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Comments on SSA Listing Revisions for Hematological and Malignant Neoplastic Disorders

The following comments are submitted on behalf of the low income children and adults who will be adversely affected by the change being proposed by the Social Security Administration. Community Legal Services, Inc., of Philadelphia, which prepared these comments, represents hundreds of claimants every year, and as SSA knows, was class counsel in Zebley v. Sullivan. The comments are also joined by the Children's Defense Fund.

SSA is proposing to do a major overhaul of these Listings, the first time that they have been changed since 1985. Although it is claimed that these Listings will be reviewed in 5 years, the 16 year gap since the last review, and SSA's history of moving extremely slowly in revising Listings, strongly suggests that these changes will affect claimants for quite a long time. It is therefore of paramount importance that these standards be carefully reviewed, not only with an eye to whether they reflect current medical knowledge, but also whether they will remain current in the future.

Unfortunately, after years of proceeding slowly, SSA is publishing four sets of highly technical regulations in a very short period of time with a very aggressive schedule for revising all the other Listings. Moreover, the Listings revisions are for both children and adults, doubling the amount of material that needs to be addressed. To gain some appreciation of how difficult this situation is for the informed public, let alone the general public, contrast the 60 day period for comments on digestive disorders, hematological and malignant neoplastic disorders, and skin disorders, all due at virtually the same time, with the 8 years that Social Security took to analyze the comments on the musculoskeletal disorder Listings. In short, the highly technical decisions embodied in these standards are extremely important and great care should be taken to insure that the standards are done right and that the criteria used are both medically and practically sound. SSA has not given adequate time for these comments, nor have they cast a wide enough net to assure that it has the benefit of the comments and suggestions of the best that the medical, disability and public spheres have to offer.

Our preliminary suggestion is that the agency extend the comment periods and do a much better job of publicizing these important changes to allow those affected individuals and groups a meaningful opportunity to respond, as well as offering pups with particular expertise an opportunity to participate in the process prior to final adoption.

In addition, since some of the most drastic changes involve the evaluation of sickle cell anemia, one of the leading causes of disability among African American children, it is of even more importance that these standards are fair and compassionate. Although the Sickle Cell listings are particularly important, there is no fiscal note attached to the

regulation (unlike some of the **other** revisions, which clearly acknowledge **that** the result of adoption **of** the proposal will be **a reduction** in eligibility). If adopted **as written**, a considerable number of children **and** adults will not **qualify** for benefits **even though there has** been no Congressional directive to restrict eligibility. The public **and Congress** should be **informed of** these facts.

In reviewing **the** regulations, **several themes** emerge. We will analyze **them** separately.

1. Many longstanding standards have been changed, sometimes drastically, with virtually no explanation for the medical and scientific justification for the change. For example, the standard for evaluating **disability** due to anemia whether **caused** by sickle cell disease or other **kinds of** anemia **has been** reduced from a persistent hematocrit **of 26%** or less **to a** hemoglobin count **of 7gm/dl** (**a hemoglobin count is** usually multiplied by about **3** to **get a** hematocrit score, so that **7gm/dl corresponds roughly to a** hematocrit of **21%** -- a reduction of **the qualifying score of more than 20%**). **All** that the **proposed** regulations say, however, is that "a hematocrit at this level does **not necessarily** correlate **with an** impairment of **Listing** level severity." See preamble to proposed 7.02C, 107.02C. (Emphasis added.) No literature or studies **are** cited **and** absolutely no justification is given for picking **7gm/dl as the standard, as opposed to 7.5, or 8, or 9, or any other level.** Indeed, a hemoglobin count **of 7gm/dl due** to sickle cell will **almost** invariably lead to **a level of** symptoms **that are** beyond what **is** necessary to establish disability. **Many of** those with hemoglobin counts **this** low will require **hospitalization and** a transfusion, which will, **of course, at least** temporarily raise the hemoglobin level to more than the requisite amount. **Our** experience **has been that** relatively **few** children meet the current hematocrit level of **26%**; **adopting** the new **standard** will all **but** eliminate **this** criterion **for** awarding **benefits** and will **deny** benefits to children who already **suffer** from **a** diminished **quality** of life. **At the** chosen level **fatigue, pain and** other symptoms **are** certain to develop. Setting the standard at **this** level will invariably lead **to** disabled children being denied benefits.

Another example of changing the **criteria** for disability **without** explanation is the evaluation **of** chronic **granulocytopenia** (neutrophil counts **reduced from 1000/mm³ to 500/mm³**); compare current 7.15, 107.15 with proposed 7.05A, 107.05A, and in evaluating chronic thrombocytopenia, where platelet counts have **been** cut without explanation or scientific justification from **40,000/mm³ to 10,000/mm³**; compare current 7.06, 107.06 with proposed 7.03, 107.03. **Even if** medical science and treatment options have advanced to the point where individuals **with** these **diseases can** be managed **without symptoms** (which we seriously **question**), why is **there** no public explanation for **these** particular, dramatic changes? **Are** we to believe SSA has simply been **misevaluating such** cases for the last 16 years? Doesn't the Administrative Procedure **Act** require **a** factual bases for rulemakings? Adoption **of** these standards without **adequate** proposed rulemaking virtually guarantees continued controversy **and** litigation.

Similarly, the former sickle cell **listing** for children had **as** one of **the** criteria for **disability, the experience of one** major **visceral complication** in 12 months, 107.05B, or **one** hyperhemolytic or aplastic crisis in 12 months, 107.05B, C. **Both** these standards

have been completely removed. **Instead**, the **criteria** have **been** changed to **three** hospitalizations for at least **24** hours in a **12** month period (each at least a month **apart from** each other)+ In other words, instead of one **such crisis** or event **in a year**, **now** a child must **show three** times **as many** events. (Some of the reasons **for** hospitalization will never **be** reached – a child's **spleen** would be removed **before** he or she had three such episodes **in** a year!)

Moreover, the proposed children's Listing even restricts the **kinds** of hospitalization that will be considered, putting **forth** a **list of 7** acceptable **reasons** for hospitalization.¹ The **list** of acceptable hospitalizations includes such **life threatening** events **as** hyperhemolytic **crisis**, aplastic **crisis** and **stroke!**² No scientific basis is given **as to why** such crises **must occur three** times as often in order **to establish** disability; **one** would *think* that **a child** would **not have** to **suffer** three **strokes** in one **year** in order to establish disability. Furthermore, if **a child is fortunate enough** to live **near a teaching hospital** with **an aggressive** outpatient sickle cell program that avoids **having** to **hospitalize many** children, there is no **way** that **they can** meet this Listing **under these** criteria, even if they experience these **crises**. **Similarly**, children with little or **no** health insurance may find it difficult to **gain admission** even **when** they experience such problems. Furthermore, serious but possibly **less** severe hospitalizations seemingly **are of** no account – a child with **a high** fever **who, for** whatever **reason**, does not receive **parenteral** antimicrobial medication (for example children **who are** allergic to such medications), **has** no way to **have the** frequency or seriousness of **such** experiences weighed in **these Listings**.

2. **SSA is repeating the mistake of evaluating the severity of symptoms by tying them to the method of treatment. This is exactly the approach that was** criticized by the Supreme Court in *Zebley v. Sullivan*, (pointing out the "constant evolution of medical . . . techniques") where SSA persisted in **using** a Listing, former Listing 103.03, that evaluated asthma **severity based** on **whether it was treated** with parenteral (i.e., injectable) medication. **Long after such drugs were administered orally, SSA was stuck with this antiquated standard in the asthma Listing. After finally getting rid of this standard, SSA now proposes to repeat its mistake by reincorporating the need for treatment by parenteral drugs, both painkillers, 107.02A(1), and anti-microbials, 7.05B, 107.02A(2), as the touchstone for whether a symptom of a disease or condition is sufficiently serious.**

¹ While it is true that the introductory part of the Listings, 107.00G(2)(a)(iv), says that **other hospitalizations may be considered, those hospitalizations must be of "equal clinical significance."** Absolutely no explanation of how this term is to be interpreted is **Given** that **several of the hospitalizations listed are literally life and death admissions (sequestration, hyperhemolytic or aplastic crisis, stroke) it is hard to determine how this equivalence will be met. Moreover, as SSA well knows, decisions as to equivalence are thought to be the province of SSA physicians. Treating physicians are never asked their opinion on equivalence. See 20 C.F.R. 416.926.**

² Thus only **when** a child had had three **strokes in a year** would he or she be eligible. Congress could *not* have **intended** such a **ridiculously high** measure of eligibility and *the* regulations have never had such stringent requirements in **the 26 years of their existence.**

Not only **are** such **standards likely** to become rapidly **outmoded**, but **they fail** to **take** into **account** other medical **considerations that** may **require** alternative treatments or approaches that have nothing to do with **the severity of** symptoms, but **rather** other **medical and social** considerations. Even a cursory examination of the **medical literature shows** that new approaches to pain treatment **are being** explored for sickle cell patients including biofeedback, inhaled nitrous oxide, **TENS units**, and new **oral** medications. Furthermore, the complications of **injected** painkillers **in** some patients may make them inappropriate for certain patients, regardless of their degree of severity. However, it is very **unlikely** that **any** explanation for choosing not to administer medications will be **placed in** the chart and therefore **those** evaluating the evidence will be unable to weigh properly the **true** level of severity.

Given the **degree of difficulty that most** Medicaid patients have **even** accessing hospital **care**, hospitalization for pain or fever **should** alone be enough. Moreover, **while** parenteral antimicrobials may **be** the standard of care for **treatment of** young patients with infections in **some** communities, our experts **remind us** that **this is** hardly a nationwide standard of care and **is therefore**, is **an unreliable** indicator of medical severity. Other pediatricians would **only** treat patients under 5 years of **age** with parenteral antimicrobial medication, **even** if they were **hospitalized** for fever.

Moreover, measuring the severity of painful **attacks** by the administration of **parenteral drugs is fraught** with danger and will make the program less **precise**. Whether or not a person receives such **drugs can** depend on a lot of extraneous **factors**, including their **desire/need** for independence, **their pain** threshold, and **their needs to function**. For example, a parent with a sickle cell child **might** elect not to receive drugs on **his or her** own, **in** order to be available to **take care of her** child. **Oftentimes**, the desire to function independently will play a **large part in** deciding the **question** of whether to accept **such** medication. **Other** times, a person's complete **medical history** will **determine whether** they **are** appropriate candidates for pain regulation by parenteral **medication**.

Similar mistakes in **measuring** severity solely by the **means** of treatment are scattered **throughout the** neoplastic disease listings, **even though this is** one of the **most** rapidly changing **areas**. (See, e.g., Listing 13.08B, requiring a failed course of **radioactive** iodine therapy in order to meet the criteria **for** neoplastic diseases.)

A similar problem **arises** when SSA attempts to **equate severity of** condition with **hospitalization**. (*We have* already discussed above some of the **problems** with SSA's closed list of reasons **for** hospitalization for children.) **This is** especially **true in areas** where the disease **manifests** itself episodically. Typically, patients **suffering from** such conditions have chronic conditions that occasionally "flare-up" and **become** acute crises. **The** Listings have generally taken **these situations into** account, **trying to** count the number of emergencies that occur and, **paying** particular attention on **the number of hospitalizations that occur**. Up to **now**, SSA has paid attention to both emergency room care and hospitalizations, **in an** attempt to evaluate **both the** frequency and severity of such flare ups. **See**, for example, 103.03 (asthma Listing).

Advocates in recent years have criticized this **approach**, pointing out **that** one **of** the main focuses of the health care industry has **been** to reduce the number of **days** spent in the hospital, and cut **back** on the number of visits to the emergency **room**. In fact, **most** state Medicaid agencies have **turned** to managed care **organizations** to **control** costs by eliminating, or at least cutting back on, such expensive services. **Many** treatment centers for episodic disease, such as sickle cell, **measure their success**, at least in **part**, by their ability to reduce the amount of **time** that their **patients** require **to** be hospitalized, both **as a** way of **demonstrating cost** effectiveness and in **order** to **reduce** the amount of disruption that frequent **hospitalization** causes in families.

Rather **than** recognizing this trend **and** attempting to come **up** with alternatives that will **allow for** a **more** flexible and realistic measure **of** crises, the current proposed **regulations** place **even more** emphasis on hospital **care** and ignoring other important measures **of** **serious** health problems. Incredibly, **SSA** at one **point** in the Listings for sickle cell even disparages regular hospitalization **as** an indicia of illness, **claiming** “**Many** children with sickle cell disease **are** hospitalized **as** a precautionary basis” **rather** than because **of** some true health emergency! See preamble to proposed regulation **107.02A**. **We** are confident that this statement is false **as it pertains** to low income children. Everyday, Medicaid covered and uninsured **children** are denied **access** to **hospital care**, even when they have a **true** emergency. **Few** hospitals admit **patients** as a “precautionary” measure, for the simple reason that if that do **so**, **they** will not be **reimbursed**. We challenge **SSA** to produce **any** literature or **other** evidence that **substantiates** this absurd **claim**. **Such** **unsubstantiated** and groundless **assertions** show that **SSA** does **not** have an accurate **picture** of the current health **care** delivery **system** that low income children and adults must **face** every day. **Most** of **our** clients regularly **are discouraged** from seeking hospital **care** and **are** frequently sent home when **they** present at the emergency **room**, even when they **are** in crisis.

Hospitalization and/or emergency room admittance **are** not **good** a sole or even main criteria for **evaluation**. Both have become false measures in today’s healthcare environment. Oftentimes, very sick patients are treated **as** **outpatients**. Seeing one’s own physician **is** often a better choice **than** an **ER** visit; similarly, **many** conditions can be **addressed** without hospitalization, especially if the family and **the** **healthcare system** work together. However, such avoidance of **hospitalization** does not **mean** that the medical event is **any less serious**, and the **care** of a sick family member at home, while desirable, carries with it costs for **the** entire **family**. The **Social Security Administration** should seek a better **form of** evaluation to determine the severity of a **condition**.

3. Hospitalizations only count if they are more than 24 hours, and only if they are more than a month apart. Under the former rules for evaluating sickle cell anemia, **7.05B**,³ hospitalizations had to be more than emergency **room** visits, in order to count as hospitalizations. **SSA** now proposes that they must be not **only** more than a visit to the **ER**, but also last at least **24** hours, leaving potential for mischief for slightly shorter **stays** that were nonetheless genuine crises. More seriously, **throughout** these and other newly

³ This listing required “extended hospitalization (beyond emergency care) at least three times during the 12 months prior to adjudication.” **7.02B, 107.02A(2)**.

promulgated regulations, **SSA also proposes to refuse to consider multiple stays, and other health care crises, if they are less than "a month" apart. 7.00E, 107.00E.** (The justification **being that SSA fears counting one incident twice. See preamble to proposed 7.00E, 107.00E.**) **Rather than simply charge its adjudicators with the responsibility to determine whether multiple hospitalizations are attributable to the same event and therefore should not be double counted, SSA irrefutably assumes all admissions with a month are part of the same incident, regardless what the medical facts actually are. Indeed, multiple admissions within a short period of time may be strong evidence that a condition is extremely grave and should be afforded great weight. For example, a child hospitalized for two strokes in a month would be considered much more medically at risk than a child experiencing only one stroke.**

Moreover, such **an arbitrary rule invites further complications and ambiguities. For example, will SSA use calendar months, 28 days, 30 days, or 31 days to determine if two admissions are within a month? Will SSA measure the requisite month hiatus from date of discharge from the first hospitalization to the date of the next admission or count from the date of the first admission to the first day of the following admission? Sadly, none of the answers to these critical questions is set forth in the Listings. Are SSA adjudicators so incompetent that they cannot avoid double counting? If they are so unable to do so, how are they capable to make nuanced determinations of equivalence at other points in the disability adjudication process?**

Assuming that **hospital admissions within a month are always part of the same crisis is particularly illogical when the admissions may be for a crisis that may be caused by an outside event, such as mild trauma, as in the case of hemophilia or for different reasons. For example, a child with sickle cell disease may be admitted once for a fever secondary to an ear infection, and again, a second time, for splenic sequestration, 28 days later. Even though the sequestration is life threatening, and even though it bears no relationships to the fever, under the proposed SSA rule, this second hospitalization would be ignored. Moreover, even when there are multiple admissions in the same month for the same crisis, however counted, doesn't that suggest a more serious condition than a condition only requiring one admission? Given the stringent regulation of today's health care environment, SSA should acknowledge that any event requiring hospitalization is extremely significant, yet SSA's standard would refuse to count the second, or even third admissions as having any medical significance at all. Not only is there no medical basis for this standard, but it defies current health care realities. Even a single hospital admission tends to be associated with a serious condition in today's health care environment.**

4. The Neoplastic Listings attempt to take into account changes in treatment but fail to do so in a fully satisfactory way. No one doubts that there haven't been changes in this area since the last revision in 1985; however, **SSA has dropped certain kinds of cancer from the Listings, usually because they say that "many," or "most" such cases are now treatable. The problem is that there is not an overall standard for cases that remain untreatable or where the prognosis is not favorable. These Listings are replete**

with statements such as **“in the absence of metastases many individuals do well,”** preamble to 13.13 Nervous system, or such conditions **“are often amenable to treatment,”** Listing 13.27, or that malignant solid tumors in children are not listed since such tumors are often treatable, and that others will have to be evaluated on a **“case by case basis.”** The problem is that there **is** no guidance for evaluating **any cases on** a case by case basis, nor **are there any** instructions **as** to how to adjudicate **the** cases of those who do not **respond well to** treatment. **SSA** needs a catchall Listing that will **deal with such** unfortunate cases,,

Similarly, throughout both the **child** and adult Listings, **SSA** has omitted cases involving **“rare”** conditions either **entirely, see** 7.07 (hereditary telangiectasia), 7.10C (bone pain), or for **children**, without announcing clear cut **standards for** evaluating **such** cases, see 113.00D (**tumors where primary cite unknown**), 113.05 (indolent lymphoma), and 113.00K (chronic lymphocytic leukemia). **“Rare”** conditions are **a particularly severe** concern for cancer patients. Known as **“orphan cancers,”** rarer cancers are some of the most **difficult** to treat. **Though** the **cancer** itself **may be me**, the disease impact **is** large. In order to **ensure** inclusion of **these** diseases, a **full listing** of conditions **is** important. **Such standards have** been promulgated in other listings (the AIDS/HIV listings come to **mind**) and there **is** no reason **why they** cannot be included here, especially **as** future **treatments** improve the **picture** even more. **Simply because a disease is rare is not a good** reason for it to be **dropped** from the Listings, especially **where** there **is** no **more general** way to evaluate **the condition** in the Listings. **It is** not acceptable to **merely state** that **such conditions will** be evaluated **further** done **in** the **sequential process**, since that **process is** often **difficult to enforce and apply uniformly** to people **of all age groups**. Especially for **children**, where decisions **have to be d e** as to whether certain functions are **“markedly”** impaired, there **is a considerable degree** of subjective judgment involved, that **is interpreted differently by different** adjudicators. **Even the** most difficult to endure **symptoms are occasionally rated as less than marked, by adjudicators** who resist finding disability, in **our** experience. While **the** adjudication of disability will always encompass a subjective element, the more guidance that **can** be offered, **the better**.

Another problem with **the** Neoplastic Listings is **the increased** tendency to **set time limits** on the period of disability. Even if those **time** limits are **supported** by medical **fact**, (which we **seriously question, given** the absence of **any scientific or medical discussion** in the **preamble**), the regulations **merely say that** after the expiration of **the time period, the** patient **is** assessed under the relevant body **system, rather than referring to** the medical improvement **standard, 20 C.F.R. 416.994, 416.994a. This is an** apparent contradiction of the law that **will have** most **serious** consequences. **Such a policy would be** contrary to the **Social Security Disability Reform Act** of 1984 and is **plainly illegal**. If **SSA** intends to apply the medical improvement **standard, then it should** clearly **say so, just as it has** for cases **where the claimant** meets **the old standard** but not **the new one**. If the **intention is to** evade **the medical** improvement **standard, we urge** the agency to reconsider, before **becoming** immersed in **the** controversy **that** required passage **of the Reform Act**.

5. **Throughout the proposed Listings there are changes in the standards for** adjudicating disability, but there **is no medical or scientific basis given for the**

change. At many points SSA has changed longstanding policy, frequently claiming **that** the agency's new position is based **on** changes in the field **of** medicine. Yet **nowhere** in these **regulations** is there **any** citation to any authority that **substantiates** these claims. At other **points** SSA makes certain changes because of these **mysterious** new developments and then **makes** changes to other criteria, not **based** on **new** developments, but in order to be **consistent** to the changes **that** have already **been** adopted. None of these changes or their justification **satisfy** the stringent requirements **of** the **Administrative Procedure Act**. **Examples of these** changes abound. Here **are** but a few:

7.06A – incidents of bleeding increased from 1 every **5 months** to 3 every 12 months.

107.00G(2)(a)(preamble) many children **are hospitalized** as a "precaution."

Pretransfusion **hemoglobin counts below 7gm/dl** are "usually asymptomatic."

7.03A(2), 7.03A(2), 7.08, **frequency criteria all changed solely** to achieve consistency with other Listings.

7.02; 107.02 -- **those** with hemoglobin scores **above 7gm/dl** are "usually asymptomatic" therefore lower **criteria** appropriate.

In **none** of **these** changes is there **any** reference to **any** published research or recognized **standard of care**. Instead, this proposed rulemaking merely relies **on** bald **statements** with no **medical** or scientific backing. Such assertions **are** not **enough** to **justify** a **valid** rulemaking and **particularly** one that reverses **longstanding** agency policy.

Respectfully submitted,



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