diesel or biodiesel in quantities between 5 percent and 20 percent." The script underneath the black band must be centered horizontally, with ⅛ inch (.32 cm) between each line. The bottom line of type is ¼ inch (.64 cm) from the bottom of the label. All type should fall no closer than 3/16 inch (.48 cm) from the side edges of the label.

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(b) *Type size and setting*—(1) *For gasoline labels.* The Helvetica series or equivalent type is used for all numbers and letters with the exception of the octane rating number. Helvetica is available in a variety of phototype setting systems, by linotype, and in a variety of computer desk-top and phototype setting systems. Its name may vary, but the type must conform in style and thickness to the sample provided here. The line "Minimum Octane Rating" is set in 12 point Helvetica Bold, all capitals, with letterspace set at 12½ points. The line "(R+M)/2 METHOD" is set in 10 point Helvetica Bold, all capitals, with letterspace set at 10½ points. The octane number is set in 96 point Franklin gothic condensed with ⅛ inch (.32 cm) space between the numbers.

(2) *For alternative liquid automotive fuel labels (one principal component).* Except as provided above, labels should conform to the following specifications. All type should be set in upper case (all caps) "Helvetica Black" or equivalent type throughout. Helvetica Black is available in a variety of computer desk-top and phototype setting systems. Its name may vary, but the type must conform in style and thickness to the sample provided here. The spacing between letters and words should be set as "normal." The type for the fuel name is 50 point (½ inch (1.27 cm) cap height) "Helvetica Black," knocked out of a 1 inch (2.54 cm) deep band. The type for the words "MINIMUM" and the principal component is 24 point (¼ inch (.64 cm) cap height). The type for percentage is 36 point (⅜ inch (.96 cm) cap height).

(3) *For alternative liquid automotive fuel labels (two components).* All type should be set in upper case (all caps) "Helvetica Black" or equivalent type throughout. Helvetica Black is available in a variety of computer desk-top and phototype setting systems. Its name may vary, but the type must conform in style and thickness to the sample provided here. The spacing between letters and words should be set as "normal." The type for the fuel name is 50 point (½ inch (1.27 cm) cap height) "Helvetica Black," knocked out of a 1 inch (2.54 cm) deep band. All other type is 24 point (¼ inch (.64 cm) cap height).

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By direction of the Commission.

**Donald S. Clark,**

*Secretary.*

[FR Doc. 2011–8097 Filed 4–7–11; 8:45 am]

**BILLING CODE 6750–01–P**

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## SOCIAL SECURITY ADMINISTRATION

## 20 CFR Parts 404 and 416

**[Docket No. SSA–2006–0114]**

**RIN 0960–AD78**

## Revised Medical Criteria for Evaluating Endocrine Disorders

**AGENCY:** Social Security Administration.

**ACTION:** Final Rules.

**SUMMARY:** We are revising the criteria in the Listing of Impairments (the listings) that we use to evaluate claims under titles II and XVI of the Social Security Act (Act) involving endocrine disorders in adults and children. The revisions reflect our adjudicative experience, advances in medical knowledge, information from medical experts, and comments we received from the public in response to an advance notice of proposed rulemaking (ANPRM), a notice of proposed rulemaking (NPRM), and at an outreach policy conference.

**DATES:** These rules are effective June 7, 2011.

**FOR FURTHER INFORMATION CONTACT:** Judy Hicks, Social Insurance Specialist, 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 Web site, Social Security Online, at *http://www.socialsecurity.gov.*

**SUPPLEMENTARY INFORMATION:**

### Background

We are making final the rules for evaluating endocrine disorders that we proposed in an NPRM we published in the **Federal Register** on December 14, 2009 (74 FR 66069). The preamble to the NPRM discussed the changes from the current rules and our reasons for proposing those changes. To the extent that we are adopting the proposed rules as published, we are not repeating that information here. Interested readers may refer to the preamble to the NPRM.[1]

### What are the listings and how do we use them?

Listings describe medical conditions that are so severe that we presume any person who has a medical condition(s) that satisfies the criteria of a listing is unable to perform any gainful activity and, therefore, is disabled. The inability to work must also have lasted or be expected to last for at least 12 continuous months or be expected to result in death; we call this provision "the duration requirement."[2] Thus, the listings are special rules that provide us with a mechanism to identify claims that should clearly be allowed. We use listings only to allow claims. We do not deny any claim solely because a person's medical condition(s) does not satisfy a listing.

### Why are we revising the listings for endocrine disorders?

We are revising the listings for endocrine disorders because medical science has made significant advances in detecting endocrine disorders at earlier stages and newer treatments have resulted in better management of these conditions since we last published final rules making comprehensive revisions to the endocrine listings in 1985. Consequently, most endocrine disorders do not reach listing-level severity because they do not become sufficiently severe or do not remain at a sufficient level of severity long enough to meet our 12-month duration requirement. Therefore, we have determined that, with the exception of children under age 6 who have diabetes mellitus (DM) and require daily insulin, we should no longer have listings in sections 9.00 and 109.00 based on endocrine disorders alone.

### When will we use these final rules?

We will use these final rules beginning on their effective date. We will continue to use the current listings until the date these final rules become effective. We will apply the final rules to new applications filed on or after the effective date of the final rules and to claims that are pending on and after the effective date.[3]

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[1] The NPRM is available at *http://www.regulations.gov/search/Regs/home.html#documentDetail?R=0900006480a6a145.*

[2] Sections 216(i), 223(d), and 1614(a)(3) of the Act. See also §§ 404.1509, 404.1520, 416.909, and 416.920 of our regulations.

[3] This means that we will use these final rules on and after their 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 rules that were in effect at the time we

**Public Comments on the NPRM**

In the NPRM, we provided the public a 60-day comment period, which ended on February 12, 2010. We received 16 public comment letters. The comments came from national medical organizations, advocacy groups, a national group of Social Security claimants' representatives, individual State agencies, a Congressman, and members of the public.

We provide below summaries of the significant comments that were relevant to this rulemaking and our responses to those comments. We did not summarize or respond to some of the comments we received. Some commenters supported the proposed changes and noted provisions with which they agreed. We appreciate those comments, but they do not require a response. Some commenters also sent us comments on subjects that were unrelated to the proposed rules. These comments were outside the scope of the proposed rulemaking, and we have not responded to them.

*Comment:* Several commenters asked us to continue to recognize DM as a disability and not to increase the burden on claimants to prove disability on the basis of DM. Another commenter, representing several physicians in a group practice, disagreed with "changes deleting diabetes." That commenter said that a significant proportion of their patients have blindness, renal failure, vascular disease, and multiple amputations.

*Response:* We will continue to recognize DM as a potential cause of disability, but we are removing the prior listings because they no longer accurately identify persons who are disabled. Contrary to what some of the commenters seemed to think, we will still consider DM to be a medically determinable impairment that can result in disability, and we will continue to consider its effects under our listings. For example, we have listings in other body systems for blindness, renal failure, vascular disease, and amputations. We are removing only the specific DM listings.

When adults' medical conditions do not satisfy a listing, we must assess the particular functional effects of their impairments; that is, we must determine their "residual functional capacity" (RFC). Considering the RFC, we then determine whether they can do any past relevant work, or if they cannot, any other work that exists in the national economy, considering their RFC, age, education, and previous work experience.[4] Most persons with DM who qualified for disability benefits under the prior rules did so based on their RFC, not under the listings we are removing. Also, many persons with DM have other medical conditions that meet listings in other body systems due to complications of DM.

When a person qualifies for disability benefits under a listing, we continue to use that same listing when we later determine if he or she is still disabled. See §§ 404.1594(c)(3)(i), 416.994(b)(2)(iv), and 416.994a(b)(2). This rule applies even if we have removed or changed the listing since we last found that the beneficiary was disabled. For this reason, we will not find that a beneficiary's disability has ended solely because we have removed the DM listings or any other endocrine disorder listing. Unless we are otherwise required to do so (for example, by statute), we do not readjudicate cases because we have revised our listings.

*Comment:* Several commenters said that not all persons can control their DM all of the time and that treatment of any sort is often inadequate. One of these commenters stated that our proposal to eliminate all listings for DM did not consider the small subset of persons with DM who will continue to experience severe fluctuations in blood glucose levels despite their best efforts at treatment. This commenter recommended that we have listings that consider severe fluctuations in blood glucose levels and the accompanying health problems that limit a person's ability to work. One commenter said that DM can never be controlled completely; another commenter thought that the proposed rules implied that DM was curable.

Some commenters thought that we assumed that all claimants had full access to state-of-the-art healthcare. Some mentioned serious outcomes of long-term, chronic fluctuations in blood glucose on other body systems. Some also mentioned that some persons with fluctuations in blood glucose experience symptoms and signs that are not covered by listings in other body systems. One commenter was concerned that our proposal to remove the DM listings might imply to our adjudicators that we want them to deny more cases involving DM. Another commenter believed that the proposed rules implied that persons with uncontrolled DM must be noncompliant with treatment. This commenter recommended that we include substantial guidance on the complexity of managing and controlling DM and guidance about how DM can intrude on the ability to work.

*Response:* We did not mean to give the impression in the NPRM that there are no persons with uncontrolled DM or that all persons have access to healthcare or the best possible treatment. We acknowledge that some persons do have difficulty controlling their blood glucose and that some of them will be disabled. We also agree with the commenters that there are valid reasons for some persons' blood glucose levels to fluctuate, including hypoglycemia unawareness, mental impairments that interfere with their ability to adequately monitor and treat their conditions, and inadequate treatment. For those reasons, we include guidance about problems associated with fluctuating blood glucose levels and their effects, including diabetic ketoacidosis (DKA) and hypoglycemia. This guidance is in 9.00B5 for adults and 109.00B5 for children.

We are not including a listing for fluctuating blood glucose levels and the medical problems it causes because the reasons are highly variable, and we cannot provide criteria that would reliably identify persons with listing-level impairments based on fluctuating blood glucose levels. In order to determine whether persons with fluctuating blood glucose levels are disabled, we must assess an adult's RFC or consider functional equivalence for a child. In making these findings, we consider the symptoms and signs of DM that the commenters named. We also have listings in other body systems for several of the serious effects of uncontrolled DM cited in the comment letters. For example, we evaluate diabetic nephropathy under our genitourinary listings (6.00 and 106.00), and peripheral neuropathies under our listings for neurological disorders (11.00 and 111.00).

Nevertheless, in response to these and other comments, we have added more guidance in final 9.00B5 and 109.00B5 explaining that DM is chronic and that some persons with type 1 and type 2 DM do not achieve good control of their disorder for a variety of valid reasons. We also indicate that both type 1 and type 2 DM can have serious, disabling complications that meet the duration

issued the decisions. If a court reverses our final decision and remands a case for further administrative proceedings after the effective date of these final rules, we will apply these final rules to the entire period at issue in the decision we make after the court's remand.

[4] The definition of disability is different for children who claim disability benefits under title XVI, but the sequential evaluation process for children also includes a step at which we consider the particular functional effects of the child's medical condition(s), called "functional equivalence." Act, section 1614(a)(3)(C); §§ 416.906, 416.924, and 416.926a.

requirement. This guidance will apply not only to DKA but also to other problems associated with uncontrolled and fluctuating blood glucose levels. We did not agree, however, that we should include guidance on the complexity of managing and controlling DM and guidance about how DM can intrude on the ability to work, which the last commenter recommended. We do not believe the recommended guidance is appropriate in the context of the listings. The commenter recognized that some of the concerns were more appropriate to discussions of RFC and other issues associated with later steps of the sequential evaluation process.

We also indicated in the NPRM that we would publish a Social Security Ruling (SSR) with more detailed information about specific endocrine disorders, including DM, the types of impairments and limitations that result from these disorders, and how we determine whether persons who have DM and other endocrine disorders are disabled.[5] The SSR will address some of the symptoms and signs of DM that are not covered by listings in other body systems.

*Comment:* One commenter said that we did not present crucial information and data needed to support our proposal to remove the DM listing and, therefore, we should withdraw the proposal. Another commenter thought that the references we provided to support our proposal to remove the DM listings showed an absence of balance. This commenter stated that there is a substantial body of opinion that supports the existence of labile or brittle diabetes. To support this opinion, this commenter cited as examples two 2007 articles that discuss "brittle" diabetes.

*Response:* We disagree with both commenters. We believe that we provided substantial information to support the proposals and that the proposals were correct. In the NPRM, we explained that we used information from a variety of sources, including:

- Medical experts in the field of endocrinology, experts in other related fields, advocacy groups for persons with DM, and persons with endocrine disorders and their families;
- Persons who make disability determinations and decisions for us in State agencies and in our Office of Disability Adjudication and Review; and
- The published sources we listed in the section of references at the end of the preamble. We listed 13 references in the NPRM, most of which were specifically about DM. We provided Internet links for as many of the references as possible and informed the public that we would make all of the references available to anyone who was interested in seeing them.[6]

We also explained that we received information from public comments that responded to an ANPRM that we published in the **Federal Register** on August 11, 2005.[7] In the ANPRM, we announced our plans to update and revise the listings for the endocrine body system, we invited interested persons and organizations to send us written comments and suggestions, and we specifically cited our listings for DM. We also included citations to references we were considering at that time.[8] In the NPRM, we provided an Internet link where interested members of the public could read all of the comments we received in response to the ANPRM. We also explained that we received comments and expert input at an outreach policy conference we hosted in Atlanta, GA. We provided an Internet link to the transcript of that conference that interested members of the public could use to read the opinions we received from medical professionals, advocates, persons with endocrine disorders and their families, and our adjudicators who spoke at the conference.

We appreciated the opportunity to consider the articles the second commenter cited, but the endocrinologists, diabetologists, and other medical experts we consulted and our review of medical literature did not support the view that there is "brittle" DM. We believe that the sources we cited in the NPRM, together with the wide variety of other information we also described, represent the prevailing opinion of experts in the medical community and provide a balance of opinions.

*Comment:* Three commenters thought that we should keep listing 9.08B for evaluating recurrent DKA in adults. These commenters noted that persons who have repeated episodes of DKA may develop other problems. One of these commenters said that we should keep all of prior listing 9.08.

*Response:* We did not adopt the comments. We recognize the serious effects of DKA in sections 9.00B5a(i) and 109.00B5b. We explain in these final rules that DKA is a potentially life-threatening condition resulting from a severe insulin deficiency and that it causes the chemical balance of the body to become dangerously hyperglycemic and acidic, which usually requires hospital treatment.

As we explained in the NPRM and in our response to the comments above, the criteria in prior listing 9.08B reflected the earlier view that persons with wide fluctuations in their blood glucose levels had uncontrollable DM. According to the medical experts and relevant references we consulted, however, the listing reflected only inadequate glucose regulation. Prior listing 9.08B, therefore, included conditions that would not be disabling. With respect to keeping all of listing 9.08, we explained in the NPRM that prior listings 9.08A and C were redundant because we have other listings that address the effects they cover.[9] We will evaluate the impairments of persons who have difficulty regulating their blood glucose levels for valid reasons on an individualized basis.

*Comment:* Three commenters suggested that we add a listing for persons who experience frequent episodes of severe hypoglycemia. They pointed out that each episode of hypoglycemia interferes with the ability to work while the person is experiencing the episode and that frequent severe episodes can effectively make a person unable to sustain work, especially since the episodes are unpredictable and would affect regular work attendance. Two commenters noted that some persons have "hypoglycemia unawareness"; that is, they lose all or most of their ability to detect early warning signs of oncoming hypoglycemia and consequently do not take steps to treat the episode when it is still early and mild. One commenter suggested listing criteria for hypoglycemia based on an average number of documented episodes per month despite best efforts to comply with treatment.

*Response:* We did not adopt the comments recommending that we add a listing for severe hypoglycemia, but we did add a reference to hypoglycemia unawareness in final 9.00B5b and 109.00B5c. As with DKA, we must make individualized determinations about disability for persons who experience frequent episodes. Moreover, as the commenters recognized, even severe hypoglycemia episodes can usually be treated readily, and most persons who experience hypoglycemia episodes are able to adequately recognize and treat their symptoms. We consider the effects that frequent episodes of hypoglycemia may have on functioning at each step of the sequential evaluation process,

[5] See 74 FR at 66069.

[6] 74 FR at 66072.

[7] 70 FR at 46792.

[8] Ibid. at 46794.

[9] 74 FR 66070.

including the steps regarding the ability to do past relevant work or other work. A listing based on an average of documented episodes would include some conditions that are not disabling, and accordingly, we did not adopt the suggestion.

*Comment:* Two commenters requested that we include a listing for diabetic neuropathy. One of these commenters noted that sympathetic neuropathy, a type of diabetic neuropathy, is difficult to evaluate and asked that we not eliminate all listing provisions for evaluating this disorder. The other commenter believed that a reference to the neurological body system was not enough and that the criteria in listing 11.04B were too vague for evaluating diabetic neuropathy. This commenter was also concerned that some of our adjudicators might not understand that neuropathy caused by DM is different from other types of neuropathy and that it does not have to result in amputation to be disabling. The commenter suggested that we should have a listing for diabetic neuropathy that addresses peripheral, autonomic, proximal, and focal neuropathies. In support of their comments, both commenters referred to remarks made by a speaker at the outreach policy conference in Atlanta. One commenter who cited the speaker's remarks said that evaluating a "diabetic gut" is a very specialized and difficult procedure. The other commenter cited the speaker's statement that a person who has not had an amputation can still be disabled by peripheral neuropathy. This commenter believed that some adjudicators and medical experts consider only amputations.

*Response:* The DM listings we are removing did not include a provision for sympathetic neuropathy, so these final rules do not remove any existing provisions about that medical problem. We also do not agree that the speaker's comments at the Atlanta outreach meeting support the suggestion that we add a DM listing for neuropathy. We reviewed the remarks to which the first commenter referred, and we believe that the doctor was referring to what he perceived as shortcomings in how we consider neuropathies, including non-diabetic neuropathies, in our neurological body system in 11.00 and 111.00 of our listings. We will consider those remarks when we revise the neurological listings. Moreover, the doctor's remarks discussed the variability of the effects of neuropathy on different persons who work at different types of jobs, and we believe that his remarks support our current policy of considering those effects on a case-by-case basis.

We also do not agree that adjudicators and medical experts think that claimants with diabetic neuropathy must have an amputation before we find them disabled. To the contrary, prior listing 9.08A cross-referred to listing 11.04B, which does not contain a criterion for amputation. Rather, that listing requires significant and persistent disorganization of motor function in two extremities, so it clearly includes persons who have not had amputations. We also provide in 11.00C that persistent disorganization of motor function may manifest as paresis, sensory disturbances, or other causes. These final rules do not affect the neurological body system, so current 11.00C and listing 11.04B will still be applicable to persons with diabetic neuropathy.

Finally, as one commenter noted, diabetic neuropathy can affect different parts of the body. We provide general guidance in final 9.00B for evaluating impairments that result from endocrine disorders under the listings for other body systems. We provide examples in 9.00B5a(ii) regarding evaluation of diabetic peripheral neurovascular disease that results in amputation under 1.00, diabetic gastroparesis that results in abnormal gastrointestinal motility under 5.00, and diabetic peripheral and sensory neuropathies under 11.00. This guidance indicates that we are not limited to any specific body system or listing in evaluating the complications of DM. We will also address diabetic neuropathies in the SSR we are preparing.

*Comment:* Four commenters approved of proposed listing 109.08 for children who have not attained age 6 and who need daily insulin, but asked us to raise the age limit in the listing. Two of these commenters stated that the age limit in the proposed listing was too restrictive and excluded many children who clearly require constant adult supervision. One of these commenters noted that the developmental abilities of children vary greatly and that a child who has attained age 6 may well have the same medical need for adult help as younger children. Another commenter suggested that we change the rule to age 9 because this is the age at which children generally begin to become able to take a significant role in their own care. This commenter believed that DM in all children below age 9 will meet the functional equivalence example requiring 24-hour-a-day supervision for medical reasons, which we cited as one justification for the proposed new listing. 20 CFR 416.926a(m)(5). Another commenter recommended that we apply the proposed listing to all children under age 18 who have DM and require daily insulin. The commenter asserted that many children age 6 and older lack the cognition to manage their daily insulin regimen without the significant involvement of an adult, and many families cannot afford the before- and after-school adult care that a child with DM may require. Another commenter noted that all children need a certain amount of adult supervision in managing DM, especially when they are ill.

*Response:* Although we did not adopt the comments suggesting that we raise the age limit in listing 109.08, we did add further guidance to the rule to ensure that adjudicators appropriately consider the effects of DM in children age 6 and older. We agree with the commenters that children of any age require some level of adult supervision or support in caring for their DM. As we explained above, however, we must set listings at a level at which we can presume disability in all persons whose impairments meet the listing criteria. For the reasons we stated in the NPRM, we determined that the attainment of age 6 is the highest age at which we could have such a rule.[10]

We recognize that not all children age 6 and older are capable of managing their own DM. In these children, however, the mere need for adult supervision does not establish disability; we need to determine the nature, frequency, and extent of the supervision they need along with any other relevant factors. Final listing 109.08 presumes that children under age 6 cannot participate in their own care at the most basic level and are at risk of dying unless they have 24-hour-a-day adult supervision. Many children age 6 and older with DM that requires daily insulin participate in their own care at least at the basic level of alerting adults when they begin to experience hypoglycemia symptoms, and they often participate at higher levels.

We agree, however, with the commenters that there are some children, including some adolescents, who have a medical need for 24-hour-a-day supervision; we must evaluate their DM on a more individualized basis. We stated in the NPRM that we would find such children disabled based on the example of functional equivalence in § 416.926a(m)(5). We also said that we expected there would be other children who do not need this level of help but who would nevertheless have impairments that functionally equal the listings for other

[10] 74 FR at 66071.

reasons.[11] We therefore included guidance in proposed (now final) section 109.00C explaining that it is possible for a child age 6 or older to have the same limitations that we presume for all children under age 6; for the same reason we referred to our rules for evaluating disability in children in §§ 416.924a and 416.926a. We nevertheless believe that our statement in the NPRM was correct; as children mature, they should be able to increasingly take part in their self-care activities related to managing their DM. As a consequence, we do not agree that the DM of all children between the ages of 6 and 18 will meet the functional equivalence example in § 416.926a(m)(5) or that they will all be disabled for any other reason. Finally, with respect to the comment that many families cannot afford the before- and after-school adult care that a child with DM may require, the Act requires us to consider only the medical effects of the child's impairment; we cannot consider a family's ability to afford care for their children.

*Comment:* One commenter asked us to acknowledge in the final rule the seriousness and difficulty of managing DM in children. Another commenter stated that many children experience significant day-to-day variability in their condition, which necessitates daily and often hourly decisionmaking and intervention either by an adult or under the close supervision of an adult.

*Response:* We added language in 109.00B5 and C to clarify these issues. We will also address them in more detail in the SSR that we will publish after these rules become effective.

**Other Comments**

*Comment:* One commenter suggested that we retain listings for complex endocrine disorders, such as diabetes insipidus (DI).

*Response:* While it was not clear to us what the commenter meant by "complex endocrine disorders," we did not adopt the suggestion to retain a listing for DI. Generally, medication will control the symptoms and signs of DI so they do not reach listing-level severity or remain at a sufficient level of severity long enough to meet our 12-month duration requirement. When DI is not controlled and problems ensue, we evaluate the effects in other body systems or on functioning.

**Other Changes**

We stated in the NPRM that, if we published the proposed rules as final rules, the rules would remain in effect for 8 years after the date they become effective, unless we extend them or revise and reissue them. In these final rules, we are revising the 8-year sunset date to 5 years to conform to the timeframes we provide in most of our recent listings revisions.[12] We will monitor these rules and update them sooner if necessary.

We are also making minor editorial changes to correct unintentional inconsistencies between 9.00 and 109.00.

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

Under the Act, we have full power and authority to make rules and regulations and to establish necessary or appropriate procedures to carry out such provisions. Sections 205(a), 702(a)(5), and 1631(d)(1).

**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 these final rules meet the requirements for a significant regulatory action under Executive Order 12866 as supplemented by Executive Order 13563 and were subject to OMB review.

*Regulatory Flexibility Act*

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

*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**

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

**Michael J. Astrue,**

*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 404.1525 by revising paragraph (c)(1) and the first sentence of paragraph (c)(3) to read as follows:

**§ 404.1525 Listing of Impairments in appendix 1.**

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(c) *How do we use the listings?* (1) Most body system sections in parts A and B of appendix 1 are in two parts: an introduction, followed by the specific listings.

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(3) In most cases, the specific listings follow the introduction in each body system, after the heading, *Category of Impairments.* * * *

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■ 3. Amend appendix 1 to subpart P of part 404 by:

■ a. Revising item 10 of the introductory text before part A;

■ b. Revising the table of contents entry for section 9.00 and section 9.00 in part A;

■ c. Removing sections 9.01 through 9.08 from part A; and

■ d. Revising the table of contents entry for section 109.00 and section 109.00 in part B.

The revisions read as follows:

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

* * * * *

10. Endocrine Disorders (9.00 and 109.00): June 7, 2016.

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[11] Ibid.

[12] See for example, "Revised Medical Criteria for Evaluating Hearing Loss," 75 FR 30693 (June 2, 2010).

**Part A**

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**9.00 Endocrine Disorders**

A. *What is an endocrine disorder?*

An endocrine disorder is a medical condition that causes a hormonal imbalance. When an endocrine gland functions abnormally, producing either too much of a specific hormone (hyperfunction) or too little (hypofunction), the hormonal imbalance can cause various complications in the body. The major glands of the endocrine system are the pituitary, thyroid, parathyroid, adrenal, and pancreas.

B. *How do we evaluate the effects of endocrine disorders?* We evaluate impairments that result from endocrine disorders under the listings for other body systems. For example:

1. *Pituitary gland disorders* can disrupt hormone production and normal functioning in other endocrine glands and in many body systems. The effects of pituitary gland disorders vary depending on which hormones are involved. For example, when pituitary hypofunction affects water and electrolyte balance in the kidney and leads to diabetes insipidus, we evaluate the effects of recurrent dehydration under 6.00.

2. *Thyroid gland disorders* affect the sympathetic nervous system and normal metabolism. We evaluate thyroid-related changes in blood pressure and heart rate that cause arrhythmias or other cardiac dysfunction under 4.00; thyroid-related weight loss under 5.00; hypertensive cerebrovascular accidents (strokes) under 11.00; and cognitive limitations, mood disorders, and anxiety under 12.00.

3. *Parathyroid gland disorders* affect calcium levels in bone, blood, nerves, muscle, and other body tissues. We evaluate parathyroid-related osteoporosis and fractures under 1.00; abnormally elevated calcium levels in the blood (hypercalcemia) that lead to cataracts under 2.00; kidney failure under 6.00; and recurrent abnormally low blood calcium levels (hypocalcemia) that lead to increased excitability of nerves and muscles, such as tetany and muscle spasms, under 11.00.

4. *Adrenal gland disorders* affect bone calcium levels, blood pressure, metabolism, and mental status. We evaluate adrenal-related osteoporosis with fractures that compromises the ability to walk or to use the upper extremities under 1.00; adrenal-related hypertension that worsens heart failure or causes recurrent arrhythmias under 4.00; adrenal-related weight loss under 5.00; and mood disorders under 12.00.

5. *Diabetes mellitus and other pancreatic gland disorders* disrupt the production of several hormones, including insulin, that regulate metabolism and digestion. Insulin is essential to the absorption of glucose from the bloodstream into body cells for conversion into cellular energy. The most common pancreatic gland disorder is *diabetes mellitus* (DM). There are two major types of DM: type 1 and type 2. Both type 1 and type 2 DM are chronic disorders that can have serious disabling complications that meet the duration requirement. Type 1 DM—previously known as "juvenile diabetes" or "insulin-dependent diabetes mellitus" (IDDM)—is an absolute deficiency of insulin production that commonly begins in childhood and continues throughout adulthood. Treatment of type 1 DM always requires lifelong daily insulin. With type 2 DM—previously known as "adult-onset diabetes mellitus" or "non-insulin-dependent diabetes mellitus" (NIDDM)—the body's cells resist the effects of insulin, impairing glucose absorption and metabolism. Treatment of type 2 DM generally requires lifestyle changes, such as increased exercise and dietary modification, and sometimes insulin in addition to other medications. While both type 1 and type 2 DM are usually controlled, some persons do not achieve good control for a variety of reasons including, but not limited to, hypoglycemia unawareness, other disorders that can affect blood glucose levels, inability to manage DM due to a mental disorder, or inadequate treatment.

a. *Hyperglycemia.* Both types of DM cause hyperglycemia, which is an abnormally high level of blood glucose that may produce acute and long-term complications. Acute complications of hyperglycemia include diabetic ketoacidosis. Long-term complications of chronic hyperglycemia include many conditions affecting various body systems.

(i) *Diabetic ketoacidosis (DKA).* DKA is an acute, potentially life-threatening complication of DM in which the chemical balance of the body becomes dangerously hyperglycemic and acidic. It results from a severe insulin deficiency, which can occur due to missed or inadequate daily insulin therapy or in association with an acute illness. It usually requires hospital treatment to correct the acute complications of dehydration, electrolyte imbalance, and insulin deficiency. You may have serious complications resulting from your treatment, which we evaluate under the affected body system. For example, we evaluate cardiac arrhythmias under 4.00, intestinal necrosis under 5.00, and cerebral edema and seizures under 11.00. Recurrent episodes of DKA may result from mood or eating disorders, which we evaluate under 12.00.

(ii) *Chronic hyperglycemia.* Chronic hyperglycemia, which is longstanding abnormally high levels of blood glucose, leads to long-term diabetic complications by disrupting nerve and blood vessel functioning. This disruption can have many different effects in other body systems. For example, we evaluate diabetic peripheral neurovascular disease that leads to gangrene and subsequent amputation of an extremity under 1.00; diabetic retinopathy under 2.00; coronary artery disease and peripheral vascular disease under 4.00; diabetic gastroparesis that results in abnormal gastrointestinal motility under 5.00; diabetic nephropathy under 6.00; poorly healing bacterial and fungal skin infections under 8.00; diabetic peripheral and sensory neuropathies under 11.00; and cognitive impairments, depression, and anxiety under 12.00.

b. *Hypoglycemia.* Persons with DM may experience episodes of hypoglycemia, which is an abnormally low level of blood glucose. Most adults recognize the symptoms of hypoglycemia and reverse them by consuming substances containing glucose; however, some do not take this step because of hypoglycemia unawareness. Severe hypoglycemia can lead to complications, including seizures or loss of consciousness, which we evaluate under 11.00, or altered mental status and cognitive deficits, which we evaluate under 12.00.

C. *How do we evaluate endocrine disorders that do not have effects that meet or medically equal the criteria of any listing in other body systems?* If your impairment(s) does not meet or medically equal a listing in another body system, you may or may not have the residual functional capacity to engage in substantial gainful activity. In this situation, we proceed to the fourth and, if necessary, the fifth steps of the sequential evaluation process in §§ 404.1520 and 416.920. When we decide whether you continue to be disabled, we use the rules in §§ 404.1594, 416.994, and 416.994a.

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**Part B**

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**109.00 Endocrine Disorders**

A. *What is an endocrine disorder?*

An endocrine disorder is a medical condition that causes a hormonal imbalance. When an endocrine gland functions abnormally, producing either too much of a specific hormone (hyperfunction) or too little (hypofunction), the hormonal imbalance can cause various complications in the body. The major glands of the endocrine system are the pituitary, thyroid, parathyroid, adrenal, and pancreas.

B. *How do we evaluate the effects of endocrine disorders?* The only listing in this body system addresses children from birth to the attainment of age 6 who have diabetes mellitus (DM) and require daily insulin. We evaluate other impairments that result from endocrine disorders under the listings for other body systems. For example:

1. *Pituitary gland disorders* can disrupt hormone production and normal functioning in other endocrine glands and in many body systems. The effects of pituitary gland disorders vary depending on which hormones are involved. For example, when pituitary growth hormone deficiency in growing children limits bone maturation and results in pathological short stature, we evaluate this linear growth impairment under 100.00. When pituitary hypofunction affects water and electrolyte balance in the kidney and leads to diabetes insipidus, we evaluate the effects of recurrent dehydration under 106.00.

2. *Thyroid gland disorders* affect the sympathetic nervous system and normal metabolism. We evaluate thyroid-related changes in linear growth under 100.00; thyroid-related changes in blood pressure and heart rate that cause cardiac arrhythmias or other cardiac dysfunction under 104.00; thyroid-related weight loss under 105.00; and cognitive limitations, mood disorders, and anxiety under 112.00.

3. *Parathyroid gland disorders* affect calcium levels in bone, blood, nerves, muscle, and other body tissues. We evaluate

parathyroid-related osteoporosis and fractures under 101.00; abnormally elevated calcium levels in the blood (hypercalcemia) that lead to cataracts under 102.00; kidney failure under 106.00; and recurrent abnormally low blood calcium levels (hypocalcemia) that lead to increased excitability of nerves and muscles, such as tetany and muscle spasms, under 111.00.

4. *Adrenal gland disorders* affect bone calcium levels, blood pressure, metabolism, and mental status. We evaluate adrenal-related linear growth impairments under 100.00; adrenal-related osteoporosis with fractures that compromises the ability to walk or to use the upper extremities under 101.00; adrenal-related hypertension that worsens heart failure or causes recurrent arrhythmias under 104.00; adrenal-related weight loss under 105.00; and mood disorders under 112.00.

5. *Diabetes mellitus and other pancreatic gland disorders* disrupt the production of several hormones, including insulin, that regulate metabolism and digestion. Insulin is essential to the absorption of glucose from the bloodstream into body cells for conversion into cellular energy. The most common pancreatic gland disorder is *diabetes mellitus* (DM). There are two major types of DM: type 1 and type 2. Both type 1 and type 2 DM are chronic disorders that can have serious, disabling complications that meet the duration requirement. Type 1 DM—previously known as "juvenile diabetes" or "insulin-dependent diabetes mellitus" (IDDM)—is an absolute deficiency of insulin secretion that commonly begins in childhood and continues throughout adulthood. Treatment of type 1 DM always requires lifelong daily insulin. With type 2 DM—previously known as "adult-onset diabetes mellitus" or "non-insulin-dependent diabetes mellitus" (NIDDM)—the body's cells resist the effects of insulin, impairing glucose absorption and metabolism. Type 2 is less common than type 1 DM in children, but physicians are increasingly diagnosing type 2 DM before age 18. Treatment of type 2 DM generally requires lifestyle changes, such as increased exercise and dietary modification, and sometimes insulin in addition to other medications. While both type 1 and type 2 DM are usually controlled, some children do not achieve good control for a variety of reasons including, but not limited to, hypoglycemia unawareness, other disorders that can affect blood glucose levels, inability to manage DM due to a mental disorder, or inadequate treatment.

a. *Hyperglycemia.* Both types of DM cause hyperglycemia, which is an abnormally high level of blood glucose that may produce acute and long-term complications. Acute complications of hyperglycemia include diabetic ketoacidosis. Long-term complications of chronic hyperglycemia include many conditions affecting various body systems but are rare in children.

b. *Diabetic ketoacidosis (DKA).* DKA is an acute, potentially life-threatening complication of DM in which the chemical balance of the body becomes dangerously hyperglycemic and acidic. It results from a severe insulin deficiency, which can occur due to missed or inadequate daily insulin therapy or in association with an acute illness. It usually requires hospital treatment to correct the acute complications of dehydration, electrolyte imbalance, and insulin deficiency. You may have serious complications resulting from your treatment, which we evaluate under the affected body system. For example, we evaluate cardiac arrhythmias under 104.00, intestinal necrosis under 105.00, and cerebral edema and seizures under 111.00. Recurrent episodes of DKA in adolescents may result from mood or eating disorders, which we evaluate under 112.00.

c. *Hypoglycemia.* Children with DM may experience episodes of hypoglycemia, which is an abnormally low level of blood glucose. Most children age 6 and older recognize the symptoms of hypoglycemia and reverse them by consuming substances containing glucose; however, some do not take this step because of hypoglycemia unawareness. Severe hypoglycemia can lead to complications, including seizures or loss of consciousness, which we evaluate under 111.00, or altered mental status, cognitive deficits, and permanent brain damage, which we evaluate under 112.00.

C. *How do we evaluate DM in children?*

Listing 109.08 is only for children with DM who have not attained age 6 and who require daily insulin. For all other children (that is, children with DM who are age 6 or older and require daily insulin, and children of any age with DM who do not require daily insulin), we follow our rules for determining whether the DM is severe, alone or in combination with another impairment, whether it meets or medically equals the criteria of a listing in another body system, or functionally equals the listings under the criteria in § 416.926a, considering the factors in § 416.924a. The management of DM in children can be complex and variable from day to day, and all children with DM require some level of adult supervision. For example, if a child age 6 or older has a medical need for 24-hour-a-day adult supervision of insulin treatment, food intake, and physical activity to ensure survival, we will find that the child's impairment functionally equals the listings based on the example in § 416.926a(m)(5).

D. *How do we evaluate other endocrine disorders that do not have effects that meet or medically equal the criteria of any listing in other body systems?* If your impairment(s) does not meet or medically equal a listing in another body system, we will consider whether your impairment(s) functionally equals the listings under the criteria in § 416.926a, considering the factors in § 416.924a. When we decide whether you continue to be disabled, we use the rules in § 416.994a.

109.01 *Category of Impairments, Endocrine*

109.08 *Any type of diabetes mellitus in a child who requires daily insulin and has not attained age 6.* Consider under a disability until the attainment of age 6. Thereafter, evaluate the diabetes mellitus according to the rules in 109.00B5 and C.

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

■ 9. 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).

■ 10. Amend § 416.925 by revising paragraph (c)(1) and the first sentence of paragraph (c)(3) to read as follows:

**§ 416.925 Listing of Impairments in appendix 1 of subpart P of part 404 of this chapter.**

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(c) *How do we use the listings?* (1) Most body system sections in parts A and B of appendix 1 are in two parts: an introduction, followed by the specific listings.

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(3) In most cases, the specific listings follow the introduction in each body system, after the heading, *Category of Impairments.* * * *

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[FR Doc. 2011–8389 Filed 4–7–11; 8:45 am]

BILLING CODE 4191–02–P

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

### 33 CFR Part 165

**[Docket No. USCG–2010–0992]**

**RIN 1625–AA00**

## Safety Zone; Repair of High Voltage Transmission Lines to Logan International Airport, Saugus River, Saugus, MA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone on the Saugus River, Lynn, Massachusetts, within the Captain of the Port (COTP) Boston Zone to allow for repair of high voltage transmission lines to Logan Airport. This safety zone is required to provide for the safety of life on navigable waters during the repair of high voltage transmission lines. Entering into, transiting through, mooring or anchoring within this zone is prohibited unless authorized by the COTP.