

**FOR FURTHER INFORMATION CONTACT:** A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

**SUPPLEMENTARY INFORMATION:** The notice of the Presidential disaster declaration for the State of LOUISIANA, dated 03/13/2016 is hereby amended to include the following areas as adversely affected by the disaster:

*Primary Counties: (Physical Damage and Economic Injury Loans):* Catahoula, East Carroll, Franklin, Lincoln, Saint Helena.

*Contiguous Counties: (Economic Injury Loans Only):* Louisiana; Concordia, East Feliciana, Mississippi; Issaquena.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59008)

**Lisa Lopez-Suarez,**

*Acting Associate Administrator for Disaster Assistance.*

[FR Doc. 2016-08404 Filed 4-12-16; 8:45 am]

**BILLING CODE 8025-01-P**

## SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA-2015-0061]

### Social Security Ruling, SSR 16-4p; Titles II and XVI: Using Genetic Test Results To Evaluate Disability

**AGENCY:** Social Security Administration.

**ACTION:** Notice of Social Security Ruling (SSR).

**SUMMARY:** We are giving notice of SSR 16-4p. This SSR explains how we consider the results of genetic tests in disability claims and continuing disability reviews under titles II and XVI of the Social Security Act, consistent with our policies for determination of disability.

**DATES:** *Effective Date:* April 13, 2016.

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

**SUPPLEMENTARY INFORMATION:** Although 5 U.S.C. 552(a)(1) and (a)(2) do not require us to publish this SSR, we are doing so under 20 CFR 402.35(b)(1).

Through SSRs, we make available to the public precedential decisions

relating to the Federal old-age, survivors, disability, supplemental security income, and special veterans benefits programs. We may base SSRs on determinations or decisions made at all levels of administrative adjudication, Federal court decisions, Commissioner's decisions, opinions of the Office of the General Counsel, or other interpretations of the law and regulations.

Although SSRs do not have the same force and effect as statutes or regulations, they are binding on all components of the Social Security Administration. 20 CFR 402.35(b)(1).

This SSR will remain in effect until we publish a notice in the **Federal Register** that rescinds it, or we publish a new SSR that replaces or modifies it.

(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; 96.006 Supplemental Security Income.)

Dated: April 6, 2016.

**Carolyn W. Colvin,**

*Acting Commissioner of Social Security.*

## POLICY INTERPRETATION RULING

### Titles II and XVI: Using Genetic Test Results To Evaluate Disability

**PURPOSE:** This SSR explains how we consider medical evidence containing the results of genetic tests and helps adjudicators, including disability examiners and medical and psychological consultants, consistently apply our policies in disability claims.<sup>1</sup>

**CITATIONS:** Sections 216(i), 223(d), 223(f), 1614(a)(3) and 1614(a)(4) of the Social Security Act, as amended; 20 CFR part 401; 20 CFR 401.55, 404.1505, 404.1508, 404.1512, 404.1513, 404.1519a, 404.1519m, 404.1520, 404.1520b, 404.1527, 404.1528, 404.1529, 404.1545, 416.905, 416.906, 416.908, 416.911, 416.912, 416.913, 416.919a, 416.919m, 416.920, 416.920b, 416.924, 416.924a, 416.926a, 416.927, 416.928, 416.929, and 416.945; and 20 CFR part 404, appendix 1.

**INTRODUCTION:** In all claims for disability, we need objective medical evidence to establish the existence of a medically determinable impairment (MDI). Genetic test results sometimes are a part of this objective medical

<sup>1</sup>For simplicity, we refer in this SSR only to initial claims for disability benefits under titles II and XVI of the Social Security Act (Act). However, the policy interpretations in this SSR also apply to continuing disability reviews of adults and children under sections 223(f) and 1614(a)(4) of the Act, and to redeterminations of eligibility for benefits we make in accordance with section 1614(a)(3)(H) of the Act when a child who is receiving title XVI payments based on disability attains age 18.

evidence and can also be of value at other points in the sequential evaluation process. In this ruling, we provide basic information about genetic testing and clarify how we apply our policies when evaluating genetic test results found in the medical evidence of record (MER).

**POLICY INTERPRETATION:** We consider all medical evidence, including genetic test results, when evaluating a claim for disability benefits. The information that follows is presented in question and answer format and provides details about medical genetics and how to consider MER containing genetic test results under our disability policy. Questions 1 through 3 provide basic background information about genetic tests and their use in the medical setting. Question 4 discusses the relevance of genetic test results to our disability program. Question 5 discusses whether genetic test results alone are sufficient to make a disability determination. Question 6 clarifies that we do not purchase genetic testing. Questions 7 through 11 specify how adjudicators should handle evidence containing genetic test results at various points of the adjudication process. Question 12 addresses our policy on the disclosure of genetic information.

### List of Questions

1. *What is genetic testing?*
2. *How do genetic variants relate to medical disorders?*
3. *Why do medical professionals order genetic tests?*
4. *Why are genetic tests relevant to us?*
5. *Are genetic test results alone sufficient to make a disability determination or decision?*
6. *Will we purchase genetic testing by way of consultative examination (CE)?*
7. *Do we consider medical evidence that includes the results of genetic tests?*
8. *Do we require genetic test results to find a claimant disabled?*
9. *Who typically provides genetic test evidence?*
10. *Can we consider genetic test results in the sequential evaluation process?*
11. *If a person is found disabled, can we use genetic test results when setting a diary for continuing disability review (CDR)?*
12. *What is our policy regarding the disclosure of the results of genetic tests?*

### Answers

#### 1. *What is genetic testing?*<sup>2</sup>

Genetic testing is a type of medical test that identifies variations in genetic

<sup>2</sup>For help with the definitions of the terms and concepts related to genetic testing in this SSR, see the National Human Genome Research Institute (NHGRI) Talking Glossary of Genetic Terms, available at <http://www.genome.gov/glossary/index.cfm>.

material. Genetic testing uses laboratory methods to detect genetic variations associated with a disease, condition, or genetic disorder. For the purposes of this ruling, we will consider tests that analyze *chromosomes*, *deoxyribonucleic acid* (DNA), or *ribonucleic acid* (RNA) for the purpose of identifying congenital genetic variations to be genetic tests.<sup>3</sup> Different types of laboratory tests constitute genetic tests. For example, *karyotyping*, which counts and examines the appearance of chromosomes in a cell, is a type of genetic test. Some other types of genetic tests read and evaluate the sequence of the nucleotide bases that make up a DNA molecule or examine changes at one specific place in the genome. Differences from the normal (or reference) sequence are known as mutations or variants. Variants also encompass partial or complete loss or gain of gene copies.

## 2. How do genetic variants relate to medical disorders?

People generally have two copies of every gene in their body, one contributed by their biological mother, the other contributed by their biological father. Some disorders are caused by a variation in a single gene. In certain cases, having a variation in just one of the two copies of the gene is enough to lead to a disorder. If a variant's occurrence in only one copy of the gene is sufficient for a person to develop the disorder, the disorder is *dominant*. The disorder is *recessive* if an associated variant must occur in both copies of the gene for a person to develop the disorder.

Even when a person knows that he or she has a genetic variant associated with or causative of a certain disorder, he or she may not always develop the condition. *Penetrance* is the term that describes the frequency with which people in a population with a given genetic variant actually display signs and symptoms of the associated disorder. It is often expressed as a percentage. *Complete penetrance* indicates that all people in a population with the genetic variant will develop the disorder. *Incomplete or reduced penetrance*, which is far more common, means that only some people in a population with the variant will actually get the disorder. The probability that a given person will have a disorder given that they have the variant is known as *risk* or *chance*.

<sup>3</sup> Clinicians may perform gene expression profiling for certain types of malignant tumors to gather information for cancer treatment. We do not consider such tests in this SSR.

Variants can interact either with one another or with environmental influences (such as ultraviolet light, diet, or smoking) to result in a disorder. These types of disorders are called *complex* or *multifactorial* disorders. Even when genetic variants associated with complex disorders are known, it may be difficult to determine the risk of developing such disorders based on genetic test results. For example, changes in a person's exposure to relevant environmental influences can modify the risk of developing a disease or the severity of a genetic condition.

Chromosomal abnormalities can lead to disorders as well. A chromosome is an organized package of DNA located in the nucleus of a cell. People generally have 2 copies of each of 23 chromosomes in their cells. *Aneuploidy* means an incorrect number of chromosomes. Down syndrome is an example of a genetic disorder caused by aneuploidy. It is the result of a person having an extra copy of chromosome 21 in some or all of his or her cells. A defect in a chromosome's structure may also cause a genetic condition. Cri du chat syndrome is an example of a disorder that results from a structural chromosomal abnormality. It is due to one chromosome 5 missing a part.

## 3. Why do medical professionals order genetic tests?

Like other laboratory tests or procedures, genetic tests can help medical professionals diagnose a particular disease or disorder. They assist in predicting the extent of disease features or risk of developing a certain disorder, aid in therapy, and provide useful information for reproductive purposes.

### a. Diagnostic Tests

Medical professionals may use genetic tests to diagnose a particular disorder. They will usually order or perform these tests when a person has medical signs or symptoms consistent with that disorder and a link between specific genetic variations and the disorder is well-characterized. They may also use testing when a disorder is present but unrecognized (or undiagnosed) to work through a list of possibilities, *i.e.*, differential diagnoses. Such tests are known as *diagnostic* genetic tests. Hemochromatosis is an example of a disease for which medical professionals use a diagnostic genetic test to help confirm a diagnosis.<sup>4</sup>

<sup>4</sup> See the Genetics Home Reference page for hemochromatosis available at <http://ghr.nlm.nih.gov/condition/hemochromatosis>.

### b. Predictive Tests

A person might choose to have a genetic test even if he or she does not have medical signs or symptoms indicative of a disorder. Instead, he or she may undergo testing to find out whether he or she has a genetic variant that might put him or her at risk for developing a disorder in the future. This type of test is a *predictive* genetic test. A positive predictive test result may result in a pre-symptomatic diagnosis of a genetic condition, or just knowledge of an increased risk of developing that condition. Examples of predictive genetic tests are those looking for variations in the genes *BRCA1* and *BRCA2*, which assess a person's risk for certain inherited breast and ovarian cancer syndromes.<sup>5</sup>

It is important to note that, for many conditions, predictive genetic tests cannot tell with certainty whether a person will develop a disorder. The results of predictive genetic tests generally give a probability or range of probabilities that a disorder will eventually develop in the person being tested. Predictive genetic tests also generally cannot tell a person precisely how the disorder will affect him or her. Many times, predictive genetic testing is most helpful when a person has a known family history of a disease, and not knowing the disease risk would lead to serious consequences. A person may choose to undergo predictive genetic testing to make decisions about future medical care or to implement lifestyle changes to help mitigate potential risk for adverse health effects.

### c. Pharmacogenetic Tests

Medical professionals might order *pharmacogenetic* tests for a patient who needs to receive pharmaceutical therapy for his or her disorder. The information from this kind of genetic test can help medical staff understand how a patient may react to a particular drug and assist in selection of the safest, most effective type and dosage of medicine for that specific person.

### d. Tests for Reproductive Purposes

There are genetic tests that people obtain prior to having a child in order to inform them about the potential for a genetic disorder in their child. These reproductive genetic tests include *carrier* tests, *prenatal* tests, and *predictive* tests for a late-onset

<sup>5</sup> See the National Cancer Institute, at the National Institutes of Health's, discussion of *BRCA1* and *BRCA2*, available at <http://www.cancer.gov/cancertopics/pdq/genetics/breast-and-ovarian/HealthProfessional/page2>.

dominant disorder in an at-risk parent.<sup>6</sup> Carrier genetic tests are performed on people who display no symptoms for a genetic disorder but may be at risk for passing it on to their children. Diagnostic prenatal genetic tests show if the developing baby has a certain genetic condition. A parent with a family history of a genetic disorder with dominant inheritance that does not manifest until after childbearing years may wish to get a predictive genetic test for that disorder to understand the risk of passing that disorder to his or her child.

#### 4. Why are genetic tests relevant to us?

Scientific researchers are discovering an increasing number of associations between genetic variants and medical disorders.<sup>7</sup> With this knowledge often comes the ability to perform a laboratory test to determine whether a person carries a genetic variation associated with a particular disorder. There are tens of thousands of genetic tests available for clinical use and the number continues to grow. These tests can identify thousands of genetic disorders.<sup>8</sup> The results of such tests may appear in disability case records. Genetic tests are more widely available and genetic test results are now more commonplace within disability case files.

#### 5. Are genetic test results alone sufficient to make a disability determination or decision?

With the sole exception of non-mosaic Down syndrome, genetic test results alone are not sufficient to make a disability determination or decision. A person may be found disabled based on meeting the criteria for non-mosaic Down syndrome in the Listing of Impairments (listings) under 10.06A and 110.06A, when this condition is documented by a karyotype report

<sup>6</sup> We do not make a determination of disability for fetuses. We can, however, consider the results of certain prenatal genetic tests as part of the MER in accordance with our policy once the child is born and a disability claim has been filed on his or her behalf.

<sup>7</sup> Current statistics on genetic variants and corresponding conditions can be found at the Online Mendelian Inheritance in Man database on the "Statistics" page, available at <http://www.ncbi.nlm.nih.gov/clinvar/submitters/> or <http://www.omim.org/statistics/entry>.

<sup>8</sup> See the NCBI Genetic Testing Registry, available at <http://www.ncbi.nlm.nih.gov/gtr/all/tests/?term=all%5bsb> (last visited August 2015). See also, the American Medical Association (AMA) page regarding genetic testing, available at <http://www.ama-assn.org/ama/pub/physician-resources/medical-science/genetics-molecular-medicine/related-policy-topics/genetic-testing.page>. See also, the Centers for Disease Control and Prevention (CDC) page regarding genetic testing, available at <http://www.cdc.gov/genomics/gtesting/>.

signed by a physician.<sup>9</sup> Genetic test results alone are otherwise not sufficient to make a disability determination; however, in two other medical listings, we use genetic test results as part of the criteria to evaluate whether a person's impairment meets the listing.<sup>10</sup> Additional evidence, including signs and symptoms of a person's impairment, is generally necessary to make a disability determination. As genetic testing continues to advance, we will consider appropriate changes to our program policy.

#### 6. Will we purchase genetic testing by way of consultative examination (CE)?

No. We will not order genetic testing in a CE. While genetic test results may provide valuable information when they appear as part of a large body of MER, they are not necessary to establish a finding of disability.

#### 7. Do we consider medical evidence that includes the results of genetic tests?

Yes, we consider all evidence we receive, including genetic test results, when evaluating a disability claim.<sup>11</sup> In considering a disability claim, we generally request evidence about a person's medical impairment(s) for a period of at least the 12 months (and a longer duration if circumstances warrant) preceding the month in which a person files an application.<sup>12</sup> This includes objective medical evidence, a claimant's reported symptoms, statements from others about the effects of the claimant's impairment(s), and opinion evidence.<sup>13</sup>

The results of genetic tests constitute laboratory findings, which are considered objective medical evidence. Consistent with our regulations, when genetic test results are available, we will consider them, together with all relevant evidence available in the case record, such as signs, symptoms, other laboratory findings, and medical opinion evidence.<sup>14</sup> When evidence is inconsistent, such as when genetic test results are inconsistent with other substantial evidence, we will resolve the

<sup>9</sup> Under listings 10.06A and 110.06A, a laboratory report of karyotype analysis not signed by a physician is also sufficient if it is accompanied by a statement of a physician that the person has Down syndrome.

<sup>10</sup> These listings are for xeroderma pigmentosum (8.07A and 108.07A), 20 CFR part 404, subpart P, appendix 1.

<sup>11</sup> 20 CFR 404.1512(b)(1), 404.1513(b)(3), 404.1520(a)(3), 404.1528(c), 416.912(b)(1), 416.913(b)(3), 416.920(a)(3), 416.928(c).

<sup>12</sup> 20 CFR 404.1512(d), 404.1519m, 416.912(d), and 416.919m.

<sup>13</sup> 20 CFR 404.1512(b), 404.1513(d), 404.1527, 416.912(b), 416.913(d), and 416.927. SSR 06-03p.

<sup>14</sup> 20 CFR 404.1512(b), 404.1520(a)(3), 416.912(b), 416.920(a)(3), 416.924(a), and 416.924a(a)(1)(i).

inconsistency when it is material to the disability determination, as we do with all medical evidence.<sup>15</sup>

#### 8. Do we require genetic test results to find a claimant disabled?

No, genetic test results are not required for a finding of disability. A finding of disability requires a claimant to have an MDI, which can be expected to result in death or which has lasted or can be expected to last for a continuing period of not less than 12 months.<sup>16</sup> We establish physical and mental impairments by medical evidence consisting of signs, symptoms, and laboratory findings.<sup>17</sup> While several medical listings require or reference the use of genetic test results as a way to meet the applicable listing at step 3 of the sequential evaluation process,<sup>18</sup> our rules do not require the results of genetic tests in order to determine that a person is disabled.

#### 9. Who typically provides genetic test evidence?

We typically receive the results of genetic tests in medical evidence from clinical geneticists, other physicians, and genetic counselors. Claimants sometimes provide results of "direct-to-consumer" (DTC) medical tests. We will consider genetic test results from all sources, medical and otherwise.<sup>19</sup>

##### a. Geneticists and Other Physicians

Clinical geneticists are physicians specializing in the diagnosis and management of hereditary disorders. Clinical geneticists and other licensed physicians have a medical degree and are acceptable medical sources (AMS). We establish the existence of an MDI using objective medical evidence (signs or laboratory results) from an AMS. Cytogeneticists, biochemical geneticists, and molecular geneticists may hold a Ph.D. or a medical degree (e.g., M.D. or D.O.); those without a medical degree are generally not AMSs. For example, Ph.D. cytogeneticists typically work in laboratories or act as clinical consultants, but do not regularly interact with patients. These types of geneticists may be involved in obtaining genetic testing results and may be board-certified, but they are not AMSs if they are not also licensed physicians or otherwise classified as an AMS.

<sup>15</sup> 20 CFR 404.1520b and 416.920b

<sup>16</sup> 20 CFR 404.1505(a) and 416.905(a).

<sup>17</sup> 20 CFR 404.1508 and 416.908.

<sup>18</sup> Listings 8.07, 10.06A, 10.06B, 108.07, 110.06A, and 110.06B, 20 CFR part 404, subpart P, appendix 1, require genetic testing results in order for these impairments (genetic photosensitivity disorders and non-mosaic Down syndrome) to meet the listing.

<sup>19</sup> 20 CFR 404.1513(a), 404.1513(d), 416.913(a), and 416.913(d).

## b. Genetic Counselors

Genetic counselors assess and communicate genetic risk for medical conditions in a person and members of his or her biological family. They obtain and evaluate personal and family medical histories as well as identify and coordinate genetic tests and other diagnostic studies, as appropriate, to obtain needed information for a genetic assessment. They are also able to explain the clinical implications of genetic laboratory tests and other diagnostic studies and their results.<sup>20</sup>

These professionals typically hold a master's degree in Genetic Counseling and may be board-certified by the American Board of Genetic Counseling (denoted by the use of the credential "Certified Genetic Counselor" or CGC). However, we do not consider a genetic counselor to be an AMS under our rules unless the individual is also a licensed physician or other AMS provider. This is true even when the genetic counselor is licensed to practice genetic counseling by his or her State. We cannot establish the existence of an MDI based solely on a report from a genetic counselor. We can use evidence from genetic counselors working in an independent capacity to show the severity of a person's impairment and how it affects the person's ability to work, or, for children, how the child typically functions compared to children of the same age who do not have impairments.<sup>21</sup>

## c. "Direct-to-Consumer" (DTC) Tests

DTC genetic tests are available and appear to be growing in popularity. These tests are generally marketed directly to consumers via television, print advertisements, or the internet. A person typically collects a DNA sample at home, such as by swabbing the inside of the cheek, and mails the sample back to the laboratory for testing. In some cases, the person must visit a health clinic to have blood drawn. The samples are analyzed and consumers are directly notified of the results by mail, over the telephone, or online.<sup>22</sup>

There is currently little regulation and oversight of DTC genetic testing, leading

to concerns about its accuracy, reliability, and clinical relevance.<sup>23</sup> DTC services generally do not establish an appropriate chain of custody of the DNA sample. There is no assurance that DTC genetic test results belong to a given claimant, as the entire transaction typically takes place with no personal interaction with a medical source or without any type of oversight that confirms the identity of the person providing the sample. For these reasons, DTC genetic test results cannot be the basis for establishing an MDI, regardless of AMS adoption or involvement.<sup>24</sup> Nevertheless, DTC results, when consistent with independent credible objective medical evidence, can help corroborate other findings or the claimant's allegations.<sup>25</sup>

### 10. Can we consider genetic test results in the sequential evaluation process?

Yes, we consider genetic test results and all other evidence in varying ways throughout the sequential evaluation process.<sup>26</sup> At step 2 we establish whether a person has an MDI and whether the impairment or combination of impairments is severe, *i.e.*, whether it significantly limits the physical or mental ability to do basic work activities.<sup>27</sup> Information from genetic test results can help establish an MDI if they are from an AMS and not based on DTC test results. However, a genetic test alone cannot typically show whether or not an impairment is severe. At step 3 we consider whether the impairment meets or medically equals the requirements of a listed impairment in the medical listings. Several of our medical listings include criteria that require appropriate genetic test results for an impairment to meet the listing.<sup>28</sup>

If a person's MDI does not meet or medically equal a listing, we assess whether the impairment(s) results in functional limitations that would prevent him or her from performing past relevant work or other work at steps 4

and 5 of sequential evaluation.<sup>29</sup> For children, we assess whether the impairment(s) causes marked and severe functional limitations.<sup>30</sup> Genetic test results generally do not provide us with significant information about impairment severity or functional capacities.

### a. Can we use genetic test results to establish an MDI (Step 2)?

When genetic test results come from an AMS and are not based on DTC genetic testing, we can use the evidence to establish an MDI if there are signs and symptoms consistent with the impairment.<sup>31</sup> We can consider the results of previously-performed genetic testing in establishing an MDI, if signs and symptoms of an impairment are present. We cannot use the results of genetic tests, in the absence of any signs or symptoms, as the sole basis for establishing an MDI, even if the results are highly-suggestive of the eventual development of an impairment.<sup>32</sup> We must be able to establish that a person has an MDI at the disability onset date.

Although non-physician geneticists are generally not AMSs, a physician or other AMS typically reviews or evaluates test results produced by a non-physician geneticist and incorporates these test results into an individual's medical record. In such a case, the evidence can be used to help establish an MDI. Similarly, genetic counselors are generally not AMSs. Therefore, we cannot establish the existence of an MDI based solely on a report from a genetic counselor. However, genetic counselors typically work in a setting where they are in close collaboration with a physician or other AMS. When a person is referred for diagnostic testing by a genetic counselor, the results are often reviewed, evaluated, interpreted, or used by a physician and incorporated into a medical record. In such a case, this evidence can help establish an MDI.

Similar to imaging from an x-ray or MRI, which requires AMS involvement to establish an MDI, a genetic test result without AMS involvement cannot establish an MDI. A DTC genetic test result, even if evaluated, interpreted, or otherwise utilized by an AMS, cannot lead to the establishment of an MDI

<sup>20</sup> 20 CFR 404.1520(f), 404.1520(g), 416.920(f), and 416.920(g).

<sup>29</sup> 20 CFR 416.906 and 416.926a.

<sup>30</sup> Predictive, as opposed to diagnostic, test results from an AMS do not constitute laboratory results that can establish an MDI.

<sup>31</sup> For example, see FN5 regarding the predictive nature of genetic tests for *BRCA1* and *BRCA2*. The meeting of listings 10.06 or 110.06, based on a karyotype report signed by a physician, would be an exception.

<sup>20</sup> See the National Society of Genetic Counselors (NSGC) page regarding genetic counselor licensure, available at <http://nsgc.org/p/cm/ld/fid=18>.

<sup>21</sup> 20 CFR 404.1513(d) and 416.913(d).

<sup>22</sup> See the Genetics Home Reference page, a service of the U.S. National Library of Medicine, detailing what direct-to-consumer genetic testing is, available at <http://ghr.nlm.nih.gov/handbook/testing/directtoconsumer>. See also, the American College of Preventative Medicine's Genetic Testing Clinical Reference for Clinicians and Genetic Testing Time tool pages, illustrating the growth of genetic testing, available at <http://www.acpm.org/?GeneticTestClinRef>.

<sup>23</sup> See Yale Journal of Biology and Medicine, Direct-to-Consumer Genetic Testing: A Comprehensive View. (Yale J Biol Med. Sep 2013; 86(3): 359–365). See also, the American Society of Human Genetics statement on direct-to-consumer genetic testing in the United States. (Am. J. Hum. Genet. 2007; 81: 635–637).

<sup>24</sup> 20 CFR 404.1508 and 416.908.

<sup>25</sup> 20 CFR 404.1520b and 416.920b.

<sup>26</sup> Step 1 of the sequential evaluation process considers work activity and whether a claimant is engaged in substantial gainful activity. Genetic testing or genetic test results do not impact this step.

<sup>27</sup> For children, we will consider whether you have more than a slight abnormality or combination of slight abnormalities that cause more than minimal functional limitations. See 20 CFR 404.1520(c), 416.920(c), and 416.924(c).

<sup>28</sup> See FN 18.

because there is no assurance that the test results belong to a given claimant and no appropriate chain of custody of the sample is established.

Many disorders with a known genetic basis can be, and often are, established by means other than genetic tests. For example, although diagnostic genetic tests for cystic fibrosis exist, as do guidelines surrounding their use, the most common confirmatory test for this disease is the sweat chloride test, which measures the concentrations of a certain electrolyte in a person's sweat.<sup>33</sup> It is not a genetic test. While we consider genetic test results in conjunction with the rest of the objective medical evidence when they are available, we do not require a person to undergo such testing to prove they have an MDI or are disabled.

b. Can we evaluate impairment severity using the results of genetic tests (Step 2)?

To some extent, genetic test results can be helpful in our overall impairment evaluation, but generally they do not help us determine whether or not an impairment is severe. For an impairment to be severe, it must significantly limit an adult's physical or mental ability to do basic work activities.<sup>34</sup> In the case of a child, for an impairment to be severe it must be more than a slight abnormality that causes more than minimal functional limitations.<sup>35</sup>

Genetic test results generally do not provide information about the degree of functional limitation associated with an impairment, but they can be used to help evaluate for consistency with or supportability of alleged symptoms and limitations. With the exception of non-mosaic Down Syndrome, we need evidence other than genetic test results to show a person's impairment is severe. This evidence comes from other medical records, a claimant's report of symptoms, and statements from nonmedical sources.<sup>36</sup>

c. Can we evaluate medical listings with genetic test results (Step 3)?

For several medical listings, we use genetic test results to evaluate whether a person's impairment meets a medical listing. Four of our medical listings include, as part of the criteria for an

impairment to meet a listing, the use of appropriate genetic test results.<sup>37</sup> Listings 10.06 and 110.06 for non-mosaic Down syndrome (trisomy 21) use the results of genetic tests. Karyotyping for Down syndrome is the "gold standard" for diagnosis. We typically require the results of karyotype analysis for an impairment to meet 10.06A, 10.06B, 110.06A, or 110.06B.<sup>38</sup> Additionally, we require diagnostic genetic test results for xeroderma pigmentosum to meet listing 8.07A or 108.07A.

We may also use genetic test results indicating the presence of a catastrophic congenital disorder, such as Edward's syndrome (trisomy 18), to find a child's impairment meets listing 110.08. Other medical listings are for disorders, such as cystic fibrosis<sup>39</sup> and chronic myelogenous leukemia, with at least one known genetic basis and an available associated test.<sup>40</sup> Often, additional medical evidence is required to find a person's impairment meets a relevant listing.<sup>41</sup>

d. Can we evaluate the degree of limitation and residual functional capacity (RFC) using genetic test results (Steps 4 and 5)?

While genetic tests may help to establish the presence of a disorder and assist in determining whether an impairment meets or medically equals a listing, the results alone generally do not provide us with information about the degree of a person's limitation due to the impairment. A claimant's RFC reflects the most he or she can do despite his or her limitations.<sup>42</sup> If an

adult's impairment does not meet or medically equal a listing at step 3 of the sequential evaluation process, we assess RFC, which applies to both steps 4 and 5. If a child's impairment does not meet or medically equal a listing, we assess functional equivalence. Functional equivalence deals with broad areas of functioning intended to capture all of what a child can or cannot do.<sup>43</sup> As is the case with RFC, genetic test results alone generally do not provide us with information about the degree of limitation as it relates to functional equivalence.

To assess a claimant's impairments beyond step 3, we need non-genetic evidence about the impairment's effect on a person's functioning to determine the most the person can do despite his or her limitations and restrictions.<sup>44</sup> Many disorders associated with known gene mutations are multifactorial in nature. Environmental and other influences that are not well-understood affect the development of medical signs and symptoms resulting from the disorder and the degree of limitation a person with the disorder experiences. Therefore, additional evidence is necessary to adequately assess a person's RFC and ability to engage in work activities.

However, results of genetic tests can be assessed for consistency with a person's symptoms and alleged limitations. For example, genetic test results may lead an AMS to diagnose familial Mediterranean fever. A common symptom is painful inflammation in various areas of the body, including joints.<sup>45</sup> If someone complains of significant joint pain and has genetic test results leading to a diagnosis of familial Mediterranean fever, we can take into account that the claimant's reported symptoms are consistent with the genetic test results.

*11. If a person is found disabled, can we use genetic test results when setting a diary for continuing disability review (CDR)?*

Yes. We consider all impairments and case facts to determine when to conduct a CDR. We conduct a full evaluation of all evidence, including genetic test results, when setting diary dates. Due to the diversity of types of genetic tests and the differing types of information that genetic test results can provide, the

<sup>37</sup> These listings include those for xeroderma pigmentosum (8.07A and 108.07A) and non-mosaic Down syndrome (10.06A and 110.06A), 20 CFR part 404, subpart P, appendix 1.

<sup>38</sup> Listings 10.06 and 110.06, 20 CFR part 404, subpart P, appendix 1, require that a claimant's non-mosaic Down syndrome be documented by: A. a laboratory report of karyotype analysis signed by a physician, or both a laboratory report of karyotype analysis not signed by a physician and a statement by a physician that you have Down syndrome (see 10.00C1); B. a physician's report stating that you have chromosome 21 trisomy or chromosome 21 translocation consistent with prior karyotype analysis with the distinctive facial or other physical features of Down syndrome (see 10.00C2a); or C. a physician's report stating that you have Down syndrome with the distinctive facial or other physical features and evidence demonstrating that you function at a level consistent with non-mosaic Down syndrome (see 10.00C2b).

<sup>39</sup> Listings 3.04 and 103.04, 20 CFR part 404, subpart P, appendix 1.

<sup>40</sup> Listings 13.06B and 113.06B, 20 CFR part 404, subpart P, appendix 1.

<sup>41</sup> 20 CFR part 404, subpart P, appendix 1. For example, Marfan syndrome (listings 4.00H and 104.00F) and genetic photosensitivity disorders other than xeroderma pigmentosum (listing 8.07 and 108.07).

<sup>42</sup> 20 CFR 404.1545 and 416.945.

<sup>43</sup> 20 CFR 416.906 and 416.926a.

<sup>44</sup> 20 CFR 404.1545(a), 416.945(a), and SSR 96-8p, Titles II and XVI: Assessing Residual Functional Capacity in Initial Claims (1996), 61 FR 34474, available at <http://www.socialsecurity.gov/OP-Home/rulings/di/01/SSR96-08-di-01.html>.

<sup>45</sup> See <http://ghr.nlm.nih.gov/condition/familial-mediterranean-fever>.

<sup>33</sup> See <http://www.nlm.nih.gov/medlineplus/ency/article/003630.htm>.

<sup>34</sup> 20 CFR 404.1520(c) and 416.920(c).

<sup>35</sup> 20 CFR 416.924(c).

<sup>36</sup> In cases of a catastrophic congenital disorder, as detailed in listing 110.08, 20 CFR part 404, subpart P, appendix 1, or other extreme cases, genetic test results alone may show a person's impairment is severe.

impact of genetic test results on diary lengths will vary.

*12. What is our policy regarding the disclosure of the results of genetic tests?*

The Privacy Act of 1974 (5 U.S.C. 552a), section 1106 of the Social Security Act (42 U.S.C. 1306), and our disclosure regulations (20 CFR part 401) govern the collection, maintenance, and use of an individual's information in our systems of records. Although these authorities do not specifically address requirements for the disclosure of genetic test results, they apply to the extent we maintain this type of information in our records.

Under the Privacy Act and our disclosure regulations, we generally cannot disclose genetic test results without the consent of the subject of the record. For example, if an individual's MER contains genetic test results and he or she authorizes us to disclose this specific information to a third party, we will do so with a valid, written consent that meets our regulatory requirements.

In addition, the Privacy Act grants individuals a right of access to any records we maintain about them in our systems of records. Therefore, any genetic test results we maintain in an individual's MER (including records a medical consultative examiner may have generated on our behalf) are subject to these access requirements, as is the case with all medical evidence. However, if we determine that direct access to the medical information is likely to have an adverse effect on the subject of the record, we will follow certain procedures in providing access to the information.<sup>46</sup>

**EFFECTIVE DATE:** This SSR is effective on April 13, 2016.

**CROSS REFERENCES:** SSR 86–8, Titles II and XVI: The Sequential Evaluation Process; SSR 96–2p, Titles II and XVI: Giving Controlling Weight to Treating Source Medical Opinions; SSR 96–5p, Titles II and XVI: Medical Source Opinions on Issues Reserved to the Commissioner; SSR 96–7p, Titles II and XVI: Evaluation of Symptoms in Disability Claims: Assessing the Credibility of an Individual's Statements; SSR 96–8p, Titles II and XVI: Assessing Residual Functional Capacity in Initial Claims; SSR 06–3p, Titles II and XVI: Considering Opinions and Other Evidence from Sources Who Are Not "Acceptable Medical Sources" in Disability Claims; Considering Decisions on Disability by Other Governmental and Nongovernmental Agencies; and Program Operations Manual System (POMS) DI 00115.015,

DI 22501.001, DI 22505.001, DI 22505.003, DI 24501.020, DI 24515.001, DI 24515.061, DI 24515.062, DI 25201.005.

[FR Doc. 2016–08467 Filed 4–12–16; 8:45 am]

**BILLING CODE 4191–02–P**

## DEPARTMENT OF STATE

[Public Notice: 9515]

### Advisory Committee on International Economic Policy

**ACTION:** Notice of open meeting.

The Advisory Committee on International Economic Policy (ACIEP) will meet from 2:00 p.m. until 5:00 p.m., on Tuesday, May 17, in Washington, DC at the State Department, 320 21st Street NW., in conference room 4477. The meeting will be hosted by the Assistant Secretary of State for Economic and Business Affairs, Charles H. Rivkin and Committee Chair Paul R. Charron. The ACIEP serves the U.S. government in a solely advisory capacity, and provides advice concerning topics in international economic policy. It is expected that during this meeting, the ACIEP subcommittees on sanctions policy, investment policy, and the Stakeholder Advisory Board will provide updates on their recent work.

This meeting is open to the public, though seating is limited. Entry to the building is controlled. To obtain pre-clearance for entry, members of the public planning to attend should *no later than Monday, May 9*, provide their full name and professional affiliation to Alan Krill by email: [Krilla@state.gov](mailto:Krilla@state.gov). Requests for reasonable accommodation should be made to Alan Krill before Monday, May 9. Requests made after that date will be considered, but might not be possible to fulfill.

For additional information, contact Alan Krill, Bureau of Economic and Business Affairs, at (202) 647–0812, or [Krilla@state.gov](mailto:Krilla@state.gov).

Dated: April 6, 2016.

**Alan Krill,**  
*Designated Federal Officer, U.S. Department of State.*

[FR Doc. 2016–08502 Filed 4–12–16; 8:45 am]

**BILLING CODE 4710–AE–P**

## STATE JUSTICE INSTITUTE

### SJI Board of Directors Meeting

**AGENCY:** State Justice Institute.

**ACTION:** Notice of meeting.

**SUMMARY:** The SJI Board of Directors will be meeting on Monday, April 18,

2016 at 1:00 p.m. The meeting will be held at the Supreme Court of Kentucky in Frankfort, Kentucky. The purpose of this meeting is to consider grant applications for the 2nd quarter of FY 2016, and other business. All portions of this meeting are open to the public.

**ADDRESSES:** Supreme Court of Kentucky, State Capitol, Room 235, Frankfort, KY 40601.

**FOR FURTHER INFORMATION CONTACT:** Jonathan Mattiello, Executive Director, State Justice Institute, 11951 Freedom Drive, Suite 1020, Reston, VA 20190, 571–313–8843, [contact@sjj.gov](mailto:contact@sjj.gov).

**Jonathan D. Mattiello,**

*Executive Director.*

[FR Doc. 2016–08468 Filed 4–12–16; 8:45 am]

**BILLING CODE P**

## TENNESSEE VALLEY AUTHORITY

### Meeting of the Regional Resource Stewardship Council; Correction

**AGENCY:** Tennessee Valley Authority (TVA).

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

**SUMMARY:** This is a correction to the **Federal Register** Notice regarding the location for the TVA Regional Resource Stewardship Council (RRSC) meeting on April 26, 2016 that was originally published in the **Federal Register** on April 8, 2016. This corrects the meeting location noted in the address section of the original **Federal Register** Notice.

The RRSC was established to advise TVA on its natural resource stewardship activities. Notice of this meeting is given under the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2.

The meeting agenda includes the following:

1. Introductions
2. Updates on Natural Resources issues
3. Presentations regarding TVA Stewardship Initiatives and Reservoir Release Improvement Program
4. Public Comments
5. Council Discussion

The RRSC will hear opinions and views of citizens by providing a public comment session starting at 10:15 a.m., EDT, on Tuesday, April 26. Persons wishing to speak are requested to register at the door by 9:45 a.m. EDT on Tuesday, April 26 and will be called on during the public comment period. Handout materials should be limited to one printed page. Written comments are also invited and may be mailed to the Regional Resource Stewardship Council, Tennessee Valley Authority, 400 West Summit Hill Drive, WT–9 D, Knoxville, Tennessee 37902.

<sup>46</sup> 20 CFR 401.55.