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February 1, 2008

Director, Regulations Management (00REG)
Department of Veterans Affairs
810 Vermont Ave., NW, Room 1068
Washington, DC 20420

Re: Comments from the Brain Injury Association of America on RIN 2900-AM75-"Schedule for Rating Disabilities; Evaluation of Residuals of Traumatic Brain Injury (TBI)."

Dear Director:

These comments on the Proposed Rule, "Schedule for Rating Disabilities; Evaluation of Residuals of Traumatic Brain Injury (TBI)," (RIN 2900-AM75) are submitted on behalf of the Brain Injury Association of America ("BIAA"). Founded in 1980, BIAA is the leading national organization serving and representing individuals, families and professionals who are touched by a life-altering, often devastating, traumatic brain injury (TBI). Together with its network of more than 40 chartered state affiliates, as well as hundreds of local chapters and support groups across the country, BIAA provides information, education and support to assist the 5.3 million Americans currently living with traumatic brain injury and their families. BIAA strongly supports policies that ensure access to rehabilitative care so that individuals with disability, injuries or chronic conditions—including those with traumatic brain injury (TBI)—may regain and/or maintain their maximum level of independent function.

On January 3, 2008, the Department of Veterans Affairs issued a Proposed Rule to amend the VA Schedule for Rating Disabilities by revising that portion of the Schedule that addresses neurological conditions and convulsive disorders, in order to provide detailed and updated criteria for evaluating residuals of traumatic brain injury (TBI). BIAA acknowledges that the proposed amendments to the VA Schedule in regards to evaluating disability stemming from TBI represent a marked improvement from the system which is currently used for evaluating neurological conditions and convulsive disorders, such as TBI. Having acknowledged the Proposed Rule as a significant improvement over the current system, however, BIAA wishes to respectfully communicate serious concerns regarding several of the proposed revisions to the material under diagnostic code 8045 (currently, "Brain disease due to trauma,") in 38 CFR §4.124a ("neurological conditions and convulsive disorders.")

BIAA strongly urges the Department of Veterans Affairs to recognize the multidimensional and complex aspects of brain injury, which is a medical condition evidenced by research as being disease-accelerative and disease-causative in many cases. A variety of health problems

that don't exist immediately after a traumatic brain injury become evident later. For example, recent research has shown that TBI poses a substantial risk of hypothalamic and pituitary insult, and that a substantial risk of hypopituitarism confronts patients with TBI, although clinical manifestations of pituitary deficits may not appear until many years after the TBI itself.[1] There are myriad other diseases that develop over time.

At this time, there is a great deal that is still unknown about the short and long-term impacts of traumatic brain injury sustained during combat operations. It is important that the VA Schedule for Rating Disabilities utilizes research about TBI outcomes related to combat injuries where this research does exist. Yet, when it comes to rating the degree of impairment and disability caused by TBI, it is equally important that the VA Schedule acknowledge where a consensus of research on the types and severity of disability resulting from TBIs sustained during combat operations does not currently exist, and err on the side of providing more – rather than less – compensation to Veterans for their reported TBI-related impairments.

The reality of brain injury is that it is not always linear. While it is understandable that any disability rating schedule would likely be designed to minimize the possibility of symptom over-reporting or magnification, the complex, and often compound, nature of impairments arising from brain injury presents a unique challenge to achieving a disability rating system which is both accurate and fair. This Proposed Rule reflects this challenge, as it contains multiple instances where disability arising from the disease of brain injury unfortunately stands to be understated, under-documented, and under-realized.

As several Veterans with TBIs have remarked with anguish, it is impossible for one to attain a prosthetic device to replace his or her damaged brain. Anyone who has sustained a significant brain injury can tell you that one's mind, and life, is never the same after such an injury. In addition, brain injury is both a dynamic and lifelong condition, and the VA Schedule for Rating Disabilities should reflect greater sensitivity to the potential immense significance of any TBI-related impairment in terms of major loss in quality of life, regardless of how "mild" a symptom may appear to be on paper. BIAA agrees with multiple brain injury experts who have surmised that the term "mild TBI" is an oxymoron. **For other injuries, such as spinal cord or amputation, the VA compensates individuals for loss of quality of life, regardless of residuals, and BIAA strongly advocates for all Veterans with documented TBIs – including mild TBIs - to receive similar compensation.**

BIAA would like to provide the following comments on specific provisions in the Proposed Rule (RIN 2900 – AM75) revising the material under diagnostic code 8045 in 38 CFR §4.124a:

[1] "Consensus guidelines on screening for hypopituitarism following traumatic brain injury." E. Ghigo, et al. *Brain Injury*, 20 August 2005; 19(9); 711-724.

Proposed changing of the title of diagnostic code 8045 from “Brain disease due to trauma” to “Residuals of traumatic brain injury (TBI)”

BIAA is concerned that this proposed title change represents an obfuscation of the disease process which is brain injury. In so doing, it seems more likely that disability raters could misunderstand the conditions they are evaluating as static versus dynamic, potentially evolving conditions.

Definition of TBI

The Proposed Rule defines TBI as “an injury to the brain from an external force that results in immediate effects such as loss or alteration of consciousness, amnesia, and sometimes neurological impairments.”

BIAA is concerned that the use of the term, “immediate effects” would discount effects that emerge later as is often the case with a mild TBI. Instead BIAA suggests incorporating a common definition of mild TBI into this more general definition of TBI. BIAA suggests using guidelines developed by the Mild Traumatic Brain Injury Committee of the Head Injury Interdisciplinary Special Interest Group of the American Congress of Rehabilitation Medicine:

“Definition of mild traumatic brain injury.

A patient with mild traumatic brain injury is a person who has had a traumatically induced physiological disruption of brain function, as manifested by at least one of the following:

1. any period of loss of consciousness;
2. any loss of memory for events immediately before or after the accident;
3. any alteration in mental state at the time of the accident (e.g., feeling dazed, disoriented, or confused); and
4. focal neurological deficit(s) that may or may not be transient; but where the severity of the injury does not exceed the following:

- loss of consciousness of approximately 30 minutes or less;
- after 30 minutes, an initial Glasgow Coma Scale (GCS) of 13-15; and
- posttraumatic amnesia (PTA) not greater than 24 hours.[2]

BIAA also believes that the Schedule for Ratings Disabilities should be expanded to address Veterans with resultant impairment from anoxia, as massive blood loss is common in cases of traumatic injuries caused by explosive blasts, and this blood loss can result in brain injury due to a lack of oxygen to the brain.

[2] *J Head Trauma Rehabil* 1993;8(3);86-87 © 1993 Aspen Publishers, Inc.

The Proposed Rule also states that the abnormalities resulting from a TBI "may all be transient, but more prolonged or even permanent problems with a wide range of impairment in such areas as physical, mental, and emotional/behavioral function may occur."

BIAA is concerned that this description of abnormalities caused by TBI is too narrow and recommends the following description be substituted in its place: "These abnormalities may all be transient, but more prolonged or even permanent problems with a wide range of impairment in such areas as cognitive, physical, mental, communicative, emotional, behavioral, social, vocational or medical (neurological, cardiovascular, neuroendocrine, immunological, orthopedic, respiratory, renal) function may occur."

Evaluating Physical Dysfunction

The Proposed Rule directs raters to "consider special monthly compensation for such problems as loss of use of an extremity, certain sensory impairments, bowel and bladder impairments, erectile dysfunction, the need for aid and attendance (including when assistance or supervision is needed on the basis of cognitive impairment), and being housebound."

BIAA applauds this recognition of the need for aid and attendance which is so often a critical need for individuals with TBI as well as their caregivers. However, parameters for such consideration of special monthly compensation are not defined, and need to be explicitly delineated in order to achieve consistency and fairness. BIAA encourages the VA to take into account that even though they may not necessarily require regular supervision by a licensed health-care professional, many individuals with TBI require someone to be available for assistance at all times. In such cases, caregivers—including family members—should be appropriately compensated for their role in assisting with the management of medical care, and for their work in organizing personal affairs and obtaining support outside of the home necessary to aid the rehabilitation and reintegration of Veterans into their communities.

Evaluating the Symptoms Cluster Due to TBI

In describing the cluster of symptoms which commonly follow TBI, the Rule proposes "replacing the current guidance concerning the evaluation of subjective complaints after brain trauma under diagnostic code 8045 with a set of criteria to evaluate this symptoms cluster, with evaluation levels of 20, 30, and 40 percent."

BIAA is concerned that these levels of evaluation are not, in fact, consistent with the range of disability that may result from these symptoms. Although BIAA recognizes the need to elucidate disability ratings criteria which would promote consistent evaluations, the first priority for any rating should be to accurately reflect the true degree of functional impairment resulting from the injury. The reality is that subjective complaints such as headache, traumatic dizziness

or vertigo, and fatigue can be extremely disabling (more than 40 percent) as individual symptoms. Rather than an averaging approach, BIAA recommends the use of high-quality neurological assessments including symptom validity testing.

Evaluating Cognitive Impairment

The Proposed Rule states, "Cognitive impairment of varying degrees is most common and most severe following moderate or severe TBI. Therefore, primarily those who experienced a moderate or severe TBI would require evaluation under these criteria. However, an individual with mild TBI may also have these conditions."

BIAA is concerned that this assertion is unnecessary and potentially misleading, and could negate evaluations for those with mild TBIs. This phrasing creates a prejudice, as individuals with mild TBI can be totally disabled from cognitive and other disability. The research literature does not support this assertion for patients who have sustained one or more mild TBIs in combat. Accordingly, expert neuropsychological evaluation that assesses cognitive function under cognitive loading should be required individuals with all types of TBI.

The Rule also proposes "using the table we have developed for evaluating cognitive impairment that includes the 11 most important types or facets of impairment, titled 'EVALUATION OF COGNITIVE IMPAIRMENT UNDER DIAGNOSTIC CODE 8045.' In addition, we propose providing separate criteria, representing logical increments of functioning for each facet, for assessing the severity of each of these 11 common facets of impairment following TBI. Scores of severity for each facet would range from 0 to 4."

BIAA has several concerns about the use of this table and the proposed scoring method.

In general, BIAA is concerned that there is no discussion of the issues of inter-rater reliability and validity regarding use of the proposed table. Therefore, it appears that the Department of Veterans Affairs wishes to go forward with an essentially untested tool which has not been validated. BIAA is also concerned by the lack of specificity about what data will be used to determine the ratings. For example, will ratings be assigned based solely on a review of an individual's medical records? Will input from family, caregivers, and/or the full spectrum medical and rehabilitation professionals working with the individual be used to determine the rating? Can ratings be assigned without neuropsychological testing? How will issues such as the rating of an individual whose primary language is Spanish and his second language is English be undertaken? How will the level of education be taken into consideration?

Much greater specificity in direction to disability raters is needed to answer such questions regarding use of the proposed table.

Further, BIAA has concerns about the levels of impairment assigned to several of the facets of cognitive impairment included in the table:

Work or School

BIAA is concerned that this table and rating scale does not take into sufficient account issues related to a loss of higher-level abstract reasoning abilities. For example, an individual could have an injury resulting in severe impairment of the ability to reason abstractly that would be quite disabling but which does not seem to be captured by this rating scale.

Judgment

BIAA is concerned that the Proposed Rule does not state how the disability rater will acquire the information to determine the rating of such characteristic as subjective as "judgment." Again, greater specificity in order to assist the disability rater is needed.

Supervision for Safety

BIAA is concerned at the lack of specificity about how judgments in regard to issues such as safety and social situations will be arrived at. Who will the data be obtained from? Individuals without insight may not describe themselves as having problems with safety or in social functioning.

Other Neurobehavioral Effects

BIAA is concerned that any one of the neurobehavioral effects listed could individually result in much graver disability than is allowed for by the proposed scoring method in the table. For example, if an individual was determined to be physically aggressive, even without displaying any of the other neurobehavioral symptoms, he or she may require institutionalization. Similar outcomes could also be associated with being verbally aggressive, impulsive, uninhibited, or other neurobehavioral issues. Yet, if any of these neurobehavioral issues appeared in isolation, a score of only "1" would be awarded, resulting in an inappropriate and far too low 10 percent disability rating.

BIAA is also concerned with more global issues related to this table and overall Proposed Rule. It is concerning that the rating procedure proposed in this table seems to diminish the extent to which the disability resulting from a TBI, effectively taking a range of disability that can range from 0 to 100 percent in reality and reducing rating to just four categories. BIAA is concerned that the lack of specificity in the overall rating process as outlined above, combined with restricted ratings available for subjective complaints and now this dilution via calculation could result in nearly all disability ratings for TBI being under-rated. BIAA is also strongly concerned

about the lack of incorporation of any type of neuropsychological testing in the Proposed Schedule.

Conclusion

The Brain Injury Association of America acknowledges that this Proposed Rule represents a significant improvement over the current system. However, BIAA strongly recommends that the types of information utilized to determine disability ratings be more thoroughly specified, and that concurrently, a minimum level of disability compensation be awarded to all Veterans with TBI.

Ideally, the entire Rule proposing changes to the VA Schedule for Rating Disabilities in relation to TBI should be pilot tested before there is widespread implementation. Validation against current instruments is also recommended.

In addition, there is a great need for a large outcome study to be conducted to look at individual recovery trajectories over time in order to aid the development of valid ways of determining disability resulting from TBIs sustained during combat operations. At this point, the scientific community simply does not have the data in large enough samples to really know what happens over time. Again, while this knowledge is in development, BIAA believes it is essential that a minimum level of disability compensation be awarded to all Veterans with TBI.

Thank you for this opportunity to comment.

Sincerely,

Susan H. Connors
President/CEO