not accept a fluorescence in situ hybridization (FISH) test because it does not distinguish between the mosaic and non-mosaic forms of Down syndrome.

b. If a physician (see §§ 404.1513(a)(1) and 416.913(a)(1) of this chapter) has not signed the laboratory report of karyotype analysis, the evidence must also include a physician's statement that you have Down syndrome.

c. For purposes of 10.06A, we do not require additional evidence stating that you have the distinctive facial or other physical features of Down syndrome.

2. If we do not have a laboratory report of karyotype analysis showing that you have non-mosaic Down syndrome, we may find you disabled under 10.06B or 10.06C.

a. Under 10.06B, we need a physician's report stating: (i) your karyotype diagnosis or evidence that documents your type of Down syndrome is consistent with prior karyotype analysis (for example, reference to a diagnosis of "trisomy 21"), and (ii) that you have the distinctive facial or other physical features of Down syndrome. We do not require a detailed description of the facial or other physical features of the disorder. However, we will not find that your disorder meets 10.06B if we have evidence—such as evidence of functioning inconsistent with the diagnosis—that indicates that you do not have non-mosaic Down syndrome.

b. If we do not have evidence of prior karyotype analysis (you did not have testing, or you had testing but we do not have information from a physician about the test results), we will find that your disorder meets 10.06C if we have: (i) a physician's report stating that you have the distinctive facial or other physical features of Down syndrome, and (ii) evidence that your functioning is consistent with a diagnosis of non-mosaic Down syndrome. This evidence may include medical or nonmedical information about your physical and mental abilities, including information about your education, work history, or the results of psychological testing. However, we will not find that your disorder meets 10.06C if we have evidence—such as evidence of functioning inconsistent with the diagnosis—that indicates that you do not have non-mosaic Down syndrome.

D. How do we evaluate mosaic down syndrome and other congenital disorders that affect multiple body systems?

1. *Mosaic Down syndrome.* Approximately 2 percent of people with Down syndrome have the mosaic form. In mosaic Down syndrome, there are some cells with an extra copy of chromosome 21 and other cells with the normal two copies of chromosome 21. Mosaic Down syndrome can be so slight as to be undetected clinically, but it can also be profound and disabling, affecting various body systems.

2. *Other congenital disorders that affect multiple body systems.* Other congenital

disorders, such as congenital anomalies, chromosomal disorders, dysmorphic syndromes, inborn metabolic syndromes, and perinatal infectious diseases, can cause deviation from, or interruption of, the normal function of the body or can interfere with development. Examples of these disorders include both the juvenile and late-onset forms of Tay-Sachs disease, trisomy X syndrome (XXX syndrome), fragile X syndrome, phenylketonuria (PKU), caudal regression syndrome, and fetal alcohol syndrome. For these disorders and other disorders like them, the degree of deviation, interruption, or interference, as well as the resulting functional limitations and their progression, may vary widely from person to person and may affect different body systems.

3. *Evaluating the effects of mosaic Down syndrome or another congenital disorder under the listings.* When the effects of mosaic Down syndrome or another congenital disorder that affects multiple body systems are sufficiently severe we evaluate the disorder under the appropriate affected body system(s), such as musculoskeletal, special senses and speech, neurological, or mental disorders. Otherwise, we evaluate the specific functional limitations that result from the disorder under our other rules described in 10.00E.

E. *What if your disorder does not meet a listing?* If you have a severe medically determinable impairment(s) that does not meet a listing, we will consider whether your impairment(s) medically equals a listing. See §§ 404.1526 and 416.926 of this chapter. If your impairment(s) does not meet or medically equal a listing, you may or may not have the residual functional capacity to engage in substantial gainful activity. We proceed to the fourth, and if necessary, the fifth steps of the sequential evaluation process in §§ 404.1520 and 416.920 of this chapter. We use the rules in §§ 404.1594 and 416.994 of this chapter, as appropriate, when we decide whether you continue to be disabled.

10.01 Category of Impairments, Congenital Disorders That Affect Multiple Body Systems

10.06 *Non-mosaic Down syndrome* (chromosome 21 trisomy or chromosome 21 translocation), documented by:

A. A laboratory report of karyotype analysis signed by a physician, or both a laboratory report of karyotype analysis not signed by a physician and a statement by a physician that you have Down syndrome (see 10.00C1).

Or

B. A physician's report stating that you have chromosome 21 trisomy or chromosome 21 translocation consistent with prior karyotype analysis with the distinctive facial or other physical features of Down syndrome (see 10.00C2a).

OR

C. A physician's report stating that you have Down syndrome with the distinctive facial or other physical features and evidence demonstrating that you function at a level consistent with non-mosaic Down syndrome (see 10.00C2b).

* * * * *

5. Amend part B of appendix 1 to subpart P of part 404 by revising the body system name in section 110.00 in the table of contents to read as follows:

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110.00 Congenital Disorders That Affect Multiple Body Systems

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6. Revise section 110.00 in part B of appendix 1 to subpart P of part 404 to read as follows:

Appendix 1 to Subpart P of Part 404—Listing of Impairments

* * * * *

Part B

* * * * *

110.00 Congenital Disorders That Affect Multiple Body Systems

A. *Which disorders do we evaluate under this body system?* We evaluate non-mosaic Down syndrome and catastrophic congenital disorders under this body system.

B. *What is non-mosaic Down syndrome?* Non-mosaic Down syndrome is a genetic disorder. Most children with non-mosaic Down syndrome have three copies of chromosome 21 in all of their cells (chromosome 21 trisomy); some have an extra copy of chromosome 21 attached to a different chromosome in all of their cells (chromosome 21 translocation). Virtually all children with non-mosaic Down syndrome have characteristic facial or other physical features, delayed physical development, and intellectual disability. Children with non-mosaic Down syndrome may also have congenital heart disease, impaired vision, hearing problems, and other disorders. We evaluate non-mosaic Down syndrome under 110.06. If you have non-mosaic Down syndrome documented as described in 110.00C, we consider you disabled from birth.

C. What evidence do we need to document non-mosaic Down syndrome under 110.06?

1. Under 110.06A, we will find you disabled based on laboratory findings.

a. To find that your disorder meets 110.06A, we need a copy of the laboratory report of karyotype analysis, which is the definitive test to establish non-mosaic Down syndrome. We will not purchase karyotype analysis. We will not accept a fluorescence in situ hybridization (FISH) test because it does not distinguish between the mosaic and non-mosaic forms of Down syndrome.

b. If a physician (see §§ 404.1513(a)(1) and 416.913(a)(1) of this chapter) has not signed the laboratory report of karyotype analysis, the evidence must also include a physician's statement that you have Down syndrome.

c. For purposes of 110.06A, we do not require evidence stating that you have the distinctive facial or other physical features of Down syndrome.

2. If we do not have a laboratory report of karyotype analysis documenting that you have non-mosaic Down syndrome, we may find you disabled under 110.06B or 110.06C.

a. Under 110.06B, we need a physician's report stating: (i) Your karyotype diagnosis or

evidence that documents your type of Down syndrome that is consistent with prior karyotype analysis (for example, reference to a diagnosis of “trisomy 21”) and (ii) that you have the distinctive facial or other physical features of Down syndrome. We do not require a detailed description of the facial or other physical features of the disorder. However, we will not find that your disorder meets 110.06B if we have evidence—such as evidence of functioning inconsistent with the diagnosis—that indicates that you do not have non-mosaic Down syndrome.

b. If we do not have evidence of prior karyotype analysis (you did not have testing, or you had testing but we do not have information from a physician about the test results), we will find that your disorder meets 110.06C if we have: (i) a physician’s report stating that you have the distinctive facial or other physical features of Down syndrome and (ii) evidence that your functioning is consistent with a diagnosis of non-mosaic Down syndrome. This evidence may include medical or nonmedical information about your physical and mental abilities, including information about your development, education, work history, or the results of psychological testing. However, we will not find that your disorder meets 110.06C if we have evidence—such as evidence of functioning inconsistent with the diagnosis—that indicates that you do not have non-mosaic Down syndrome.

D. *What are catastrophic congenital disorders?* Some catastrophic congenital disorders, such as anencephaly, cyclopia, chromosome 13 trisomy (Patau syndrome or trisomy D), and chromosome 18 trisomy (Edwards’ syndrome or trisomy E) are usually expected to result in early death. Others such as cri du chat syndrome (chromosome 5p deletion syndrome) and the infantile onset form of Tay-Sachs disease interfere very seriously with development. We evaluate catastrophic congenital disorders under 110.08. The term “very seriously” in 110.08 has the same meaning as in the term “extreme” in § 416.926a(e)(3) of this chapter.

E. *What evidence do we need under 110.08?*

We need one of the following to determine if your disorder meets 110.08A or B:

1. A laboratory report of the definitive test that documents your disorder (for example, genetic analysis or evidence of biochemical abnormalities) signed by a physician.

2. A laboratory report of the definitive test that documents your disorder that is not signed by a physician *and* a report from a physician stating that you have the disorder.

3. A report from a physician stating that you have the disorder with the typical clinical features of the disorder and that you had definitive testing that documented your disorder. In this case, we will find that your disorder meets 110.08A or B unless we have evidence that indicates that you do not have the disorder.

4. If we do not have the definitive laboratory evidence we need under E1, E2, or E3, we will find that your disorder meets 110.08A or B if we have: (i) a report from a physician stating that you have the disorder and that you have the typical clinical features of the disorder, *and* (ii) other evidence that

supports the diagnosis. This evidence may include medical or nonmedical information about your development and functioning.

5. For obvious catastrophic congenital anomalies that are expected to result in early death, such as anencephaly and cyclopia, we need evidence from a physician that demonstrates that the infant has the characteristic physical features of the disorder. In these rare cases, we do not need laboratory testing or any other evidence that confirms the disorder.

F. *How do we evaluate mosaic Down syndrome and other congenital disorders that affect multiple body systems?*

1. *Mosaic Down syndrome.* Approximately 2 percent of children with Down syndrome have the mosaic form. In mosaic Down syndrome, there are some cells with an extra copy of chromosome 21 and other cells with the normal two copies of chromosome 21. Mosaic Down syndrome can be so slight as to be undetected clinically, but it can also be profound and disabling, affecting various body systems.

2. *Other congenital disorders that affect multiple body systems.* Other congenital disorders, such as congenital anomalies, chromosomal disorders, dysmorphic syndromes, inborn metabolic syndromes, and perinatal infectious diseases, can cause deviation from, or interruption of, the normal function of the body or can interfere with development. Examples of these disorders include both the juvenile and late-onset forms of Tay-Sachs disease, trisomy X syndrome (XXX syndrome), fragile X syndrome, phenylketonuria (PKU), caudal regression syndrome, and fetal alcohol syndrome. For these disorders and other disorders like them, the degree of deviation, interruption, or interference, as well as the resulting functional limitations and their progression, may vary widely from child to child and may affect different body systems.

3. *Evaluating the effects of mosaic Down syndrome or another congenital disorder under the listings.* When the effects of mosaic Down syndrome or another congenital disorder that affects multiple body systems are sufficiently severe we evaluate the disorder under the appropriate affected body system(s), such as musculoskeletal, special senses and speech, neurological, or mental disorders. Otherwise, we evaluate the specific functional limitations that result from the disorder under our other rules described in 110.00G.

G. *What if your disorder does not meet a listing?* If you have a severe medically determinable impairment(s) that does not meet a listing, we will consider whether your impairment(s) medically equals a listing. See § 416.926 of this chapter. If your impairment(s) does not meet or medically equal a listing, we will consider whether it functionally equals the listings. See §§ 416.924a and 416.926a of this chapter. We use the rules in § 416.994a of this chapter when we decide whether you continue to be disabled.

110.01 Category of Impairments, Congenital Disorders That Affect Multiple Body Systems

110.06 *Non-mosaic Down syndrome* (chromosome 21 trisomy or chromosome 21 translocation), documented by:

A. A laboratory report of karyotype analysis signed by a physician, or both a laboratory report of karyotype analysis not signed by a physician *and* a statement by a physician that the child has Down syndrome (see 110.00C1).

OR

B. A physician’s report stating that the child has chromosome 21 trisomy or chromosome 21 translocation consistent with karyotype analysis with the distinctive facial or other physical features of Down syndrome (see 110.00C2a).

OR

C. A physician’s report stating that the child has Down syndrome with the distinctive facial or other physical features *and* evidence demonstrating that the child is functioning at the level of a child with non-mosaic Down syndrome (see 110.00C2b).

110.08 *A catastrophic congenital disorder* (see 110.00D and 110.00E) with:

A. Death usually expected within the first months of life.

OR

B. Very serious interference with development or functioning.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–109006–11]

RIN 1545–BK13

Modifications of Certain Derivative Contracts; Hearing Cancellation

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Cancellation of notice of public hearing on notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: This document cancels a public hearing on notice of proposed rulemaking by cross-reference to temporary regulations relating to whether an exchange for purposes of § 1.1001–1(a) occurs for the nonassigning counterparty when there is an assignment of certain derivative contracts.

DATES: The public hearing, originally scheduled for October 27, 2011 at 10 a.m., is cancelled.

FOR FURTHER INFORMATION CONTACT: Richard A. Hurst of the Publications and