

Peoria, IL, General Downing—Peoria Intl, RNAV (GPS) RWY 4, Amdt 2
 Peoria, IL, General Downing—Peoria Intl, RNAV (GPS) RWY 13, Amdt 1A
 Peoria, IL, General Downing—Peoria Intl, RNAV (GPS) RWY 22, Amdt 1B
 Peoria, IL, General Downing—Peoria Intl, RNAV (GPS) RWY 31, Amdt 1B
 Peoria, IL, General Downing—Peoria Intl, Takeoff Minimums and Obstacle DP, Amdt 2
 Peoria, IL, Mount Hawley Auxiliary, VOR—A, Amdt 4, CANCELED
 Peoria, IL, Mount Hawley Auxiliary, VOR/DME—A, Orig
 Baton Rouge, LA, Baton Rouge Metropolitan, Ryan Field, ILS OR LOC RWY 13, Amdt 27E
 Baton Rouge, LA, Baton Rouge Metropolitan, Ryan Field, ILS OR LOC RWY 22R, Amdt 11B
 Baton Rouge, LA, Baton Rouge Metropolitan, Ryan Field, NDB RWY 31, Amdt 2D
 Baton Rouge, LA, Baton Rouge Metropolitan, Ryan Field, RNAV (GPS) RWY 31, Amdt 1D
 Baton Rouge, LA, Baton Rouge Metropolitan, Ryan Field, VOR RWY 4L, Amdt 17C
 Baton Rouge, LA, Baton Rouge Metropolitan, Ryan Field, VOR/DME RWY 22R, Amdt 8H
 Gonzales, LA, Louisiana Rgnl, RNAV (GPS) RWY 17, Amdt 1B
 Gonzales, LA, Louisiana Rgnl, VOR/DME—A, Amdt 2A
 Lafayette, LA, Lafayette Rgnl, RNAV (GPS) RWY 29, Orig-B
 New Roads, LA, False River Rgnl, LOC RWY 36, Amdt 1A
 New Roads, LA, False River Rgnl, NDB RWY 36, Amdt 2A
 New Roads, LA, False River Rgnl, RNAV (GPS) RWY 18, Orig-A
 New Roads, LA, False River Rgnl, RNAV (GPS) RWY 36, Orig-A
 New Roads, LA, False River Rgnl, VOR/DME—A, Amdt 4A
 Detroit, MI, Willow Run, Takeoff Minimums and Obstacle DP, Amdt 10A
 Minneapolis, MN, Minneapolis-St Paul Intl/Wold-Chamberlain, ILS V RWY 35 (CONVERGING), Amdt 4
 Minneapolis, MN, Minneapolis-St Paul Intl/Wold-Chamberlain, ILS Z OR LOC RWY 35, ILS Z RWY 35 (SA CAT I), ILS Z RWY 35 (CAT II), ILS Z RWY 35 (CAT III), Amdt 4
 Minneapolis, MN, Minneapolis-St Paul Intl/Wold-Chamberlain, RNAV (GPS) Z RWY 30L, Amdt 4
 Minneapolis, MN, Minneapolis-St Paul Intl/Wold-Chamberlain, RNAV (GPS) Z RWY 35, Amdt 3
 Minneapolis, MN, Minneapolis-St Paul Intl/Wold-Chamberlain, RNAV (RNP) Y RWY 12L, Orig

Minneapolis, MN, Minneapolis-St Paul Intl/Wold-Chamberlain, RNAV (RNP) Y RWY 12R, Orig
 Minneapolis, MN, Minneapolis-St Paul Intl/Wold-Chamberlain, RNAV (RNP) Y RWY 30L, Orig
 New Ulm, MN, New Ulm Muni, NDB RWY 15, Amdt 2A, CANCELED
 New Ulm, MN, New Ulm Muni, NDB RWY 33, Amdt 2A, CANCELED
 Steele, MO, Steele Muni, RNAV (GPS) RWY 18, Orig
 Steele, MO, Steele Muni, RNAV (GPS) RWY 36, Orig
 Steele, MO, Steele Muni, Takeoff Minimums and Obstacle DP, Orig
 Billings, MT, Billings Logan Intl, ILS OR LOC/DME RWY 28R, Amdt 2
 Billings, MT, Billings Logan Intl, RNAV (GPS) Y RWY 10L, Amdt 3
 Billings, MT, Billings Logan Intl, RNAV (GPS) Y RWY 28R, Amdt 3
 Billings, MT, Billings Logan Intl, RNAV (RNP) Z RWY 28R, Orig
 Kalispell, MT, Glacier Park Intl, ILS OR LOC RWY 2, Amdt 7
 Ahoskie, NC, Tri-County, GPS RWY 1, Orig, CANCELED
 Ahoskie, NC, Tri-County, GPS RWY 19, Orig, CANCELED
 Ahoskie, NC, Tri-County, RNAV (GPS) RWY 1, Orig
 Ahoskie, NC, Tri-County, RNAV (GPS) RWY 19, Orig
 Ahoskie, NC, Tri-County, VOR/DME—A, Amdt 6
 Charlotte, NC, Charlotte/Douglas Intl, ILS OR LOC RWY 18L, Amdt 8
 Charlotte, NC, Charlotte/Douglas Intl, ILS OR LOC RWY 18R, ILS RWY 18R (SA CAT I), ILS RWY 18R (CAT II), ILS RWY 18R (CAT III), Amdt 1
 Charlotte, NC, Charlotte/Douglas Intl, ILS OR LOC RWY 36L, ILS RWY 36L (SA CAT I), ILS RWY 36L (CAT II), ILS RWY 36L (CAT III), Amdt 1
 Charlotte, NC, Charlotte/Douglas Intl, ILS OR LOC RWY 36R, ILS RWY 36R (SA CAT I), ILS RWY 36R (CAT II), ILS RWY 36R (CAT III), Amdt 12
 Charlotte, NC, Charlotte/Douglas Intl, RNAV (GPS) Y RWY 18L, Amdt 4
 Charlotte, NC, Charlotte/Douglas Intl, RNAV (GPS) Y RWY 18R, Amdt 1
 Charlotte, NC, Charlotte/Douglas Intl, RNAV (GPS) Y RWY 36L, Amdt 1
 Charlotte, NC, Charlotte/Douglas Intl, RNAV (GPS) Y RWY 36R, Amdt 4
 Smithfield, NC, Johnston Regional, ILS OR LOC Y RWY 3, Orig
 Smithfield, NC, Johnston Regional, ILS OR LOC Z RWY 3, Amdt 2
 Smithfield, NC, Johnston Regional, NDB RWY 3, Amdt 2
 Smithfield, NC, Johnston Regional, RNAV (GPS) RWY 3, Amdt 1
 Smithfield, NC, Johnston Regional, RNAV (GPS) RWY 21, Amdt 1
 Smithfield, NC, Johnston Regional, Takeoff Minimums and Obstacle DP, Amdt 4

Curtis, NE., Curtis Muni, RNAV (GPS) RWY 12, Orig
 Curtis, NE., Curtis Muni, RNAV (GPS) RWY 30, Orig
 Curtis, NE., Curtis Muni, Takeoff Minimums and Obstacle DP, Orig
 Oklahoma City, OK, Wiley Post, RNAV (GPS) RWY 17L, Amdt 2A
 Houston, TX, Houston Executive, RNAV (GPS) RWY 18, Orig-A
 Kingsville, TX, Kleberg County, NDB RWY 13, Amdt 6, CANCELED
 New Braunfels, TX, New Braunfels Rgnl, RNAV (GPS) RWY 13, Amdt 1
 New Braunfels, TX, New Braunfels Rgnl, RNAV (GPS) RWY 31, Amdt 1
 Price, UT, Carbon County Rgnl/Buck Davis Field, RNAV (GPS) RWY 1, Amdt 2
 Siren, WI, Burnett County, RNAV (GPS) RWY 5, Orig
 Siren, WI, Burnett County, RNAV (GPS) RWY 14, Orig
 Siren, WI, Burnett County, RNAV (GPS) RWY 23, Orig
 Siren, WI, Burnett County, RNAV (GPS) RWY 32, Orig
 Siren, WI, Burnett County, VOR RWY 5, Amdt 3

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SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404 and 416

[Docket No. SSA-2011-0081]

RIN 0960-AG28

Revised Listings for Growth Disorders and Weight Loss in Children

AGENCY: Social Security Administration.
ACTION: Final rule.

SUMMARY: This rule adopts, with one change, the rule for evaluating growth disorders in children we proposed in a notice of proposed rulemaking (NPRM) published in the **Federal Register** on May 22, 2013. Several body systems in the Listing of Impairments (listings) contain listings for children based on impairment of linear growth or weight loss. We are replacing those listings with new listings for low birth weight (LBW) and failure to thrive; a new listing for genitourinary impairments; and revised listings for growth failure in combination with a respiratory, cardiovascular, digestive, or immune system disorder. These revisions reflect our program experience, advances in medical knowledge, and comments we received from medical experts and the public.

DATES: This rule is effective June 12, 2015.

FOR FURTHER INFORMATION CONTACT:

Cheryl A. Williams, Office of Medical Policy, 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:**Background**

We are adopting, as final, the rule for evaluating growth disorders in children we proposed in an NPRM published in the **Federal Register** on May 22, 2013 at 78 FR 30249. We made one addition to this rule as the result of a public comment suggesting we provide guidance for evaluating LBW in children born at less than 32 weeks gestation or weighing less than 1325 grams. We revised the table in listing 100.04B to include 32 weeks in the Gestational Age column because we believe that this guidance is appropriate.

The preamble to the NPRM discussed the remaining changes from our current rule and our reasons for proposing those changes. To the extent that we are adopting the proposed rule as published, we are not repeating that information here. Interested readers may refer to the preamble to the NPRM, available at <http://www.regulations.gov> under docket number SSA-2011-0081.

Why are we revising the listings for evaluating growth disorders in children?

We are revising the listings for evaluating growth disorders in children to update the medical criteria, provide more information on how we evaluate growth disorders, reflect our program experience, and address adjudicator questions.

Public Comments on the NPRM

In the NPRM, we provided the public with a 60-day comment period, which ended on July 22, 2013. We received six comments. The commenters included state agencies that make disability determinations for us, the National Association of Disability Examiners, medical organizations, such as the American Academy of Pediatrics, and advocacy groups, such as the Endocrine Society. We carefully considered all of the comments, summarized the commenters' views, and responded to all of the significant issues that were within the scope of this rule. Some commenters noted provisions with which they agreed and did not make

suggestions for changes in those provisions. We did not summarize or respond to those comments.

Listing 100.04 Low Birth Weight in Infants From Birth to Attainment of Age 1**Low Birth Weight**

Comment: One commenter suggested that we provide guidance in the listings at 100.04A or 100.04B, or in the introductory text at 100.00, on diaries used to schedule continuing disability reviews (CDR) for LBW infants. The commenter believes that, while this guidance is already in our internal operating instructions, providing it in the regulations would reduce the number of incorrect diaries being set for LBW cases.

Response: We did not adopt this comment. In 100.00B, we include a reference to our rule for CDRs for LBW cases at § 416.990(b)(11). Additionally, the Act requires, with one exception, that we perform a CDR not later than 12 months after the birth of an infant whose LBW is a contributing factor material to the determination that the infant is disabled. We will continue to provide guidance on diaries for LBW cases and cases involving other disabling impairments in our internal operating instructions. We do not believe it is necessary to repeat this guidance in the regulation.

Comment: One commenter expressed concern that listing 100.04 suggests that LBW is a disability. The commenter felt that it should be clear that weight is "a proxy measure for prematurity, dysphagia, and other functional impairments that are associated with disabilities, rather than weight as a disability itself." The commenter did not provide suggested language to include in our rule.

Response: We did not adopt this comment. We agree that, for the purposes of listing 100.04, weight is a proxy measure for disability in infants from birth to the attainment of age 1. However, we do not believe that providing additional guidance is necessary for the clarity of our rule. As we noted in the preamble to the proposed rule, we based listing 100.04 on sections 416.926a(m)(6) and (m)(7) of our functional equivalence rule.¹ Our adjudicators have over 20 years of experience evaluating claims filed on behalf of children based on LBW under our functional equivalence rule. In our experience applying this rule, we have not found that the type of guidance the

commenter suggested is necessary in order to apply the rule properly.

Evaluating Infants Born at 33 Weeks Weighing Less Than 1325 Grams

Comment: One commenter suggested that we add guidance for evaluating infants who weigh between 1200 grams and 1325 grams, and who are born at gestational ages of 32 weeks or less.

Response: We partially adopted this comment. We agree that it is appropriate to provide guidance for evaluating LBW in infants who are born at 32 weeks gestational age. We revised the table in 100.04B to provide a birth weight value of 1250 grams or less for the gestational age of 32 weeks. However, we did not provide birth weight values for gestational ages less than 32 weeks. The birth weight values that we would provide for infants born at less than 32 weeks would be less than 1200 grams and, thus, the birth weight would meet the criterion in 100.04A.

Listing 100.05 Failure To Thrive in Children From Birth to Attainment of Age 3**Growth Measurements**

Comment: One commenter recommended including growth curves in 100.05A to make administrative processing for pediatricians easier. Another commenter suggested that we make determinations based on growth measurements alone without requiring a diagnosis of developmental delay.

Response: We did not adopt these comments. In 100.05A, we require three weight-for-length measurements or body mass index (BMI)-for-age measurements that are within a 12-month period, at least 60-days apart, and less than the third percentile on the appropriate table in listing 105.08B.2. The adjudicator making the disability determination uses the information from growth curves provided by the child's pediatrician to find the corresponding values on the tables provided. We do not believe it is necessary to include the growth curves in the listing because our adjudicators use the listing, rather than the pediatrician who evaluates a child.

As we stated in the NPRM, our program experience has shown that growth failure alone is not disabling (78 FR at 30251). To meet the severity requirements for listing 100.05B, the child must have growth failure with a developmental delay of the appropriate severity required by the listing. Children with growth failure without developmental delay may be evaluated in the appropriate body system of the underlying condition causing the growth failure.

¹ 78 FR at 30350.

Developmental Testing

Comment: One commenter questioned the requirement for two narrative developmental reports in 100.05C and the requirement that these two reports be at least 120 days apart. This commenter suggested that, if we keep the requirement for two reports, we should require a shorter period of either 30 or 60 days between them. Another commenter also expressed concern about the requirements for the evidence of developmental delay. This commenter was concerned about the availability of these records from providers.

Response: We did not adopt these comments. In 100.05C, we require two narrative developmental reports when a report of a standardized developmental assessment required by 100.05B is not available. As we explained in the NPRM, abnormal findings noted on repeated examinations, and information in narrative developmental reports, that may include the results of developmental screening tests, can identify a child who is not developing or achieving skills within expected timeframes.²

We do not believe that 30 or 60 days is enough time for these kinds of changes to appear on testing. We believe that 120 days is an appropriate period for developmental testing to be performed and to allow for any changes in development to show on testing.

While we understand the commenter's concern about the availability of evidence, we believe that, for the children whose impairments we evaluate under listing 100.05, evidence generally will be available from providers because these children are likely to be identified, and subsequently treated because of their identification, by early intervention programs.

Comment: One commenter noted that most early intervention programs use "a 25 percent delay criteria as opposed to the two-thirds criteria" required in 100.05C. However, the commenter did not provide any suggestions for changing the criterion.

Response: We did not adopt this comment. We recognize that early intervention programs often use a 25 percent delay criterion to determine eligibility for intervention services and to identify the needed services. In contrast, we evaluate a child's delay to determine whether the underlying impairment is disabling because it results in "marked and severe functional limitations." An impairment results in "marked and severe

functional limitations" only if it meets, medically equals, or functionally equals the listings. An impairment is of listing-level severity if it results in "marked" limitations in two domains of functioning or an "extreme" limitation in one domain.³ The level of delay that we require in 100.05C is consistent with our definition of "marked limitation" in § 416.926a(e)(2)(ii).

Comment: One commenter expressed concern about acceptable timeframes for performing developmental testing in relation to disability determinations stated in 100.05B and 100.05C. The commenter suggested that the testing to establish the child's current level of development be performed within 6 months of adjudication.

Response: We partially adopted this comment. We agree that evidence about a child's development must be recent and current in relation to a disability determination, and we have revised listings 100.05B and 100.05C2 to clarify this requirement. However, the facts in a specific case determine whether the evidence is current. Determining factors include, but are not limited to, the age of the child, the amount of delay, and the developmental trajectory documented over time. We are not setting specific timeframes for when developmental testing must be performed, but we are specifying that the evidence must reflect the child's current development.

Linear Growth

Comment: One commenter agreed with our use of weight-for-length and BMI-for-age charts to evaluate growth failure, rather than of linear (height or length) growth charts. The commenter expressed concern, however, that an underlying condition could cause a child to have such profound growth failure that BMI for the child's age would become normal, despite his or her significant growth failure.

Response: We did not adopt this comment. We understand the commenter's concerns that some children may have underlying conditions that cause linear growth impairments while their BMI-for-age measurements are normal. After attainment of age 2, most children without an underlying medical disorder follow a growth trajectory that remains fairly constant during childhood.

Our adjudicative experience has shown that a declining linear growth rate is not always indicative of a disabling condition. Short stature, length, or height below the third percentile, in and of itself, is not a

medically determinable impairment, although it can be the result of a medically determinable impairment. We will evaluate children with growth failure that does not meet the requirements of listings 100.04 and 100.05 and is associated with a known medically determinable impairment under the affected body system.

Comment: One commenter was concerned that, while the majority of children over the age of 3 with growth failure have signs and symptoms of an underlying disorder in the respiratory, cardiovascular, digestive, genitourinary, or immune body system, some children over the age of 3 will not. This commenter suggested that we include exceptions for conditions, such as Turner syndrome (female hypogonadism) and acquired growth hormone deficiency, where growth failure may be a significant component of the disease process.

Response: We did not adopt this comment. After a child attains age 3, we will evaluate his or her impairment under the affected body system. The two examples provided by the commenter are endocrine disorders. Although these two disorders are not listed impairments for children, they may rise to listing-level severity because of their effects in other body systems. As the commenter explained, children with Turner syndrome may experience complications, such as heart disease, to a degree that is disabling. We would evaluate the complications under the affected body system.

Listing 103.06 Growth Failure Due to Any Chronic Respiratory Disorder

Comment: Two commenters were concerned with the requirement for oxygen supplementation in 103.06A. The commenters noted that some respiratory disorders, such as asthma, bronchiectasis, and cystic fibrosis, could result in listing-level growth failure without requiring oxygen supplementation.

Response: We did not adopt these comments. We agree with the commenters that some respiratory disorders could result in listing-level growth failure without requiring oxygen supplementation; however, we did not revise 103.06 as a result. We use other listings, such as 103.02, 103.03, and 103.04, in the respiratory body system to evaluate these disorders.⁴ We believe that these respiratory listings, and our functional equivalence rule for evaluating disability in children,

² 78 FR at 30251.

³ See 20 CFR 416.926a(a).

⁴ See 20 CFR part 404, subpart P, Appendix 1.

adequately address the disorders referred to by the commenters.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.⁶

When will we use this final rule?

We will begin to use this final rule on its effective date. We will continue to use the current listings until the date this final rule becomes effective. We will apply the final rule to new applications filed on or after the effective date of the final rule and to claims that are pending on or after the effective date.⁷

How long will this final rule be effective?

This final rule will remain in effect for 5 years after the date it becomes effective, unless we extend it or revise and issue it again.

Regulatory Procedures

Executive Order 12866, as Supplemented by Executive Order 13563

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

Regulatory Flexibility Act

We certify that this final rule would not have a significant economic impact on a substantial number of small entities because they affect individuals only. Therefore, a regulatory flexibility analysis is not required under the Regulatory Flexibility Act, as amended.

Paperwork Reduction Act

This final rule does not create any new or affect any existing collections and, therefore, does not require OMB

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

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; Aged, Blind, Disability benefits; Public assistance programs; Reporting and recordkeeping requirements; Supplemental Security Income (SSI).

Carolyn W. Colvin,

Acting Commissioner of Social Security.

For the reasons set out in the preamble, we are amending 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—)

■ 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. Amend appendix 1 to subpart P of part 404 as follows:

- a. Revise item 1 of the introductory text before part A of appendix 1.
- b. Amend part B by revising the body system name for section 100.00 in the table of contents.
- c. Revise sections 100.00 and 100.01 of part B.
- d. Remove sections 100.02 and 100.03 of part B.
- e. Add sections 100.04 and 100.05 of part B.
- f. Add section 103.00F of part B.
- g. Add listing 103.06 of part B.
- h. Revise section 104.00C2b introductory text of part B.
- i. Revise section 104.00C2b(ii) of part B.
- j. Add section 104.00C3 of part B.
- k. Revise listing 104.02C of part B.
- l. Revise section 105.00G of part B.
- m. Revise listing 105.08 of part B.

■ n. Redesignate section 106.00C5 of part B as 106.00C6 and add new section 106.00C5.

■ o. Add listing 106.08 of part B.

■ p. Add section 114.00F4d of part B.

■ q. Revise listing 114.08H of part B.

The revisions and additions read as follows:

APPENDIX 1 TO SUBPART P OF PART 404—LISTING OF IMPAIRMENTS

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1. Low Birth Weight and Failure to Thrive (100.00): June 12, 2020.

* * * * *

Part B

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100.00 Low Birth Weight and Failure to Thrive.

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100.00 LOW BIRTH WEIGHT AND FAILURE TO THRIVE

A. *What conditions do we evaluate under these listings?* We evaluate low birth weight (LBW) in infants from birth to attainment of age 1 and failure to thrive (FTT) in infants and toddlers from birth to attainment of age 3.

B. *How do we evaluate disability based on LBW under 100.04?* In 100.04A and 100.04B, we use an infant's birth weight as documented by an original or certified copy of the infant's birth certificate or by a medical record signed by a physician. *Birth weight* means the first weight recorded after birth. In 100.04B, *gestational age* is the infant's age based on the date of conception as recorded in the medical record. If the infant's impairment meets the requirements for listing 100.04A or 100.04B, we will follow the rule in § 416.990(b)(11) of this chapter.

C. *How do we evaluate disability based on FTT under 100.05?*

1. *General.* We establish FTT with or without a known cause when we have documentation of an infant's or a toddler's growth failure and developmental delay from an acceptable medical source(s) as defined in § 416.913(a) of this chapter. We require documentation of growth measurements in 100.05A and developmental delay described in 100.05B or 100.05C within the same consecutive 12-month period. The dates of developmental testing and reports may be different from the dates of growth measurements. After the attainment of age 3, we evaluate growth failure under the affected body system(s).

2. *Growth failure.* Under 100.05A, we use the appropriate table(s) under 105.08B in the digestive system to determine whether a child's growth is less than the third percentile. The child does not need to have a digestive disorder for purposes of 100.05.

a. For children from birth to attainment of age 2, we use the weight-for-length table corresponding to the child's gender (Table I or Table II).

b. For children age 2 to attainment of age 3, we use the body mass index (BMI)-for-age table corresponding to the child's gender (Table III or Table IV).

⁵ See 20 CFR 416.924a and 416.926a.

⁶ 42 U.S.C. 405(a), 902(a)(5), and 1383(d)(1).

⁷ This means that we will use this final rule on and after its effective date in any case in which we make a determination or decision. We expect that Federal courts will review our final decisions using the rule that was in effect at the time we issued the decisions. If a court reverses our final decision and remands a case for further administrative proceedings after the effective date of this final rule, we will apply this final rule to the entire period at issue in the decision we make after the court's remand.

c. BMI is the ratio of a child's weight to the square of his or her height. We calculate BMI using the formulas in 105.00G2c.

d. *Growth measurements.* The weight-for-length measurements for children from birth to the attainment of age 2 and BMI-for-age measurements for children age 2 to attainment of age 3 that are required for this listing must be obtained within a 12-month period and at least 60 days apart. If a child attains age 2 during the evaluation period, additional measurements are not needed. Any measurements taken before the child attains age 2 can be used to evaluate the impairment under the appropriate listing for the child's age. If the child attains age 3 during the evaluation period, the measurements can be used to evaluate the impairment in the affected body system.

3. *Developmental delay.*

a. Under 100.05B and C, we use reports from acceptable medical sources to establish delay in a child's development.

b. Under 100.05B, we document the severity of developmental delay with results from a standardized developmental assessment, which compares a child's level of development to the level typically expected for his or her chronological age. If the child was born prematurely, we may use the corrected chronological age (CCA) for comparison. (See § 416.924b(b) of this chapter.) CCA is the chronological age adjusted by a period of gestational prematurity. CCA = (chronological age) — (number of weeks premature). Acceptable medical sources or early intervention specialists, physical or occupational therapists, and other sources may conduct standardized developmental assessments and developmental screenings. The results of these tests and screenings must be accompanied by a statement or records from an acceptable medical source who established the child has a developmental delay.

c. Under 100.05C, when there are no results from a standardized developmental assessment in the case record, we need narrative developmental reports from the child's medical sources in sufficient detail to assess the severity of his or her developmental delay. A narrative developmental report is based on clinical observations, progress notes, and well-baby check-ups. To meet the requirements for 100.05C, the report must include: The child's developmental history; examination findings (with abnormal findings noted on repeated examinations); and an overall assessment of the child's development (that is, more than one or two isolated skills) by the medical source. Some narrative developmental reports may include results from developmental screening tests, which can identify a child who is not developing or achieving skills within expected timeframes. Although medical sources may refer to screening test results as supporting evidence in the narrative developmental report, screening test results alone cannot establish a diagnosis or the severity of developmental delay.

D. *How do we evaluate disorders that do not meet one of these listings?*

1. We may find infants disabled due to other disorders when their birth weights are

greater than 1200 grams but less than 2000 grams and their weight and gestational age do not meet listing 100.04. The most common disorders of prematurity and LBW include retinopathy of prematurity (ROP), chronic lung disease of infancy (CLD, previously known as bronchopulmonary dysplasia, or BPD), intraventricular hemorrhage (IVH), necrotizing enterocolitis (NEC), and periventricular leukomalacia (PVL). Other disorders include poor nutrition and growth failure, hearing disorders, seizure disorders, cerebral palsy, and developmental disorders. We evaluate these disorders under the affected body systems.

2. We may evaluate infants and toddlers with growth failure that is associated with a known medical disorder under the body system of that medical disorder, for example, the respiratory or digestive body systems.

3. If an infant or toddler has a severe medically determinable impairment(s) that does not meet the criteria of any listing, we must also consider whether the child has an impairment(s) that medically equals a listing (see § 416.926 of this chapter). If the child's impairment(s) does not meet or medically equal a listing, we will determine whether the child's impairment(s) functionally equals the listings (see § 416.926a of this chapter) considering the factors in § 416.924a of this chapter. We use the rule in § 416.994a of this chapter when we decide whether a child continues to be disabled.

100.01 Category of Impairments, Low Birth Weight and Failure to Thrive

100.04 *Low birth weight in infants from birth to attainment of age 1.*

A. Birth weight (see 100.00B) of less than 1200 grams.

OR

B. The following gestational age and birth weight:

Gestational age (in weeks)	Birth weight
37–40	2000 grams or less.
36	1875 grams or less.
35	1700 grams or less.
34	1500 grams or less.
33	1325 grams or less.
32	1250 grams or less.

100.05 *Failure to thrive in children from birth to attainment of age 3* (see 100.00C), documented by A and B, or A and C.

A. Growth failure as required in 1 or 2:

1. *For children from birth to attainment of age 2*, three weight-for-length measurements that are:

a. Within a consecutive 12-month period; and

b. At least 60 days apart; and

c. Less than the third percentile on the appropriate weight-for-length table in listing 105.08B1; or

2. *For children age 2 to attainment of age 3*, three BMI-for-age measurements that are:

a. Within a consecutive 12-month period; and

b. At least 60 days apart; and

c. Less than the third percentile on the appropriate BMI-for-age table in listing 105.08B2.

AND

B. Developmental delay (see 100.00C1 and C3), established by an acceptable medical source and documented by findings from one current report of a standardized developmental assessment (see 100.00C3b) that:

1. Shows development not more than two-thirds of the level typically expected for the child's age; or

2. Results in a valid score that is at least two standard deviations below the mean.

OR

C. Developmental delay (see 100.00C3), established by an acceptable medical source and documented by findings from two narrative developmental reports (see 100.00C3c) that:

1. Are dated at least 120 days apart (see 100.00C1); and

2. Indicate current development not more than two-thirds of the level typically expected for the child's age.

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103.00 RESPIRATORY SYSTEM

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F. *How do we evaluate growth failure due to any chronic respiratory disorder?*

1. To evaluate growth failure due to any chronic respiratory disorder, we require documentation of the oxygen supplementation described in 103.06A and the growth measurements in 103.06B within the same consecutive 12-month period. The dates of oxygen supplementation may be different from the dates of growth measurements.

2. Under 103.06B, we use the appropriate table(s) under 105.08B in the digestive system to determine whether a child's growth is less than the third percentile.

a. For children from birth to attainment of age 2, we use the weight-for-length table corresponding to the child's gender (Table I or Table II).

b. For children age 2 to attainment of age 18, we use the body mass index (BMI)-for-age table corresponding to the child's gender (Table III or Table IV).

c. BMI is the ratio of a child's weight to the square of his or her height. We calculate BMI using the formulas in 105.00G2c.

* * * * *

103.06 *Growth failure due to any chronic respiratory disorder* (see 103.00F), documented by:

A. Hypoxemia with the need for at least 1.0 L/min of oxygen supplementation for at least 4 hours per day and for at least 90 consecutive days.

AND

B. Growth failure as required in 1 or 2:

1. *For children from birth to attainment of age 2*, three weight-for-length measurements that are:

a. Within a consecutive 12-month period; and

b. At least 60 days apart; and

c. Less than the third percentile on the appropriate weight-for-length table under 105.08B1; or

2. *For children age 2 to attainment of age 18*, three BMI-for-age measurements that are:

- a. Within a consecutive 12-month period; and
 b. At least 60 days apart; and
 c. Less than the third percentile on the appropriate BMI-for-age table under 105.08B2.

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104.00 CARDIOVASCULAR SYSTEM

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C. Evaluating Chronic Heart Failure

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2. What evidence of CHF do we need?

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b. To establish that you have *chronic* heart failure, we require that your medical history and physical examination describe characteristic symptoms and signs of pulmonary or systemic congestion or of limited cardiac output associated with abnormal findings on appropriate medically acceptable imaging. When a remediable factor, such as arrhythmia, triggers an acute episode of heart failure, you may experience restored cardiac function, and a chronic impairment may not be present.

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(ii) During infancy, other manifestations of chronic heart failure may include repeated lower respiratory tract infections.

* * * * *

3. How do we evaluate growth failure due to CHF?

a. To evaluate growth failure due to CHF, we require documentation of the clinical findings of CHF described in 104.00C2 and the growth measurements in 104.02C within the same consecutive 12-month period. The dates of clinical findings may be different from the dates of growth measurements.

b. Under 104.02C, we use the appropriate table(s) under 105.08B in the digestive system to determine whether a child's growth is less than the third percentile.

(i) For children from birth to attainment of age 2, we use the weight-for-length table corresponding to the child's gender (Table I or Table II).

(ii) For children age 2 to attainment of age 18, we use the body mass index (BMI)-for-age table corresponding to the child's gender (Table III or Table IV).

(iii) BMI is the ratio of a child's weight to the square of his or her height. We calculate BMI using the formulas in 105.00G2c.

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104.02 * * *

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C. Growth failure as required in 1 or 2:

1. For children from birth to attainment of age 2, three weight-for-length measurements that are:

- a. Within a consecutive 12-month period; and
 b. At least 60 days apart; and
 c. Less than the third percentile on the appropriate weight-for-length table under 105.08B1; or

2. For children age 2 to attainment of age 18, three BMI-for-age measurements that are:

- a. Within a consecutive 12-month period; and
 b. At least 60 days apart; and
 c. Less than the third percentile on the appropriate BMI-for-age table under 105.08B2.

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105.00 DIGESTIVE SYSTEM

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G. How do we evaluate growth failure due to any digestive disorder?

1. To evaluate growth failure due to any digestive disorder, we require documentation of the laboratory findings of chronic nutritional deficiency described in 105.08A and the growth measurements in 105.08B within the same consecutive 12-month period. The dates of laboratory findings may

be different from the dates of growth measurements.

2. Under 105.08B, we evaluate a child's growth failure by using the appropriate table for age and gender.

a. For children from birth to attainment of age 2, we use the weight-for-length table (see Table I or Table II).

b. For children age 2 to attainment of age 18, we use the body mass index (BMI)-for-age table (see Tables III or IV).

c. BMI is the ratio of a child's weight to the square of the child's height. We calculate BMI using one of the following formulas:

English Formula

$$\text{BMI} = [\text{Weight in Pounds}/(\text{Height in Inches} \times \text{Height in Inches})] \times 703$$

Metric Formulas

$$\text{BMI} = \text{Weight in Kilograms}/(\text{Height in Meters} \times \text{Height in Meters})$$

$$\text{BMI} = [\text{Weight in Kilograms}/(\text{Height in Centimeters} \times \text{Height in Centimeters})] \times 10,000$$

* * * * *

105.08 Growth failure due to any digestive disorder (see 105.00G), documented by A and B:

A. Chronic nutritional deficiency present on at least two evaluations at least 60 days apart within a consecutive 12-month period documented by one of the following:

1. Anemia with hemoglobin less than 10.0 g/dL; or
 2. Serum albumin of 3.0 g/dL or less;

AND

B. Growth failure as required in 1 or 2:

1. For children from birth to attainment of age 2, three weight-for-length measurements that are:

- a. Within a 12-month period; and
 b. At least 60 days apart; and
 c. Less than the third percentile on Table I or Table II; or

TABLE I—MALES BIRTH TO ATTAINMENT OF AGE 2

[Third Percentile Values for Weight-for-Length]

Length (centimeters)	Weight (kilograms)	Length (centimeters)	Weight (kilograms)	Length (centimeters)	Weight (kilograms)
45.0	1.597	64.5	6.132	84.5	10.301
45.5	1.703	65.5	6.359	85.5	10.499
46.5	1.919	66.5	6.584	86.5	10.696
47.5	2.139	67.5	6.807	87.5	10.895
48.5	2.364	68.5	7.027	88.5	11.095
49.5	2.592	69.5	7.245	89.5	11.296
50.5	2.824	70.5	7.461	90.5	11.498
51.5	3.058	71.5	7.674	91.5	11.703
52.5	3.294	72.5	7.885	92.5	11.910
53.5	3.532	73.5	8.094	93.5	12.119
54.5	3.771	74.5	8.301	94.5	12.331
55.5	4.010	75.5	8.507	95.5	12.546
56.5	4.250	76.5	8.710	96.5	12.764
57.5	4.489	77.5	8.913	97.5	12.987
58.5	4.728	78.5	9.113	98.5	13.213
59.5	4.966	79.5	9.313	99.5	13.443
60.5	5.203	80.5	9.512	100.5	13.678
61.5	5.438	81.5	9.710	101.5	13.918
62.5	5.671	82.5	9.907	102.5	14.163
63.5	5.903	83.5	10.104	103.5	14.413

TABLE II—FEMALES BIRTH TO ATTAINMENT OF AGE 2

[Third Percentile Values for Weight-for-Length]

Length (centimeters)	Weight (kilograms)	Length (centimeters)	Weight (kilograms)	Length (centimeters)	Weight (kilograms)
45.0	1.613	64.5	5.985	84.5	10.071
45.5	1.724	65.5	6.200	85.5	10.270
46.5	1.946	66.5	6.413	86.5	10.469
47.5	2.171	67.5	6.625	87.5	10.670
48.5	2.397	68.5	6.836	88.5	10.871
49.5	2.624	69.5	7.046	89.5	11.074
50.5	2.852	70.5	7.254	90.5	11.278
51.5	3.081	71.5	7.461	91.5	11.484
52.5	3.310	72.5	7.667	92.5	11.691
53.5	3.538	73.5	7.871	93.5	11.901
54.5	3.767	74.5	8.075	94.5	12.112
55.5	3.994	75.5	8.277	95.5	12.326
56.5	4.220	76.5	8.479	96.5	12.541
57.5	4.445	77.5	8.679	97.5	12.760
58.5	4.892	78.5	8.879	98.5	12.981
59.5	5.113	79.5	9.078	99.5	13.205
60.5	5.333	80.5	9.277	100.5	13.431
61.5	5.552	81.5	9.476	101.5	13.661
62.5	5.769	82.5	9.674	102.5	13.895
63.5	5.769	83.5	9.872	103.5	14.132

2. For children age 2 to attainment of age 18, three BMI-for-age measurements that are:

a. Within a consecutive 12-month period; and
b. At least 60 days apart; and

c. Less than the third percentile on Table III or Table IV.

TABLE III—MALES AGE 2 TO ATTAINMENT OF AGE 18

[Third Percentile Values for BMI-for-Age]

Age (yrs. and mos.)	BMI	Age (yrs. and mos.)	BMI	Age (yrs. and mos.)	BMI
2.0 to 2.1	14.5	10.11 to 11.2	14.3	14.9 to 14.10	16.1
2.2 to 2.4	14.4	11.3 to 11.5	14.4	14.11 to 15.0	16.2
2.5 to 2.7	14.3	11.6 to 11.8	14.5	15.1 to 15.3	16.3
2.8 to 2.11	14.2	11.9 to 11.11	14.6	15.4 to 15.5	16.4
3.0 to 3.2	14.1	12.0 to 12.1	14.7	15.6 to 15.7	16.5
3.3 to 3.6	14.0	12.2 to 12.4	14.8	15.8 to 15.9	16.6
3.7 to 3.11	13.9	12.5 to 12.7	14.9	15.10 to 15.11	16.7
4.0 to 4.5	13.8	12.8 to 12.9	15.0	16.0 to 16.1	16.8
4.6 to 5.0	13.7	12.10 to 13.0	15.1	16.2 to 16.3	16.9
5.1 to 6.0	13.6	13.1 to 13.2	15.2	16.4 to 16.5	17.0
6.1 to 7.6	13.5	13.3 to 13.4	15.3	16.6 to 16.8	17.1
7.7 to 8.6	13.6	13.5 to 13.7	15.4	16.9 to 16.10	17.2
8.7 to 9.1	13.7	13.8 to 13.9	15.5	16.11 to 17.0	17.3
9.2 to 9.6	13.8	13.10 to 13.11	15.6	17.1 to 17.2	17.4
9.7 to 9.11	13.9	14.0 to 14.1	15.7	17.3 to 17.5	17.5
10.0 to 10.3	14.0	14.2 to 14.4	15.8	17.6 to 17.7	17.6
10.4 to 10.7	14.1	14.5 to 14.6	15.9	17.8 to 17.9	17.7
10.8 to 10.10	14.2	14.7 to 14.8	16.0	17.10 to 17.11	17.8

TABLE IV—FEMALES AGE 2 TO ATTAINMENT OF AGE 18

[Third Percentile Values for BMI-for-Age]

Age (yrs. and mos.)	BMI	Age (yrs. and mos.)	BMI	Age (yrs. and mos.)	BMI
2.0 to 2.2	14.1	10.8 to 10.10	14.0	14.3 to 14.5	15.6
2.3 to 2.6	14.0	10.11 to 11.2	14.1	14.6 to 14.7	15.7
2.7 to 2.10	13.9	11.3 to 11.5	14.2	14.8 to 14.9	15.8
2.11 to 3.2	13.8	11.6 to 11.7	14.3	14.10 to 15.0	15.9
3.3 to 3.6	13.7	11.8 to 11.10	14.4	15.1 to 15.2	16.0
3.7 to 3.11	13.6	11.11 to 12.1	14.5	15.3 to 15.5	16.1
4.0 to 4.4	13.5	12.2 to 12.4	14.6	15.6 to 15.7	16.2
4.5 to 4.11	13.4	12.5 to 12.6	14.7	15.8 to 15.10	16.3
5.0 to 5.9	13.3	12.7 to 12.9	14.8	15.11 to 16.0	16.4
5.10 to 7.6	13.2	12.10 to 12.11	14.9	16.1 to 16.3	16.5

TABLE IV—FEMALES AGE 2 TO ATTAINMENT OF AGE 18—Continued
[Third Percentile Values for BMI-for-Age]

Age (yrs. and mos.)	BMI	Age (yrs. and mos.)	BMI	Age (yrs. and mos.)	BMI
7.7 to 8.4	13.3	13.0 to 13.2	15.0	16.4 to 16.6	16.6
8.5 to 8.10	13.4	13.3 to 13.4	15.1	16.7 to 16.9	16.7
8.11 to 9.3	13.5	13.5 to 13.7	15.2	16.10 to 17.0	16.8
9.4 to 9.8	13.6	13.8 to 13.9	15.3	17.1 to 17.3	16.9
9.9 to 10.0	13.7	13.10 to 14.0	15.4	17.4 to 17.7	17.0
10.1 to 10.4	13.8	14.1 to 14.2	15.5	17.8 to 17.11	17.1
10.5 to 10.7	13.9				

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106.00 GENITOURINARY IMPAIRMENTS

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C. *What other factors do we consider when we evaluate your genitourinary disorder?*

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5. *Growth failure due to any chronic renal disease.*

a. To evaluate growth failure due to any chronic renal disease, we require documentation of the laboratory findings described in 106.08A and the growth measurements in 106.08B within the same consecutive 12-month period. The dates of laboratory findings may be different from the dates of growth measurements.

b. Under 106.08B, we use the appropriate table(s) under 105.08B in the digestive system to determine whether a child's growth is less than the third percentile.

(i) For children from birth to attainment of age 2, we use the weight-for-length table corresponding to the child's gender (Table I or Table II).

(ii) For children age 2 to attainment of age 18, we use the body mass index (BMI)-for-age table corresponding to the child's gender (Table III or Table IV).

(iii) BMI is the ratio of a child's weight to the square of his or her height. We calculate BMI using the formulas in 105.00G2c.

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106.08 *Growth failure due to any chronic renal disease* (see 106.00C5), with:

A. Serum creatinine of 2 mg/dL or greater, documented at least two times within a consecutive 12-month period with at least 60 days between measurements.

AND

B. Growth failure as required in 1 or 2:

1. *For children from birth to attainment of age 2*, three weight-for-length measurements that are:

a. Within a consecutive 12-month period; and

b. At least 60 days apart; and

c. Less than the third percentile on the appropriate weight-for-length table under 105.08B1; or

2. *For children age 2 to attainment of age 18*, three BMI-for-age measurements that are:

a. Within a consecutive 12-month period; and

b. At least 60 days apart; and

c. Less than the third percentile on the appropriate BMI-for-age table under 105.08B2.

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114.00 IMMUNE SYSTEM DISORDERS

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F. * * *

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4. *HIV infection manifestations specific to children.*

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d. *Growth failure due to HIV immune suppression.*

(i) To evaluate growth failure due to HIV immune suppression, we require documentation of the laboratory values described in 114.08H1 and the growth measurements in 114.08H2 or 114.08H3 within the same consecutive 12-month period. The dates of laboratory findings may be different from the dates of growth measurements.

(ii) Under 114.08H2 and 114.08H3, we use the appropriate table under 105.08B in the digestive system to determine whether a child's growth is less than the third percentile.

(A) For children from birth to attainment of age 2, we use the weight-for-length table corresponding to the child's gender (Table I or Table II).

(B) For children age 2 to attainment of age 18, we use the body mass index (BMI)-for-age table corresponding to the child's gender (Table III or Table IV).

(C) BMI is the ratio of a child's weight to the square of his or her height. We calculate BMI using the formulas in 105.00G2c.

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114.08 * * *

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H. *Immune suppression and growth failure* (see 114.00F4d) documented by 1 and 2, or by 1 and 3.

1. CD4 measurement:

a. *For children from birth to attainment of age 5*, CD4 percentage of less than 20 percent; or

b. *For children age 5 to attainment of age 18*, absolute CD4 count of less than 200 cells/mm³, or CD4 percentage of less than 14 percent; and

2. *For children from birth to attainment of age 2*, three weight-for-length measurements that are:

a. Within a consecutive 12-month period; and

b. At least 60 days apart; and

c. Less than the third percentile on the appropriate weight-for-length table under 105.08B1; or

3. *For children age 2 to attainment of age 18*, three BMI-for-age measurements that are:

a. Within a consecutive 12-month period; and

b. At least 60 days apart; and

c. Less than the third percentile on the appropriate BMI-for-age table under 105.08B2.

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

Subpart I—[Amended]

■ 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 1383b); 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. Amend § 416.924b by revising paragraph (b) to read as follows:

§ 416.924b Age as a factor of evaluation in the sequential evaluation process for children.

* * * * *

(b) *Correcting chronological age of premature infants.* We generally use chronological age (a child's age based on birth date) when we decide whether, or the extent to which, a physical or mental impairment or combination of impairments causes functional limitations. However, if you were born prematurely, we may consider you younger than your chronological age when we evaluate your development. We may use a “corrected” chronological age (CCA); that is, your chronological age adjusted by a period of gestational prematurity. We consider an infant born at less than 37 weeks' gestation to be born prematurely.

(1) We compute your CCA by subtracting the number of weeks of prematurity (the difference between 40 weeks of full-term gestation and the number of actual weeks of gestation) from your chronological age. For example, if your chronological age is 20

weeks but you were born at 32 weeks gestation (8 weeks premature), then your CCA is 12 weeks.

(2) We evaluate developmental delay in a premature child until the child's prematurity is no longer a relevant factor, generally no later than about chronological age 2.

(i) If you have not attained age 1 and were born prematurely, we will assess your development using your CCA.

(ii) If you are over age 1 and have a developmental delay, and prematurity is still a relevant factor, we will decide whether to correct your chronological age. We will base our decision on our judgment and all the facts in your case. If we decide to correct your chronological age, we may correct it by subtracting the full number of weeks of prematurity or a lesser number of weeks. If your developmental delay is the result of your medically determinable impairment(s) and is not attributable to your prematurity, we will decide not to correct your chronological age.

(3) Notwithstanding the provisions in paragraph (b)(1) of this section, we will not compute a CCA if the medical evidence shows that your treating source or other medical source has already taken your prematurity into consideration in his or her assessment of your development. We will not compute a CCA when we find you disabled under listing 100.04 of the Listing of Impairments.

§ 416.926a [Amended]

■ 5. Amend § 416.926a by removing paragraphs (m)(6) and (m)(7) and redesignating paragraph (m)(8) as (m)(6).

■ 6. Amend § 416.934 by adding paragraphs (j) and (k) to read as follows:

§ 416.934 Impairments which may warrant a finding of presumptive disability or presumptive blindness.

* * * * *

(j) Infants weighing less than 1200 grams at birth, until attainment of 1 year of age.

(k) Infants weighing at least 1200 but less than 2000 grams at birth, and who are small for gestational age, until attainment of 1 year of age. (Small for gestational age means a birth weight that is at or more than 2 standard deviations below the mean or that is less than the third growth percentile for the gestational age of the infant.)

[FR Doc. 2015-08185 Filed 4-10-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1020

[Docket No. FDA-2015-N-0828]

Performance Standards for Ionizing Radiation Emitting Products; Fluoroscopic Equipment; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending a Federal performance standard for ionizing radiation to correct a drafting error regarding fluoroscopic equipment measurement. We are taking this action to ensure clarity and improve the accuracy of the regulations.

DATES: This rule is effective August 26, 2015. Submit electronic or written comments on this direct final rule or its companion proposed rule by June 29, 2015.

ADDRESSES: You may submit comments by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written comments in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. FDA-2015-N-0828 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Scott Gonzalez, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4641, Silver Spring, MD 20993-0002, 301-796-5889.

SUPPLEMENTARY INFORMATION:

I. What is the background of this Rule?

FDA is correcting a drafting error regarding fluoroscopic equipment measurement in § 1020.32 (21 CFR 1020.32). We are publishing this direct final rule because it is intended to make a noncontroversial amendment to § 1020.32, and we do not anticipate any significant adverse comments. Specifically, this amendment changes the words "any linear dimension" in the current regulation to read "every linear dimension" (§ 1020.32(b)(4)(ii)(A)). The alternative performance standard, § 1020.32(b)(4)(ii)(B), currently contains the same phrase but remains unchanged. We are amending the language to make the performance standards mutually exclusive. This will ensure clarity and improve the accuracy of the regulations.

FDA first proposed the performance standards in the **Federal Register** of December 10, 2002 (67 FR 76056), to account for technological changes in fluoroscopic equipment. The proposed rule did not specify which measurement of the visible area of an image receptor determined the applicable performance standard (67 FR 76056 at 76092). When we addressed comments to the proposed rule in the **Federal Register** of June 10, 2005, we agreed with one comment that adding the words "any linear dimension" would clarify the determination of the performance standard (70 FR 33998 at 34007).

FDA ultimately incorporated the phrase in two places, potentially reducing the clarity of the rule (70 FR 33998 at 34040). Section 1020.32(b)(4)(ii) sets performance standards based on a threshold, so the language for each standard should be mutually exclusive. That is, only one standard, and not the other, should apply to the image receptor in question. However, some image receptors may have linear dimensions that are both greater than and less than 34 cm, for example, receptors with a hexagonal shape. In such cases, the performance standards may not be mutually exclusive, so both standards may appear to apply. This direct final rule amends § 1020.32(b)(4)(ii)(A) to read "every linear dimension" to ensure the standards are mutually exclusive. The amendment will improve the clarity and accuracy of the regulations.