

February 15, 2019

Nancy Berryhill Acting Commissioner Social Security Administration 6401 Security Boulevard Baltimore, MD 21235-6401

Submitted via www.regulations.gov

Re: Advanced Notice of Proposed Rulemaking on Consideration of Pain in the Disability Determination Process, 83 Fed. Reg. 64493 (December 17, 2018), Docket No. SSA-2018-0017

Dear Acting Commissioner Berryhill:

These comments are submitted on behalf of the Social Security Task Force of the Consortium for Citizens with Disabilities (CCD). CCD is a working coalition of national consumer, advocacy, provider, and professional organizations working together with and on behalf of the 57 million children and adults with disabilities and their families living in the United States. CCD's Social Security Task Force ("CCD Task Force") focuses on disability policy issues in the Title II disability programs and the Title XVI Supplemental Security Income (SSI) program.

The undersigned organizations appreciate the opportunity to provide information regarding the consideration of pain in the disability determination process. The evaluation of pain plays a central role in determining whether an individual is entitled to Social Security disability benefits under Title II or Title XVI of the Social Security Act in hundreds of thousands disability claims each year. Many chronic conditions with pain as a primary symptom are hard to diagnose and are often diagnosed through a process of exclusion. When the condition, like fibromyalgia or lupus, has yet to be diagnosed, the lack of objective testing to prove the existence of the pain, not to mention the inability of objective testing to provide any sense of the pain's scope or intensity, can be stressful and mentally draining to the person searching for an explanation of what is happening in his or her body. Objective tests, not only to establish the existence and intensity of pain but also regarding the effect pain has on a person's ability to function and work, would be helpful for people with disabilities and chronic conditions who often feel that people don't believe them when they describe the agony they are in or how severely the pain limits their activities. They are often told by people who have never experienced chronic pain to "tough it out" or "get over it." Unfortunately for people who have impairments of which pain is a

symptom, no objective tests exist to diagnose or evaluate or quantify the expected relief an individual might get from any given treatment. Because pain is considered in determining disability in the listing of impairments for nearly every body system, it is important that the Social Security Administration's (SSA) rules regarding its consideration be based on the most up to date science regarding diagnosis, evaluation, and treatment of pain. Fortunately, SSA's current regulations and Social Security Rulings (specifically SSR 16-3p), do reflect current clinical and scientific research and findings. There is no scientific research or clinical findings to support changing the way SSA considers pain in its disability determination and adjudication processes.

The undersigned organizational members of the CCD Social Security Task Force cannot stress enough that the evaluation of pain must be an individualized determination. To begin with, the Social Security Act requires it. In the context of the consideration of pain in the disability determination process, this requirement is even more vital because "[p]ain is, literally by definition, a subjective experience. That makes self-report the only true measure." Science has yet to develop a method to objectively measure pain, despite centuries of research attempting to do so. The most widely relied on (and clinically accepted) measures rely on self-reporting of pain using a variety of pain scales. This is because science has not discovered objective ways to measure or test the existence of pain, or to determine its scope or intensity

The lack of basic scientific knowledge regarding the pain process combined with two basic pain-related concepts that have been recognized for centuries - pain threshold and pain tolerance - strongly supports the notion that the evaluation of pain must be individualized and rely on self-reporting. Essentially these concepts mean that whether something hurts a person and, if it does, whether the pain impacts his or her ability to function, is highly individualized. Both pain threshold and pain tolerance impact the individual's experience of pain because what hurts to one person doesn't hurt another and a level of pain that is completely incapacitating for one person barely impacts another person. Given the inability to measure how much stimulus a person may be able to receive from a particular condition or impairment before they experience pain and the inability to know when the individual's pain threshold is reached and how that impacts his or her ability to function, evaluating pain in the context of a Social Security disability claim must necessarily be an individualized inquiry.⁵

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¹ Heckler v. Campbell, 461 US 467, 1983, "It is true that the statutory scheme contemplates that disability hearings will be individualized determinations based on evidence adduced at a hearing. See 42 U.S.C. § 423(d)(2)(A) (specifying consideration of each individual's condition); 42 U.S.C. § 405(b) (1976 ed., Supp. V) (disability determination to be based on evidence adduced at hearing)."

² Karen Davis, a researcher at the Krembil Brain Institute, in Toronto, quoted in Twilley, supra.

³ Nicola Twilley, The Neuroscience of Pain: Brain imaging is illuminating the neural patterns behind pain's infinite variety, *The New Yorker*, July 2, 2018, available at: https://tinyurl.com/y7pntnpt.

⁴ See https://www.practicalpainmanagement.com/sites/default/files/pain scales table.pdf for a table of approximately 2 dozen recognized valid and reliable pain scales.

⁵ See John Walsh, How Much Does It Hurt, The Independent, January 10, 2017 for a discussion of how pain impacts different people differently and a review of the current ability of science to explain pain. Available at https://www.independent.co.uk/life-style/health-and-families/pain-how-much-does-it-hurt-pancreatitus-methods-doctors-measure-a7513101.html.

The fact that research shows that an individual's state of mind about pain (e.g. anticipating the pain, expecting something to hurt) has an impact on the way that pain affects the individual, as does the person's state of mind about other things going on in the individual's life (e.g. stress such as the inability to pay bills; anxiety; worry; and doubt), strongly supports SSA taking psychological and psychosocial factors into consideration when evaluating an individual's self reports of pain and the impact the pain has on an individual's functioning through an individualized assessment. Applying for Social Security disability benefits and waiting for a decision are highly stressful for many people. The fact that the decision about these vital benefits can mean the difference between keeping a roof over one's head or being evicted (or foreclosed on) and keeping food on the table and going hungry, likely has a significant impact on the pain level experienced by claimants. The fact that research has established that people's emotional and mental state impacts how they experience pain provides additional support for the use of an individualized assessment that takes into account the totality of conditions and the life situation of a disability claimant when considering pain and evaluating the impact pain has on the individual's functioning.

There is also growing evidence that chronic pain can change the way that neurons function and create a hypersensitivity to pain in people that experience it. For example, according to Dr. Irene Tracy, sometimes referred to as the "Queen of Pain," we now know that chronic pain is "something new, with a life of its own, with its own biology and its own mechanisms, most of which we really don't understand at all." She goes on to say that "we may all be predisposed by our brain stems to feel pain more acutely or less, but that in chronic-pain patients it's as if the volume knob of pain were turned all the way up and jammed there permanently. No one knows why this hypersensitization occurs." Perhaps this phenomenon is why people who have never been in chronic pain cannot understand the level of pain experienced by people who have. But perhaps, more importantly, it also emphasizes how little scientists, doctors, and other treatment professionals actually know about what causes pain, how to evaluate it, and how to treat it.

The implication of this lack of basic knowledge is that it is premature for SSA to change the way it evaluates pain. Basic science around pain has not advanced to a state where any objective, rigid, or standardized process could be helpful in evaluating a claimant's pain or the impact that pain has on the individual's ability to work. With this background in mind, the undersigned organizations offer the following answers to the specific questions outlined in the ANPRM.

<u>Question 1: Are there changes that we should consider about how we consider pain in the disability evaluation process? If so, what changes do you suggest we make?</u>

SSA does not need to make changes in the way it considers pain in the disability evaluation process. The current regulations provide for a very individualized determination of the intensity

⁶ See e.g. American Pain Society, "Biological, Psychological, and Social Factors Influence Individual Pain Differences, May, 7, 2009, available at https://www.newswise.com/articles/biological-psychological-and-social-factors-influence-individual-pain-differences; see also Roger Fillingim, "Individual Differences in Pain: Understanding the Mosaic that Makes Pain Personal," April 2018, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5350021/.

⁷ Twilley, supra.

⁸ Twilley, supra.

and duration of the pain as well as the impact that pain has on the claimant's functioning, which is currently the only medically accurate way to consider pain. 9 20 CFR §404.1529 provides:

- (3) Factors relevant to your symptoms, such as pain, which we will consider include:
- (i) Your daily activities; (ii) The location, duration, frequency, and intensity of your pain or other symptoms; (iii) Precipitating and aggravating factors; (iv) The type, dosage, effectiveness, and side effects of any medication you take or have taken to alleviate your pain or other symptoms; (v) Treatment, other than medication, you receive or have received for relief of your pain or other symptoms; (vi) Any measures you use or have used to relieve your pain or other symptoms (e.g., lying flat on your back, standing for 15 to 20 minutes every hour, sleeping on a board, etc.); and (vii) Other factors concerning your functional limitations and restrictions due to pain or other symptoms.
- (4) How we determine the extent to which symptoms, such as pain, affect your capacity to perform basic work activities. In determining the extent to which your symptoms, such as pain, affect your capacity to perform basic work activities, we consider all of the available evidence described in paragraphs (c)(1) through (c)(3) of this section. We will consider your statements about the intensity, persistence, and limiting effects of your symptoms, and we will evaluate your statements in relation to the objective medical evidence and other evidence, in reaching a conclusion as to whether you are disabled. We will consider whether there are any inconsistencies in the evidence and the extent to which there are any conflicts between your statements and the rest of the evidence, including your history, the signs and laboratory findings, and statements by your medical sources or other persons about how your symptoms affect you. Your symptoms, including pain, will be determined to diminish your capacity for basic work activities to the extent that your alleged functional limitations and restrictions due to symptoms, such as pain, can reasonably be accepted as consistent with the objective medical evidence and other evidence.

As discussed in the introduction, an individualized assessment is the only clinically valid way to determine the impact pain has on functioning in evaluating disability. This is also vital when evaluating prescribed treatments and the impact the treatment has on pain and function. Because the general mechanisms of pain in the brain are poorly understood by the scientific community, it is difficult to develop treatments to address it. Just as the intensity of pain a person feels from a given stimulus can vary significantly, so can a person's reaction to a given treatment for pain. Treatments such as physical therapy, rest, stretching or chiropractic adjustments might help one individual greatly, have no effect on another, and make a third person's pain worse. Also, that same treatment might lessen one claimant's pain at a particular point in time but eventually stop being effective as the nature of the pain changes or the person becomes hypersensitized to the pain.

It follows that the failure of a doctor to prescribe a particular treatment should never be taken as evidence that the doctor does not think his or her patient is in pain or an indication of the intensity of pain that an individual is experiencing. This is especially true when the treatment not prescribed is an opioid or other narcotic pain reliever. Given the lack of evidence regarding the effectiveness of pain treatments, each doctor will consider what treatment to provide based on his or her experience with other individuals and their particular medical history.

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^{9 20} CFR §404.1529 and 20 CFR §419.929 (future citations will refer only to regulations under Title II of the Social Security Act).

As SSA is aware, the United States faces an epidemic of opioid addiction and opioid related deaths, with more than 130 people per day dying from overdoses. 10 Although standards of care might vary in different specialties and in different circumstances (e.g. post-surgical care vs. post traumatic injury), most counsel very short-term use and the prescription of alternate treatments. The Centers for Disease Control and Prevention (CDC) for example, states that opioids should not be the "first-line or routine therapy for chronic pain." 11 The CDC also found "evidence on long-term opioid therapy for chronic pain outside of end-of-life care remains limited, with insufficient evidence to determine long-term benefits versus no opioid therapy, though evidence suggests risk for serious harms that appears to be dose-dependent."¹² States have also limited initial prescriptions by statute, with some states prohibiting use longer than four (4) days with an initial prescription.¹³

A claimant's refusal to take opioids or other narcotics if prescribed should also never be viewed as a refusal to follow treatment under 20 CFR §404.1530. Given the lack of evidence regarding clinical effectiveness, the significant side effects (that often prevent people from working – such as extreme fatigue and inability to concentrate), and potential for addiction and other negative outcomes, in many circumstances, not taking opioids even if prescribed could be a rational and appropriate response from a claimant, irrespective of the intensity of his pain and the resulting functional impairment.

SSA's current policy, as outlined in both 20 CFR §§404.1529 and 404.1530 and SSR 16-3p¹⁴ is appropriate in that it neither encourages nor discourages any specific treatment for pain, as there is no clinical evidence to support the efficacy of any particular treatment. It is also appropriate because it requires the adjudicator to make an individualized determination regarding the individual's pain, considering the self-reported levels of intensity, duration and resulting functional limitations, while recognizing that science cannot assist in those assessments because scientists are just beginning their journey and exploration to understand the causes, mechanisms, and processes surrounding pain.

Question 2: Within the United States, which standard scales, questionnaires, or other methods to evaluate the intensity and persistence of pain that are commonly accepted in the medical community do you recommend we consider and why? What information exists about the efficacy or accuracy of those scales, questionnaires, or other methods?

SSA should consider and accept all clinically accepted pain scales. Many pain scales exist that are commonly used and accepted in the United States. These different scales have different advantages and weaknesses, but as long as the scale has been found valid and reliable, SSA

¹⁰ See https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis.

¹¹ CDC Clinical Reminders for Prescribing Opioids for Chronic Pain, March 18, 2017, https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf.

¹² Id. p. 9.

¹³ See http://www.ncsl.org/research/health/prescribing-policies-states-confront-opioid-overdose-epidemic.aspx. 14 SSR 16-3p provides for a detailed individualized analysis of self-reports of pain and the individual's treatment history. Regarding how SSA will evaluate treatment, the ruling provides exceptions that recognize the severe side effects, lack of consistency in effectiveness across individuals of various pain treatment options, among other factors that might lead a doctor not prescribe treatment or an individual not to continue treatment, reflecting the current state of research and science in pan treatment and management.

should accept it. There are a variety of valid reasons a treating source might administer one pain scale over another (e.g. time available during an appointment, familiarity with or training for a particular scale but not another). A claimant should not be disadvantaged because his or her treating source did not administer a specific pain scale. There is no evidence to suggest that one scale is better than another (e.g. more reliable or valid) that would support SSA considering one scale but not another or giving more weight to one scale over another.

When evaluating what a pain scale tells SSA about a particular claimant, it is important for the agency to remember that:

- Pain levels change over time. When evaluating whether an individual's self-report of pain using one of these valid and reliable scales is consistent with objective medical evidence (and other statements made by the claimant), it is important to remember that a pain scale often shows only how the claimant was feeling on a particular day or moment when the scale was administered. In other words, a low rating on a pain scale at a particular interaction with a health care provider is not inherently inconsistent with a report of much more significant pain on another day or time (or a low rating on a scale completed years ago). SSA's analysis should include the totality of the claimant's situation (e.g. does the claimant's pain wax and wane, was the claimant undergoing treatment that was effective at the time the scale was completed but later stopped providing pain relief, what else may have been going on in the claimant's life at that time that could have minimized or exacerbated the experience of pain) to determine whether that rating was inconsistent with other statements or evidence.
- A treating source might have a variety of reasons for using one scale rather than another. This is perfectly legitimate and should not diminish the weight given to the scale when SSA considers it. For example, more detailed and complicated scales might provide SSA with more information but will take longer to administer or require a specialist or specialized training to administer not available to the claimant's treating source. The doctor might choose to administer a unidimensional scale (rate pain 1-10 or visually) because of the time constraints the doctor faces in performing patient exams or the exact reason that the treating source was administering the scale at that particular time.
- The fact that certain pain scales are primarily used to evaluate pain related to certain conditions does not mean that other scales are not valid and reliable to evaluate pain for people with that condition. For example, just because a questionnaire exists designed for adult cancer patients (the Brief Pain Inventory), does not mean the more general McGill Pain Questionnaire shouldn't be considered by SSA as valid and reliable for adult cancer patients. It is true the questions the Brief Pain Inventory asks might provide more information about the impact the pain has on the claimant's functional ability than the McGill Questionnaire does, but SSA should consider both questionnaires and evaluate them under the procedures outlined in 20 CFR §§404.1519 and 416.929 and SSR 16-3p.

Question 3: How is pain and documentation of pain in the medical evidence assessed in other Federal, State, and private disability programs?

The undersigned organizations caution against using procedures or processes for considering pain and documentation of pain in other public or private disability programs as a guide for developing policy in the Social Security disability programs. What is required to establish disability in other public or private disability programs is determined by the governing statute setting eligibility requirements or private insurance policy rules, which SSA itself has acknowledged "differ significantly" from the purpose and specific eligibility requirements under the Social Security Act. ¹⁵

For example, the United States Court of Appeals for the Federal Circuit recently found in Saunders v. Wilkie that, in veterans' disability claims, "...pain is [itself] an impairment because it diminishes the body's ability to function, and that pain need not be diagnosed as connected to a currently underlying condition to function as an impairment." (emphasis added) The Court in Saunders distinguished veterans' claims from Social Security disability claims by drawing a distinction between their authorizing statutes, citing to 42 USC §423(d)(5)(A), which specifically requires "medical signs and findings, established by medically acceptable clinical or laboratory diagnostic techniques which show the existence of a medical impairment that results from anatomical, physiological, or psychological abnormalities which could reasonably be expected to produce the pain." The court reasoned that Congress would have included a requirement that a veteran tie the pain to an underlying condition with medical evidence to establish it in 38 USC §1110 had Congress wanted it to be required. 18 The Saunders decision was issued in April of 2018 and its lasting impact on the veterans' disability compensation programs rules and procedures for evaluating pain might still be evolving. It does, however, create significant differences in the evaluation and consideration of pain between the two programs that counsel caution in trying to replicate any pain documentation or evaluation policies or procedures from veterans' disability compensation programs in the Social Security disability programs. However, when SSA receives or obtains evidence supporting a veteran's benefit determination, agency adjudicators should consider it and use it to determine whether SSA's disability standard is met.

It is difficult to apply the rules and procedures regarding the consideration of pain used by private disability programs and state level programs such as workers' compensation as well. All have different definitions of disability (e.g. only being unable to perform own occupation in

¹⁵ See Revisions to Rules Regarding the Evaluation of Evidence, 82 CFR 5849: "As we stated in the notice of proposed rulemaking (NPRM), there are four reasons why we are not requiring our adjudicators to explain their consideration of these decisions [made by other entities for other disability programs]—(1) the Act's purpose and specific eligibility requirements for disability and blindness differ significantly from the purpose and eligibility requirements of other programs; (2) the other agency or entity's decision may not be in the record or may not include any explanation of how the decision was made, or what standards applied in making the decision; (3) our adjudicators generally do not have a detailed understanding of the rules other agencies or entities apply to make their decisions; and (4) over time Federal courts have interpreted and applied our rules and Social Security Ruling (SSR) 06–03p differently in different jurisdictions."

¹⁶ Saunders v. Wilkie, No. 17-1466 (Fed. Cir. 2018) p. 13

¹⁷ Id. p. 15.

¹⁸ Id. p.12-13.

private disability policies, full and partial as well as temporary and permanent disability in workers' compensation). The definition of disability used for the program might have a different (or in the case of temporary benefits no) duration requirement that could lead to a difference in the way that pain is considered. Given these differences, the undersigned organizations urge caution in trying to apply procedures used in other programs to the Social Security disability programs.

Question 4: Should we evaluate chronic pain differently than acute pain? If so, how and why?

SSA should not consider chronic and acute pain differently. Evaluating pain, whether chronic or acute, must involve an individualized assessment of the impact of pain on the claimant's functioning using the individual's self-reports and considering the totality of the circumstances in his or her life. Social Security disability claimants probably experience pain on a spectrum from acute to chronic and it is the impact of the pain, irrespective of whether it is acute or chronic, on the functioning of the person on which the evaluation should focus.

It is also the case that, because the disability application and appeals process takes so long, someone could apply with acute pain and have his or her pain evolve into chronic pain by the time of a hearing in front of an Administrative Law Judge. Under those circumstances, if SSA created policy to consider acute pain differently than chronic pain, different rules would apply at the application level for the consideration of pain for that claimant than at the hearing level, creating a confusing and unclear process for the claimant and adjudicators. Whether pain is acute or chronic is a distinction without a difference in this context based on the lack of scientific evidence regarding pain. SSA should focus on determining how the pain, whether chronic or acute, affects claimants' functioning and how those functional limitations affect their ability to work.

Question 5: Should we evaluate nociceptive pain differently than neuropathic pain? If so, how and why?

As discussed in the introduction and in answers to previous questions, the experience of pain is subjective and highly individualized. SSA's current policies for evaluating pain are appropriate based on the current state of science and research regarding the causes. There is no evidence that testing or treatment is more effective or accurate for nociceptive pain than it is for neuropathic pain or vice versa. As such, there is no scientific evidence to justify evaluating pain in any other way than obtaining self-reports of pain using an accepted scale and questionnaire and performing an individualized assessment of the individual's pain that incorporates the totality of the claimant's circumstances (especially psychological and mental factors as outlined in the response to question 1) and the impact the pain has on the individual's ability to function.

Question 6: What information and evidence is available on the effectiveness and side effects of the traditional and alternative modalities for treating pain that we should consider?

The effectiveness of both traditional and alternative modalities for treating pain is individualized. As discussed in the answer to question 1, some treatments provide significant relief to some people, a little relief to others, and no relief to some. In addition, even if a treatment is effective

at one point in time, the effectiveness of that treatment can change over time. Generally, studies that evaluate the effectiveness of treatments rely on self-reporting because it is the only way to measure pain. Often, research focuses on treatment regimens that incorporate a variety of treatment modalities (physical and occupational therapy, pharmacological interventions, psychological interventions, acupuncture and other alternative methods) and it can be difficult to isolate the effectiveness of any one treatment. Current research cannot quantify expected improvements for an individual's pain levels or functioning from any particular treatment. SSA should not change the way it considers pain-based treatment effectiveness because the current science and research do not support doing so.

Treatments for pain have a variety of side effects. However, individuals may experience some, all, or none of the recorded side effects of a given treatment; may have side effects that are not recognized by the manufacturer of the treatment; and may experience side effects continuously or sporadically. Different side effects cause different functional limitations for different people and as such, individualized assessments are critical.

Question 7: Can health care utilization and treatment regimens employed by physicians to manage patient pain provide objective insights into the intensity and persistence of pain? When should those regimens not be an indication of the severity of an individual's pain?

In addition to taking into account our previous answers, it is also important to remember that given the lack of scientific evidence to support the efficacy of any one given treatment, the treatment that a doctor prescribes is influenced by a number of factors, including but not limited to: willingness or aversion to prescribing opioids; success or failure of a given treatment for past patients with similar conditions; the extent to which the practitioner uses an interdisciplinary approach; institutional culture; availability of a treatment modality in a given geographic location; insurance coverage of a given treatment modality (and the patient's ability to afford it). SSA will generally not have knowledge of how those factors influenced the source's decision to employ a given treatment regimen or not to employ a given treatment regimen.

Given the individualized nature of the experience of pain and its impact on individuals, the lack of scientific data and research to support the efficacy of any one treatment to address pain, and the myriad of factors that can influence what treatment modalities a treating source employs or does not employ, an individualized assessment that takes into account the self-reporting of pain by the claimant and takes into account the totality of the claimant's circumstances that might affect that claimant's experience of pain and the resulting impact on functioning as is outlined in current SSA policy is the most appropriate approach to evaluating treatment when considering pain in the disability adjudication process.

Conclusion

The consideration of pain in the Social Security disability adjudication process is integral to hundreds of thousands of disability claims each year. SSA's current policy appropriately allows for a very individualized determination of the intensity and persistence of a claimant's pain, as

¹⁹ See e.g. Svetlana Kurklinsky et al, *The Efficacy of Interdisciplinary Rehabilitation for Improving Function in People with Chronic Pain,* Pain Research and Treatment, Volume 2016, Article ID 7217684, 6 pages http://dx.doi.org/10.1155/2016/7217684.

well as the impact the pain has on the individual's ability to work. Current science supports the use of self-reports to evaluate pain and confirms that no objective test to establish the existence or intensity of pain is currently available, nor is any likely to be in the near future. Current research and evidence does not support SSA making changes to its current policies or procedures governing the consideration of pain in the Social Security disability programs.

Thank you for the opportunity to comment on this ANPRM.

Sincerely,

ACCSES

American Association on Intellectual and Developmental Disabilities
American Physical Therapy Association
Community Legal Services of Philadelphia
Easterseals
Justice in Aging
Lupus Foundation of America
National Alliance on Mental Illness
National Association of Councils on Developmental Disabilities
National Association of Disability Representatives
National Committee to Preserve Social Security and Medicare
National Disability Rights Network
National Organization of Social Security Claimants' Representatives

Paralyzed Veterans of America The Arc of the United States United Spinal Association