District, *joe.m.arca@uscg.mil,* or (212) 668–7165. If you have questions on viewing the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: The AMTRAK Dock Bridge has a vertical clearance of 24 feet at mean high water, and 29 feet at mean low water in the closed position. The existing drawbridge operating regulations are found at 33 CFR 117.739(e).

AMTRAK, requested that the Dock Bridge not open for marine traffic from 10:00 a.m. Saturday, February 1 through 1:00 a.m. Monday, February 3, 2014, to facilitate the expected movement of more than 150,000 visitors, guests and area residents to various public events and activities in the New York and New Jersey area during the Super Bowl XLVIII weekend.

Passaic River is transited primarily by commercial navigation. The bridge owner reported that there were no requests for bridge openings at the Dock Bridge for the past three years. Vessels that can pass under the closed draw may do so at all times.

Under this temporary deviation the Dock Bridge may remain closed for marine traffic from 10:00 a.m. on Saturday, February 1 through 1:00 a.m. on Monday, February 3, 2014.

In accordance with 33 CFR 117.35(e), the bridge must return to its regular operating schedule immediately at the end of the designated deviation period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: December 2, 2013.

Gary Kassof,

Bridge Program Manager, First Coast Guard District.

[FR Doc. 2013–29858 Filed 12–16–13; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900–AN89

Secondary Service Connection for Diagnosable Illnesses Associated With Traumatic Brain Injury

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) amends its adjudication regulations concerning service connection. This final rule acts upon a report of the National Academy of Sciences, Institute of Medicine (IOM), Gulf War and Health, Volume 7: Long-Term Consequences of Traumatic Brain Injury, regarding the association between traumatic brain injury (TBI) and five diagnosable illnesses. This amendment establishes that if a veteran who has a service-connected TBI also has one of these diagnosable illnesses, then that illness will be considered service connected as secondary to the TBI.

DATES: *Effective Date:* This rule is effective January 16, 2014.

FOR FURTHER INFORMATION CONTACT: Michael Ford, Regulatory Specialist, Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461–6813. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On December 10, 2012, VA published in the **Federal Register** (77 FR 73366) a proposed rule to amend VA adjudication regulations (38 CFR Part 3) by revising 38 CFR 3.310 to add five diagnosable illnesses as secondary conditions which would be held to be the proximate result of service-connected TBI. The proposed rule identified those five illnesses as: (1) Parkinsonism, including Parkinson's disease, manifested following moderate or severe TBI; (2) Unprovoked seizures manifested following moderate or severe TBI; (3) Dementias (presenile dementia of the Alzheimer type and post-traumatic dementia) if manifest within 15 years following moderate or severe TBI; (4) Depression if manifest within 3 years of moderate or severe TBI, or within 12 months of mild TBI; and (5) Diseases of hormone deficiency that result from hypothalamo-pituitary changes if manifest within 12 months of moderate or severe TBI. We provided a 60-day public-comment period, which ended on February 8, 2013, and received 201 public comments.

1. Executive Summary

A. Purpose

This final rule amends VA's regulation concerning determinations of ''secondary service connection'' by identifying circumstances under which certain illnesses will, absent clear evidence to the contrary, be found to be the secondary result of a service-connected TBI. The effect of the rule will be to eliminate the need for case-specific development and decision on that issue, thereby promoting efficiency and consistency in claim adjudications and making it easier for qualifying claimants to establish service connection for these conditions.

VA provides disability compensation and other benefits for disability resulting from disease or injury that is ''service connected,'' meaning that it arose in service, was aggravated by service, or otherwise is causally related to service. *See* 38 CFR 3.303. ''Secondary service connection'' refers to the situation in which a service-connected disease or injury causes or aggravates a distinct condition. In that situation, 38 CFR 3.310(a) provides that ''disability which is proximately due to or the result of a service-connected disease or injury shall be service connected'' and ''the secondary condition shall be considered a part of the original condition.''

Regulations in VA's Schedule for Rating Disabilities currently recognize that TBIs potentially may produce a variety of cognitive, emotional/behavioral, or physical effects, including conditions that may be diagnosed as distinct mental or physical disorders. 38 CFR 4.124a, Diagnostic Code 8045. However, when a Veteran has suffered a TBI in service and also has been diagnosed with a distinct mental or physical condition, such as depression or endocrine dysfunction, it may not be apparent whether the latter condition was caused by the TBI or resulted from some other cause. In such cases, VA ordinarily would seek to obtain a medical opinion on that question and would make a determination taking into account the medical opinion and all other relevant evidence of record.

In a report titled ''Gulf War and Health, Volume 7: Long-Term Consequences of Traumatic Brain Injury,'' the IOM analyzed the available scientific and medical literature regarding the long-term consequences of TBI. In that report, IOM identified certain diagnosable conditions as to which there is relatively strong evidence that such conditions are associated with TBI because, for example, reliable studies show that those conditions occur more frequently in persons who have suffered a TBI than in other populations. After considering the IOM report and obtaining advice from medical experts and others within VA, the Secretary determined that there is a sufficient basis to establish a rule providing that certain diagnosable illnesses will be found to be the secondary result of TBI in certain circumstances, absent clear evidence to the contrary. Establishing such a rule will eliminate the need in individual cases to obtain a medical opinion or develop other evidence to determine whether the condition is associated with a TBI.

This rule is necessary to implement the Secretary's determination. Under 38 U.S.C. 501(a)(1), the Secretary is authorized to issue regulations regarding ''the nature and extent of proof and evidence and the method of taking and furnishing them in order to establish the right to benefits.'' By eliminating the need to obtain medical opinions or other evidence in certain circumstances, this rule will enable VA to decide these claims more expeditiously and efficiently. Relatedly, this rule will make it easier for claimants to establish secondary service connection for the conditions covered by this rule. Further, this rule will ensure that claims involving the covered conditions are decided in accordance with available scientific knowledge and it will ensure consistency in the adjudication of claims.

It is important to note that this rule is intended only to identify circumstances in which, absent clear evidence to the contrary, VA must find the identified conditions to be the secondary result of service-connected TBI. It is not intended to limit or preclude a finding of secondary service connection for any other conditions or for any of the five specified conditions that are manifest outside the time periods set forth in this rule. Any claim that is not within the scope of this rule will be developed and decided under generally applicable procedures based on the evidence relating to that claim.

B. Summary of Major Provisions

This final rule revises 38 CFR 3.310 to provide that, absent clear evidence to the contrary, five diagnosable illnesses ''shall be held to be'' secondary results of TBI in certain circumstances. The identified circumstances pertain to the severity of the TBI and the period of time between the TBI and the manifestation of the secondary condition. Specifically, paragraph (d)(1) of the rule provides for secondary service connection of the following illnesses: (1) Parkinsonism, including Parkinson's disease, manifested following moderate or severe TBI; (2) Unprovoked seizures manifested following moderate or severe TBI; (3) Dementias of the following types: presenile dementia of the Alzheimer type, frontotemporal dementia, and dementia with Lewy bodies, if manifest within 15 years following moderate or severe TBI; (4) Depression if manifest within 3 years of moderate or severe TBI, or within 12 months of mild TBI; and (5) Diseases of hormone deficiency that result from hypothalamo-pituitary changes if manifest within 12 months of moderate or severe TBI. If those conditions are met, the secondary condition will be service connected and considered to be part of the service-connected TBI for purposes of providing VA disability benefits.

The time periods set forth in this rule are based upon available scientific and medical evidence, as summarized by the IOM, and reflect the finding that, when the secondary condition manifests within such time period, it is reasonable to conclude, without the need for further evidentiary development, that the condition resulted from the TBI. Because no time period is specified for Parkinsonism or unprovoked seizures following moderate or severe TBI, secondary service connection will be established if those conditions are manifest at any time after the TBI.

Paragraph (d)(3) of the final rule sets forth the criteria VA will use to determine whether a TBI in service was mild, moderate, or severe. Those criteria are the standard criteria that VA and the Department of Defense (DoD) both currently employ in evaluating the severity of a TBI. The criteria consist of five distinguishing factors, each pertaining to the effects of the injury at the time of the injury or shortly thereafter. The rule provides that a claimant need not meet all the criteria of a particular level of severity in order for VA to classify the TBI at that severity level. Rather, VA will rank the TBI at the highest level in which any criterion is met, except where the qualifying criterion is the same at both levels, in which case, VA would look to the other criterion to determine the highest level assignable.

Paragraph (d)(2) of the rule would state that neither the severity levels nor the time limits set forth in the rule will preclude a finding of service connection for conditions shown by evidence to be proximately due to service-connected TBI. It further explains that, if a claim does not meet requirements of this rule for a mandatory finding of secondary service connection, VA will develop and decide the claim under generally applicable principles of service connection without regard to paragraph (d)(10) of this rule.

2. Responses to Comments

We note that numerous commenters appeared to have slightly misunderstood the nature of the proposed rule in their comments. We are not establishing presumptions of service connection for these conditions. The proposed rule provides a legal framework for establishing the listed disabilities as service connected secondary to service-connected TBI. Presumptions, as VA generally uses them in establishing service connection, provide the nexus element between an event in service that is not itself disabling and the development of a disability. Secondary service connection, whether provided by regulation or shown by medical or lay evidence, links the secondary condition to an already established service-connected disability. However, the intent of the comments is clear, and we are responding to them as if the commenters had used ''secondary service connection'' instead of ''presumption.'' When noting the commenters' suggestions, we are using the commenters' term ''presumption'' so as to not change the commenters' meaning.

Favorable Comments

VA received numerous comments generally supporting the proposed rule and noting that when the final rule is published, it will be beneficial to veterans who have suffered a TBI. We agree with these comments and thank the commenters for submitting their views.

Comment Suggesting That the Proposed Rule Should Include a Presumption That a TBI Occurred

One commenter stated that the lack of a formal diagnosis of TBI should not be used to deny claims for conditions secondary to TBI. Instead, existence of the conditions should be used to presume the presence of TBI. Parkinsonism, Parkinson's disease, unprovoked seizures, dementia, depression, and diseases of hormone deficiency resulting from hypothalamo-pituitary changes are conditions that often occur in individuals who have no history of TBI; therefore, the mere presence of any of these conditions cannot be used to presume the presence of TBI. Further, each of these conditions manifest a distinct set of signs and symptoms that do not, by themselves, imply the preexistence of TBI. The purpose of this rulemaking is to address those situations in which a veteran has suffered a TBI during military service, later develops one of the five listed conditions, and the question arises as to whether the latter condition should be considered to be secondary to the former. Addressing situations where a veteran has one of the five listed conditions in the absence of TBI is outside the scope of this rulemaking.

Another commenter suggested that, similar to the new PTSD regulation at 38 CFR 3.304(f), lay evidence alone be sufficient evidence to demonstrate that a TBI occurred in service. The commenter reasoned that there may be

no records available for these claims given the delay of identification and onset of many of these conditions and, therefore, lay evidence may be the only way that many of these claims could be granted. This comment relates to evidence necessary to prove service connection for TBI under 38 U.S.C. 1110. This rulemaking focuses on the secondary service-connected conditions that are a proximate result of TBI; therefore, this comment is outside the scope of this rulemaking.

Comments Regarding Effective Dates

One commenter expressed the hope that the ''earliest effective date'' would provide veterans with retroactive benefits based on this rule. Another commenter asked whether this rule will be retroactive. In accordance with 5 U.S.C. 553(d), we are making this rule effective on the day 30 days after the date this notice is published in the **Federal Register**. We will apply this rule to all cases pending before VA on or after that date. If a claim that was previously and finally denied is later reopened and granted based on this rule, VA cannot pay benefits retroactive to the previously denied claim. Payments retroactive to a previously denied claim are authorized only in limited circumstances involving clear and unmistakable error or newly obtained service department records, but not where benefits are awarded based on a change in law. The U.S. Court of Appeals for the Federal Circuit has explained that, generally, ''[i]t is only by filing a [clear and unmistakable error] claim that a veteran can obtain benefits retroactive to the date of the original [VA] decision.'' *Comer* v. *Peake,* 552 F.3d 1362, 1370–71 (Fed. Cir. 2009). Further, 38 U.S.C. 5110(g) states that the effective date of an award of benefits made ''pursuant to any Act or administrative issue . . . shall not be earlier than the effective date of the Act or administrative issue.''

Although payments would not be retroactive to a previously denied claim, we note that this rule change would constitute a liberalizing VA regulation under 38 U.S.C. 5110(g) and 38 CFR 3.114. Under those provisions, a claimant is eligible for certain retroactive benefits based on the liberalizing law or VA issue, if the claimant met all eligibility criteria for the liberalized benefit on the effective date of the liberalizing VA regulation and such eligibility existed continuously from that date to the date of the administrative determination of entitlement or of the claimant's request for review. In those circumstances, the effective date of an award will be ''fixed in accordance with the facts found'' except that it ''shall not be earlier than the effective date of the Act or administrative issue'' on which the award is based and, ''[i]n no event shall such award . . . be retroactive for more than one year from the date of application therefor.'' 38 U.S.C. 5110(g). Under this statute, if a qualifying application is received within one year of the date this final rule becomes effective, VA potentially may pay benefits retroactive to the effective date of this rule. If a qualifying application is filed more than one year after the effective date of this final rule, VA may pay benefits for a retroactive period of up to one year prior to the date of the application.

Comment Suggesting That Presumption Be Extended to Conditions With Limited/Suggestive Evidence of an Association With TBI

As stated in the proposed rule, this rulemaking is based on a report of the National Academy of Sciences, IOM, Gulf War and Health, Volume 7: Long-Term Consequences of Traumatic Brain Injury, regarding the association between TBI and subsequent illness. The report ranked the illnesses it studied into five categories based on the IOM's degree of confidence in the association between TBI and the illness:

1. Sufficient evidence of a causal relationship.
2. Sufficient evidence of an association.
3. Limited/suggestive evidence of an association.
4. Inadequate/insufficient evidence to determine whether an association exists.
5. Limited/suggestive evidence of no association.

Upon review of the report, the Secretary determined that a rulemaking is warranted to establish five diagnosable illnesses, for which there is ''sufficient evidence of a causal relationship'' or ''sufficient evidence of an association,'' as secondary conditions to TBI.

One commenter noted that the proposed rule would only establish presumptions for conditions in the top two categories. The commenter urged VA to also establish presumptions for every condition that the IOM ranked in the category ''limited/suggestive evidence of an association.'' Without citing any authority, the commenter asserted, ''The first three levels describe cases where the relationship is indicated by at least a preponderance of evidence.'' The commenter also described the third category as follows: ''For example, an evaluation of 'limited/suggestive evidence of an association' may describe a condition very likely to follow TBI, but where the research has yet to satisfactorily describe the incidence, thresholds, or causal mechanism.'' The commenter noted that the presumptions in the proposed rule were all based on illnesses ranked in the top two categories and urged VA to include illnesses from the third category as well.

We disagree that the category ''limited/suggestive evidence of an association'' describes conditions ''very likely to follow TBI, but where the research has yet to satisfactorily describe the incidence, thresholds, or causal mechanism.'' Nothing in the IOM report indicates that definition. In fact, the IOM report clearly states that this category means, ''Evidence is suggestive of an association between TBI and a specific health outcome in human studies but is limited because chance, bias, and confounding could not be ruled out with reasonable confidence.'' In contrast to the IOM's findings of ''sufficient evidence'' of a causal or statistical association, the ''limited/suggestive'' classification reflects some uncertainty as to whether the condition ordinarily can be associated with TBI. Moreover, the ''preponderance of evidence'' standard to which the commenter refers is not the basis for this final rule. This rule concerns the Secretary's decision to establish a special evidentiary rule applicable to specific conditions as to which there is particularly strong evidence of an association with TBI. Evidence in equipoise is the general standard of proof VA employs when weighing the evidence in an individual veteran's case in the absence of a special evidentiary rule. In exercising his rulemaking authority under 38 U.S.C. 501, the Secretary has decided to establish a special evidentiary rule for those conditions as to which there is strong evidence of an association with TBI, while retaining the generally applicable evidentiary rules, including evidence in equipoise standard, for all other conditions.

The primary purpose of this final rule is to codify sound medical principles recognized in the IOM report. For example, in the absence of any rule establishing service connection secondary to TBI, a veteran who suffered a moderate or severe TBI in service and is diagnosed with a neuroendocrinological disorder (*i.e.,* diseases of hormone deficiency that result from hypothalamo-pituitary changes) within 12 months thereafter could obtain service connection by submitting a physician's opinion that it is as likely as not that the TBI caused

the neuroendocrinological disorder. Such a physician's opinion would be consistent with the IOM's findings. Because illnesses listed in the top two IOM categories ordinarily would, upon proper development, be found to be secondary to TBI, VA has determined that it is appropriate to establish this rule to promote efficient and consistent decisions. Because the IOM's findings of ''limited/suggestive evidence'' reflect some uncertainty as to whether the condition ordinarily can be associated with TBI, VA believes that claims involving those conditions should continue to be decided based upon full development and evaluation of all evidence in each case, including the veteran's full medical history. In claims involving any disease not covered by this final rule, VA will apply the generally applicable standards governing service connection and secondary service connection to determine, based on the evidence in each case, whether the claimant's condition resulted from a service-connected TBI or is otherwise service connected. For these reasons, we make no change based on this comment.

Comment Suggesting Presumptions Should Be Adopted When Evidence Is Inconclusive

The same commenter asserted that the proposed rule ''contradicts the VA's stated policy of adopting presumptions where the factual record or medical evidence is inconclusive.'' In support of this statement, the commenter quoted the preamble of the rulemaking that created 38 CFR 1.18, ''Guidelines for Establishing Presumptions of Service Connection for Former Prisoners of War'':

> Evidentiary presumptions of service connection serve a number of purposes. By codifying medical findings and principles that otherwise might not be familiar to VA adjudicators, they promote the efficient resolution of issues of service connection without the need for case-by-case investigation and interpretation of the available medical literature. They promote fair and consistent decision making by establishing simple adjudicatory rules to govern the claims of similarly situated veterans. They also may assist claimants who would otherwise face substantial difficulties in obtaining direct proof of service connection due to the complexity of the factual issues, the lack of contemporaneous medical records during service, or other circumstances.

69 FR 60084, Oct. 7, 2004.

The commenter noted that in that rulemaking, VA established new presumptions for former prisoners of war (POW) based partly on the proposition that relevant medical research was poorly-developed because of the unusual nature of the POW experience, because few subjects were available for study, and because there are few comparable civilian populations. Based on the preamble language of this proposed rule, the commenter asserted, ''A presumption's purpose is to produce easier and more consistent outcomes for claimants in cases where the factual record is unavailable or where the medical science is undeveloped.'' The commenter further stated that the purpose of a presumption of service connection is ''not to codify scientific certainty, but rather to avoid denying claims simply because methodological research challenges have prevented the publication of high-quality medical science.''

In applying this analysis to the proposed rule, the commenter noted that the IOM report recognized that the research on the long-term health effects of TBI is limited and that the studies that have been done were limited by the difficulty of performing controlled primary studies on these effects. The commenter went on to assert that the proposed rule ''merely codifies existing scientific certainties; it provides no aid for cases where persistent scientific uncertainty may prevent adjudicators from correctly deciding meritorious claims.'' Based on these assertions, the commenter again stated that VA should extend the TBI presumptions to include all conditions for which the IOM found ''limited/suggestive evidence'' of an association.

As a preliminary matter, we agree with the commenter that the proposed rule essentially codifies established scientific principles, as this was VA's intention in proposing the rulemaking. However, we disagree that the state of medical knowledge on the health effects of POW service is the same or similar to the state of medical knowledge on the health effects of TBI. First, there are many more TBI subjects available for study than former POWs. According to the Defense and Veterans Brain Injury Center, there are over 266,000 veterans who suffered a TBI sometime between 2000 and 2012. Defense and Veterans Brain Injury Center, ''DoD Worldwide Numbers for TBI,'' *http://www.dvbic.org/dod-worldwide-numbers-tbi* (last visited April 15, 2013). In contrast, there were only 29,350 living former POWs in 2005 (when the final rule of the cited rulemaking was published). U.S. Dept. of Veterans Affairs, Office of the Assistant Secretary for Policy and Planning, ''American Prisoners of War (POWs) and Missing in Action (MIAs)'' (2006). According to data from VA's Office of Performance Analysis & Integrity, there are now only 10,059 living former POWs.

Second, there are many more comparable civilian population studies for TBI than for former POWs, including those who suffered TBIs from motor vehicle accidents, sports injuries, and workplace injuries. There is, therefore, considerably more medical research available on TBI than on former POWs. IOM was not limited to reviewing scientific studies of veterans, and according to its report, it did an initial assessment of 30,000 titles and abstracts and out of those further reviewed approximately 1,900 peer-reviewed scientific studies. There have been far fewer studies of former POWs. There are fewer than 200 peer-reviewed scientific studies on POWs. The rulemaking cited by the commenter established rules applicable only to former POWs precisely because VA determined that the challenges facing former POWs were very different from those facing veterans alleging injury due to most other types of in-service experiences.

We disagree that it would be appropriate to establish a rule directing a finding of service connection secondary to TBI on a matter for which there has been no ''publication of high-quality medical science.'' As stated in the preamble to the POW rulemaking cited above, ''presumptions [of service connection] are generally based on scientific and medical data that provide a basis for inferring a connection between a particular disease and some circumstance regarding the veteran's service.'' We believe that the scope of the proposed rule is properly limited to conditions for which sound scientific research permits confidence that an association with TBI exists in virtually every case. Where existing scientific evidence is less conclusive, we believe it is more appropriate to decide claims based on development and analysis of the facts of each case, including medical examinations and opinions taking account of the veteran's medical condition and history. This approach is consistent with the recognition by the U.S. Court of Appeals for Veterans Claims that medical studies and treatises alone often are insufficient to establish that a particular veteran's medical condition was caused by his or her service, but that there may be instances where medical treatises provide a sufficient ''degree of certainty'' that they may provide a basis for finding service connection in an individual case. *Sacks* v. *West,* 11 Vet. App. 314, 317 (1998).

Further, we note that the rankings in the IOM report, particularly in the

broadly defined ''limited/suggestive evidence'' category, do not precisely correspond to or control the statutory standards governing service connection, which VA is responsible for implementing through rulemaking and adjudication. There may be significant differences in the strength of the evidence for different conditions in the same category. The IOM also acknowledges that its ''limited/suggestive evidence'' classifications are ''limited because chance, bias, and confounding could not be ruled out with reasonable confidence.''

Finally, we note that VA's rating schedule indicates that TBI may cause a variety of cognitive, emotional/behavioral, and physical effects and instructs VA raters to appropriately consider and rate all such effects. 38 CFR 4.124a, Diagnostic Code 8045. These provisions properly notify VA raters to fully consider all potential health effects of TBI, including distinctly diagnosed conditions that may be due to a TBI. This final rule is intended to promote efficiency and uniformity by codifying certain well established medical principles, but is not intended to imply any finding by VA that veterans who incurred TBIs in service presently face unusual difficulties in establishing the right to compensation for the effects of their injuries, due to scientific uncertainty or other causes. In instances where there is some scientific uncertainty, or where TBI is one of several potential causes of a particular health effect, we believe that case-by-case evaluation of the facts of the veteran's disability picture is appropriate and that current procedures provide an adequate basis for ensuring the full and fair evaluation of disability due to TBI.

For these reasons, we make no change based on this comment.

Comment Suggesting the Proposed Rule Applies a Higher Evidentiary Standard for Service Connection Secondary to TBI

As part of the commenter's suggestion to create presumptions for every condition in the ''limited/suggestive evidence'' category, the same commenter asserted that the proposed rule applied a higher evidentiary standard than called for by statute. In support of this assertion, the commenter cited to the ''benefit of the doubt rule'' in 38 U.S.C. 5107(b). The commenter repeated the argument that conditions in the top three categories ''describe cases where the relationship is indicated by at least a preponderance of evidence.'' The commenter also asserted that VA should establish TBI presumptions for conditions in the fourth category, ''Inadequate/insufficient evidence to determine whether an association exists,'' because this ''describes conditions where doubt exists, due to insufficient or conflicting evidence'' and, therefore, the ''benefit of the doubt'' standard is satisfied. The commenter acknowledged that the ''benefit of the doubt rule'' applies to adjudicatory facts rather than legislative facts.

The ''benefit of the doubt rule'' states:

> (b) Benefit of the Doubt.—The Secretary shall consider all information and lay and medical evidence of record in a case before the Secretary with respect to benefits under laws administered by the Secretary. When there is an approximate balance of positive and negative evidence regarding any issue material to the determination of a matter, the Secretary shall give the benefit of the doubt to the claimant.

38 U.S.C. 5107(b). There is no indication that Congress intended VA to use the benefit of the doubt principle when developing regulations, and this rulemaking is not based on the benefit of the doubt rule. Under 38 U.S.C. 501, VA has authority to issue regulations that are ''necessary or appropriate'' to carry out the laws VA administers. The evidentiary factors involved in adjudicating one claim are entirely different than the factors VA considers in drafting regulations of general applicability, and it ordinarily would not be logical to use the standard in section 5107(b) in the latter context. As previously explained, this rule establishes a special evidentiary rule for certain conditions as to which there is particularly strong evidence of an association with TBI; it does not purport to define all circumstances in which the evidence in a particular case may meet the benefit of the doubt standard. Furthermore, we note that § 3.310(d) is not an exclusive list of all of the conditions that may be secondarily service connected based on service-connected TBI; it merely establishes secondary service connection for a certain condition for which there is sound evidence of a strong association with TBI. Claimants may still file claims for secondary service connection for conditions not listed in § 3.310(d) under § 3.310(a). We make no change based on this comment.

In addition to 38 U.S.C. 5107(b), the commenter asserted that another statute, 38 U.S.C. 5103A, ''Duty to assist claimants,'' should guide VA's establishment of TBI presumptions. In support of this assertion, the commenter stated that VA's duty to assist a claimant in obtaining necessary evidence ''surely encompasses a duty not to require claimants to provide *unnecessary* evidence.'' The commenter concluded that, ''If the VA already has information sufficient to satisfy the 'benefit of the doubt rule' for a given question, then additional supporting evidence is unnecessary and the VA should not require it.'' The commenter pointed out that in some cases, VA has adopted presumptions for illnesses ranked in the limited/suggestive category, ''for conditions related to prisoner of war status, herbicide exposure, and general military service, among others.''

This comment appears to rest on the premise that the IOM's finding of ''limited/suggestive evidence'' of an association between TBI and a particular health effect is sufficient evidence to establish secondary service connection for that health effect in every case, such that any further evidentiary development would be unnecessary. VA does not agree with that premise. The IOM's own definition of ''limited/suggestive evidence'' indicates that there may be significant limitations on the conclusions and inferences that may be drawn from the available medical evidence regarding health effects in that category. Further, as the U.S. Court of Appeals for Veterans Claims has noted, evidence from medical studies and treatises of a general nature often is insufficient, standing alone, to resolve questions of causation and service connection in individual cases. Even if medical studies indicate that TBI is one possible risk factor for the development of a particular condition, it may be necessary to develop and consider each veteran's medical history regarding the onset, nature, and course of the veteran's condition and any other risk factors applicable to the veteran's case in order to determine the likelihood that the condition is related to TBI. It is VA's policy to avoid unnecessary development of evidence, and VA applies this policy on a case-by-case basis. 38 CFR 3.304(c). However, we do not believe that the IOM's findings of ''limited/suggestive evidence'' that certain conditions may be associated with TBI will obviate the need to develop and consider other medical evidence in all or most cases involving those conditions.

As noted above, VA proposed in this rulemaking to codify sound medical principles recognized in the IOM report, not to create presumptions. VA has created presumptions for certain diseases for which the IOM or VA has found ''limited/suggestive evidence of an association'' with herbicide exposure or other circumstances of service. In some instances, VA has determined that presumptions were not warranted for diseases in IOM's ''limited/suggestive

evidence'' category. Many of those determinations were made under a specific statutory formula for making such determinations in the context of the use of Agent Orange during the Vietnam War. Moreover, those prior determinations were based on the evidence and circumstances applicable to the particular condition at issue and do not establish any binding precedent for future rulemaking concerning other circumstances. Consequently, we make no change based on this comment.

Comment Suggesting That There Are Practical Reasons To Establish More Categories as Service Connected Secondary to TBI Than Proposed

In addition to the above legal arguments, the same commenter asserted that there are practical reasons for VA to expand the list of conditions beyond the five in the proposed rule. The commenter stated:

> When evaluating whether to adopt this presumption, the VA should take into consideration the very real costs that will arise if it requires claimants to jump through the hoop of re-proving facts that the VA already knows to be true. First, some claimants will fail to provide the results of the IOM Study and therefore fail to prove this element. Second, some adjudicators may incorrectly infer from the VA's decision not to adopt a presumption that the IOM Study's evidence is insufficient to satisfy the veteran's burden of proof. Third, the adjudication system is already far too burdened for the VA to saddle it with *pro forma* responsibilities. We recognize that the VA may be reluctant to disturb the veteran's statutory burden of proof, but these costs are too high a price to pay in cases where the burden of proof has become a mere formality.

The commenter's first point, that ''some claimants will fail to provide the results of the IOM Study and therefore fail to prove the [nexus] element,'' implies that the results of a scientific study or report are the only way a veteran can satisfy the nexus element in a service-connection claim. This assumption is incorrect because in most cases, the nexus element is proven via a medical opinion from an appropriate professional. The medical opinion would contain any necessary citation to medical authorities. Further, as noted above, the U.S. Court of Appeals for Veterans Claims has noted that, except where medical treatises speak with a sufficient ''degree of certainty,'' such treatises alone generally cannot establish that a particular claimant's disability is service connected and it is ordinarily necessary to obtain a medical opinion concerning the specific veteran's condition. *Sacks* v. *West,* 11 Vet. App. 314, 317 (1998). We, therefore, make no change based on this comment.

Regarding the commenter's concern that VA adjudicators may incorrectly infer from VA's decision not to issue rules directing a finding of secondary service connection for certain diseases that the IOM Study's evidence is insufficient to satisfy the veteran's burden of proof, we do not believe this is valid basis to change the proposed rule. That is because the proposed rule expressly precludes such inferences with regard to the severity of levels of the illnesses or the time limits with the following provision:

> (2) Neither the severity levels nor the time limits in paragraph (d)(1) of this section preclude a finding of service connection for conditions shown by evidence to be proximately due to service-connected TBI. If a claim does not meet the requirements of paragraph (d)(1) with respect to the time of manifestation or the severity of the TBI, or both, VA will develop and decide the claim under generally applicable principles of service connection without regard to paragraph (d)(1).

Furthermore, such inferences would also not be logical with regard to other conditions because the establishment of this rulemaking would not preclude a veteran from filing a claim for compensation with VA for a service-connected disability secondary to TBI for a condition other than the ones listed in the proposed rule. We note also that VA's rating schedule reflects that TBI may result in a variety of cognitive, emotional/behavioral, and physical effects, and directs VA raters to assign ratings applicable to all such conditions found in an individual's case to be the result of a TBI. 38 CFR 4.124a, Diagnostic Code 8045. That provision, which properly notifies VA raters to consider all health effects potentially associated with TBI, further makes clear that the beneficial provisions of this rule must not be construed to preclude compensation for other health effects associated with TBI.

The third comment, that ''the adjudication system is already far too burdened for the VA to saddle it with *pro forma* responsibilities,'' is based upon a false premise: That providing evidence of nexus by obtaining a medical opinion is inherently ''*pro forma''* whenever a veteran's claim falls outside the conditions that are listed in the proposed rule. In many cases, VA is required to obtain a medical opinion under 38 U.S.C. 5103A, ''Duty to assist claimants.'' As noted above, this statute requires VA to obtain a medical examination or a medical opinion ''when such an examination or opinion is necessary to make a decision on the claim.''

As stated above, the limitations in the scope of the proposed rule are based on sound medical and scientific principles regarding the health effects of TBI. In our judgment, there is no basis to expand these provisions as suggested by the commenter. In some cases, doing so would actually be contrary to current medical and scientific research. VA will monitor ongoing TBI research and can modify or expand the secondary service connections of TBI if medical research leads to that conclusion. For these reasons, we make no change based on this comment.

Another commenter also suggested that VA expand the diagnosable illnesses as secondary to service connection to TBI, to include post-traumatic headache, chronic post-traumatic stress disorder, exacerbation or precipitation of a psychiatric disorder (e.g., a stable bipolar patient whose bipolar illness becomes unstable following TBI), attentional disorders, sleep and wake disorders, and anxiety. The IOM report on which this rule is based did not expressly address all of those conditions and, to the extent it did address them, did not find sufficient evidence of an association between such conditions and TBI. We recognize that the health effects the commenter identifies may be found to be related to TBI in a particular case and, as noted above, VA's rating schedule for TBI instructs raters to provide appropriate evaluations for all health effects found to be related to a veteran's TBI. As to the conditions listed by the commenter, we find no basis for changing the current practice of relying upon case-by-case determinations as to whether those conditions are related to a veteran's TBI.

Another commenter suggested that the language of the proposed rulemaking be strengthened so that certain behavioral and social problems, while not diagnosable, including diminished social relationships, aggressive behaviors, long-term unemployment, be included in evaluating the severity of the claim for compensation purposes. For the reasons stated above, we believe that these types of effects are most properly evaluated on a case-by-case basis under VA's rating schedule, which provides that, in assigning a disability evaluation for TBI, due consideration will be given to emotional/behavioral dysfunction, whether or not such function is diagnosed as a mental disorder. 38 CFR 4.124a, Diagnostic Code 8045.

Comment Suggesting Language Stating That Claims That Are Not Included in This Rulemaking Will Be Given Equal Consideration

One commenter suggested that VA should use explicit language stating that cases/claims that fall outside of the established time frames of § 3.310(d) will be given equal consideration to determine whether a condition is secondarily service connected to the original TBI condition. The commenter states that many veterans do not report TBIs, which skews the entire timeframe, and inadequate screening and coping skills may delay diagnosis and screening of secondary conditions. Similarly, another commenter suggested that we remove all time limits because, in her experience, certain conditions relating to TBI do not manifest until many months after the TBI occurred.

The conditions and time limits specified in this rule reflect the IOM's findings and the Secretary's determination that IOM's findings provide a sufficient basis for concluding that, absent clear evidence to the contrary, the identified conditions will be deemed to be a secondary result of service-connected TBI in each case where they are manifest within the specified time periods. We decline to remove the time limits, because doing so would result in a broad rule going well beyond the scope of the IOM's findings. However, we emphasize that this rule is intended only to assist claimants and simplify adjudications in cases falling within the scope of this rule. It is not intended to have any adverse effect on claims involving other conditions or involving conditions manifest outside the times frames in this rule. In all claims for service connected benefits, VA evaluates all evidence of record on a case-by-case basis and applies generally applicable principles of service connection set forth in statute and regulation to determine whether the condition is service connected. This case-by-case analysis ensure that VA gives due consideration to unique circumstances in individual claims, such as delays in reporting an injury or delays in diagnosis.

Language to this effect is already included in the proposed rule at § 3.310(d)(2), which states that ''If a claim does not meet the requirements of paragraph (d)(1) with respect to the time of manifestation or the severity of the TBI, or both, VA will develop and decide the claim *under generally applicable principles of service connection without regard to paragraph (d)(1).*'' (Emphasis added.) We interpret generally applicable principles of service connection to include secondary service connection. Thus, we believe that the language that specifically refers to secondary service connection is unnecessary.

Comments Suggesting the Inclusion of Mild TBIs and Multiple Mild TBIs

At least two commenters urged VA to include mild TBI within the scope of this rulemaking. One commenter stated that the effects of mild TBI may not be apparent immediately following injury and that limiting the presumptions reflected in paragraph (d) to moderate or severe TBI, and placing time limitations for onset of symptoms, is not appropriate. Another commenter suggested that mild TBIs can swell the connections between neurons in the brain and this swelling, in turn, can cause types of dementia of the Alzheimer's type.

The primary and secondary studies cited by the IOM support its finding that there is sufficient evidence of an association between TBI (including mild TBI) and depression, as well as limited/suggestive evidence of an association between mild TBI and dementia of the Alzheimer type and parkinsonism, but only in the case of mild TBI with loss of consciousness. We did not include mild TBI in the rulemaking regarding dementia. A finding by the IOM of ''limited/suggestive evidence'' indicates that the evidence is suggestive of an association between TBI and the specific health outcome in human studies but is limited because chance, bias, and confounding factors could not be ruled out with reasonable confidence. There were no findings of a causal relationship or association between mild TBI and the other conditions that are the subject of this rulemaking. Given the findings of the IOM, and research since the IOM report was issued, VA does not believe that the rule should be amended as suggested by the commenter. We, therefore, make no changes based on this comment.

One commenter stated that multiple mild TBIs should be considered equivalent to moderate TBI for the purposes of this rulemaking. Citing the discussion by the IOM of the dose-response relationship, the commenter argued that the IOM treats multiple mild TBIs as a high-exposure cohort similar to severe TBI. In its report, the IOM described the types of evidence that were evaluated by the committee. This included data from observational studies that may infer a causal relationship between an event and possible outcome. The IOM noted that the dose-response relationship could be one element considered when inferring causality. The dose-response relationship is studied in various scientific disciplines, most notably toxicology. It describes the change in effect on an organism caused by differing levels of exposure to a stressor after a certain exposure time. On pages 107–08 of its report, the IOM observed that ''if studies of presumably low-exposure cohorts (for example, mild TBIs or a single injury) show only mild increases in risk whereas studies of presumably high-exposure cohorts (for example, moderate to severe TBIs or repeated injuries) show larger increases in risk, the pattern would be consistent with a dose-response relationship.'' VA views this as a restatement of the definition of dose-response relationship using TBI and physical injury as examples of stressors, not a finding by the IOM equating multiple mild TBIs with severe TBI. Our conclusion is consistent with a reading of the IOM report as a whole.

We note that because there is very little research on the chronic effects of mild TBI, VA and the DoD recently invested $62.2 million, to be spent over the next 5 years on a research consortium, ''Chronic Effects of Neurotrauma Consortium—CENC'' to study the chronic effects of mild TBI and common comorbidities in order to improve diagnostic and treatment options. See *http://www.va.gov/opa/pressrel/pressrelease.cfm?id=2473.*

In addition, the commenter argued that failure to include multiple mild TBIs in the proposed rule is inconsistent with VA's purpose of adopting presumptions where persistent scientific uncertainty interferes with correct adjudication. As this commenter correctly noted, in a previous rulemaking, we stated that evidentiary presumptions ''may assist claimants who would otherwise face substantial difficulties in obtaining direct proof of service connection due to the complexity of the factual issues, the lack of contemporaneous medical records during service, or other circumstances.'' 69 FR 60084, October 7, 2004. We wrote this in relation to the use of presumptions in the case of prisoners of war who may have incurred injury in circumstances in which contemporaneous medical records were not created or are not available, and in which direct confirmatory proof of an incident is difficult to obtain. Presumptions are sometimes acceptable where factual uncertainty exists. However, the primary purpose of this final rule is to codify the sound medical principles recognized in the IOM report, and thus, addressing situations where there is scientific uncertainty relating to

TBI is outside the scope of this rulemaking.

Another group also urged VA to include multiple mild TBIs within the scope of this rulemaking, citing studies performed on football players as well as a study on patients diagnosed with Chronic Traumatic Encephalopathy. VA believes that there is currently an inadequate body of reliable research equating multiple mild TBI and moderate TBI. Concussion, or mild TBI, is a condition medically distinct from moderate or severe TBI. While the cited studies are suggestive, there are significant limitations in the applicability of the findings and conclusions. VA does not believe that multiple mild TBIs should be included within the scope of this rulemaking given the current state of research.

Two commenters urged VA to revise the rule to address the health effects of multiple mild brain injuries incurred over time. One of these commenters noted that some veterans may sustain multiple traumas to the brain over time resulting in brain injury that initially might be perceived as mild to moderate but cumulatively are moderate to severe.

The IOM recognized the cumulative effect of multiple incidents of head trauma in its discussion of sports-related TBIs and Dementia Pugilistica. Studies have shown that there is a period following brain injury when the brain remains particularly vulnerable to damage from a subsequent injury. See, e.g., Prins ML et. al., ''Repeated Mild Traumatic Brain Injury: Mechanisms of Cerebral Vulnerability,'' Journal of Neurotrauma, 30(1):30–8) (2013).

The IOM also noted that in determining TBI severity, different methods have been used in the last three decades to measure the magnitude of brain damage and to predict its outcome. The most widely used tool for measuring severity is the Glasgow Coma Scale. Other methods specifically mentioned by the IOM are the Abbreviated Injury Scale and the International Classification of Diseases. In addition, clinical criteria have also been used to determine the severity of head injuries, including alteration of consciousness, loss of consciousness, CT scans, and the duration of post-traumatic amnesia. Each of these tools has its own limitations. However, the cumulative effect of multiple head trauma over a period of time is taken into account during the clinical evaluation process through a review of the patient's history, comparison to baseline readings, and diagnostic examination. This would be a case-by-case evaluation, not suitable for prescriptive application as a secondary service connection. We believe that existing rating procedures, which include consideration of the veteran's full medical history in rendering medical opinions and assigning disability ratings, ensures that due consideration will be given to the potential effects of multiple mild TBIs based on their number, proximity in time, and any other relevant factors.

Comment Suggesting Assessment of TBI Severity

In the proposed rule, we recognized that some veterans may not meet all of the criteria within a particular severity level (as described above) or may not have been examined for all the severity factors at or shortly after the time of the incurrence of the TBI. We went on to note that the simplest, most efficient, and fairest way to rank such veterans was to apply two rules: (1) VA will not require that a TBI meet all the criteria listed under a certain severity level to classify the TBI under that severity level; and (2) If a TBI meets the criteria relating to loss of consciousness, post-traumatic amnesia, or Glasgow Coma Scale in more than one severity level, then VA will rank the TBI at the highest of those levels. We included these rules in proposed paragraph (d)(3)(ii).

One commenter asserted that ''the rating criteria [in the proposed rule] differ from those of established medical practice.'' The commenter noted that the joint DoD/VA guidelines on the evaluation of severity of TBI state that when the diagnostic criteria indicate different levels of severity, the highest level of any one criterion will be assigned. In the proposed regulation, however, raters will not apply a higher level when the higher level is indicated by the ''alteration of consciousness'' or ''structural imaging of the brain'' criterion.

We note that the joint VA/DoD guidelines cited above state, ''The patient is classified as mild/moderate/severe if he or she meets any of the criteria below within a particular severity level. If a patient meets criteria in more than one category of severity, the higher severity level is assigned.'' These principles are not limited to certain factors. We agree with the principle of applying the higher of two potentially applicable severity levels. However, literal application of the above-quoted statements would yield illogical and unintended results. The ''structural imaging of the brain'' criterion identifies ''Normal structural imaging'' as a feature of mild TBI and ''Normal or abnormal structuring'' as a feature of both moderate and severe TBI. If a claimant need only meet any single criterion of the ''severe TBI'' classification, then all TBIs would be evaluated as severe, because all TBIs would involve ''Normal or abnormal structural imaging.'' Similarly, the ''alteration of consciousness'' criterion indicates that both moderate and severe TBI involve alteration of consciousness for a period exceeding 24 hours and that differentiation between moderate and severe TBI should, therefore, be ''based on other criteria.'' It would be inconsistent with that stated direction to conclude that a patient's TBI was severe solely because it met the criterion of alteration of consciousness exceeding 24 hours. Accordingly, we decline to adopt the unqualified principle that meeting any single criterion for a specific severity level will result in assignment of that severity level. In considering this comment, however, we recognized that the criteria for alteration of consciousness and structural imaging of the brain do provide meaningful distinctions between mild and moderate TBI. We believe that a TBI that meets the criterion for moderate TBI under either of those categories should be evaluated as moderate, even if it meets none of the other criteria for moderate TBI. Accordingly, we have revised (d)(3)(ii) of the proposed regulation to read, in pertinent part, ''If a TBI meets the criteria in more than one category of severity, then VA will rank the TBI at the highest level in which a criterion is met, except where the qualifying criterion is the same at both levels.'' This language is intended to clarify that VA generally will assign the highest applicable level of severity, but will not treat ''Normal or abnormal structural imaging'' or alteration of consciousness exceeding 24 hours, standing alone, as establishing that the TBI is severe rather than moderate.

The commenter also noted that because medical science on TBI is evolving ''it is likely that medical practice will change and that it will diverge from whatever criteria are published in this regulation.'' The commenter, therefore, suggested that VA insert the following language in § 3.310(d): ''(i) For diagnoses of the severity of TBI, this regulation adopts the nomenclature of the Department of Defense Assistant Secretary for Health Affairs, 'Traumatic Brain Injury: Definition and Reporting,' October 1, 2007. Medical diagnoses of the severity of TBI must be made in accordance with those standards, or with updated versions of the same standards.''

For two reasons, we decline to adopt this suggestion. First, it would make the regulation difficult to use. It would require anyone using this regulation to

find and read the DoD document referenced. It would cause confusion because the reader would not know whether DoD has published an ''updated version'' or where to find it. Second, it would bind VA to apply unknown future standards that may not be usable in the adjudication of veterans' disability claims.

Another commenter suggested that we clarify paragraph (3)(ii) to state that the severity of TBI is based on contemporaneous documentation not subsequent testimony or witness statements. Proposed paragraph (3)(ii) stated that ''[t]he determination of the severity level under this paragraph is based on the TBI symptoms at the time of injury or shortly thereafter, rather than the current level of functioning.'' Although contemporaneous evidence ordinarily will be the most probative evidence of the TBI symptoms at the time of injury or shortly thereafter, we cannot rule out the possibility that subsequent statements may also be probative evidence that VA must consider. We, therefore, make no change based on this comment.

Comment Alleging That Medical Determinations Will Be Made by VA Adjudication Staff

Under the proposed rule, VA would determine eligibility for secondary service connection based in part on the severity of the initial TBI. VA would rate the severity of the TBI in one of three categories (mild, moderate, and severe) in conformity with joint VA/DoD guidance on the assessment of TBI severity. Department of Defense Assistant Secretary for Health Affairs, ''Traumatic Brain Injury: Definition and Reporting'' 2, October 1, 2007. This guidance considers the following factors: structural imaging of the brain, the Glasgow Coma Scale, and the durations of any loss of consciousness, alteration of consciousness/mental state, or post-traumatic amnesia.

One commenter asserted that this provision in the proposed rule would improperly ''permit raters to make medical diagnoses.'' The commenter cites the seminal case *Colvin* v. *Derwinski,* 1 Vet. App. 171, 174 (1991), for the principle that VA adjudication staff ''are prohibited from relying on their own lay judgment to decide medical questions.'' The commenter goes on to assert that, ''[b]ecause the criteria that define the levels of severity are individual physiological responses rather than external factual circumstances, determining the severity of a TBI is a medical diagnosis.'' The commenter concluded that, ''[t]he fact that the protocol for determining the severity of TBI appears to be relatively mechanical does not mean that laypersons are competent to make that determination.''

As a preliminary matter, we note that the commenter misstates the concept of diagnosis. As stated in Dorland's Illustrated Medical Dictionary, diagnosis means, ''1. the determination of the nature of a case of disease'' or ''2. the art of distinguishing one disease from another.'' Dorland's Illustrated Medical Dictionary 507 (30th ed. 2003). Assessment of the severity of an injury is not a diagnosis.

Furthermore, it is well within the authority of a VA adjudicator to determine the nature and severity of an injury based on the available medical and lay evidence. For example, in 38 CFR 4.56, ''Evaluation of muscle disabilities,'' VA regulations refer to various types of ''[t]hrough and through'' gunshot wounds. In such cases, the VA adjudicator reviews the relevant medical evidence and then makes a determination whether the gunshot passed through the veteran's body. He or she can make this determination even if the medical records do not explicitly address this point. The adjudicator is merely overlaying the medical and lay evidence onto the regulatory criteria to reach a factual determination. There is no medical judgment required to do this. Similarly, a VA adjudicator is empowered under 38 CFR 4.120, ''Evaluations by comparison'' to determine the ''site and character of the injury. Likewise, in 38 CFR 4.41, ''History of injury,'' VA instructs its adjudicators, ''In considering the residuals of injury, it is essential to trace the medical-industrial history of the disabled person from the original injury, considering the nature of the injury and the attendant circumstances . . .''

The table in proposed § 3.310(d)(3) simply requires a VA adjudicator to apply certain objective criteria to the medical and lay evidence of record regarding the TBI symptoms at the time of the injury or shortly thereafter. Nothing in the proposed rule would prohibit a VA adjudicator from obtaining a medical opinion if he or she requires more precise medical information to properly determine in which of the three severity levels the veteran's TBI belongs. In fact, under VA's duty to assist (38 U.S.C. 5103A(d)), VA is required to obtain a medical examination or a medical opinion ''when such an examination or opinion is necessary to make a decision on the claim.''

If VA were to adopt the commenter's implied suggestion that we obtain a medical opinion regarding severity of the TBI in every case, we would be needlessly delaying many veterans' claims which could otherwise be granted without such an opinion. This would not only delay the claims of veterans seeking service connection for the secondary effects of their TBI, but the claims of other veterans who would be forced to wait longer for their medical exam or opinion. For these reasons, we make no change based on this comment.

Comment Suggesting Clarification on the Rating of the Secondary Condition

One commenter expressed concern that the proposed rule did not address cases in which ''a veteran with an existing rating for a secondary illness is higher than the [TBI] rating they would receive under the new rule, which could result in a reduction in the veteran's compensation and schedular rating from the application of this rule.'' The commenter further stated, ''This could also result in situations where a veteran is not adequately compensated for the severity of the secondary illness and its impact on quality of life/functioning.'' This same commenter also alleges that the proposed rule does not address the rule's applicability to prior determinations made by VA regarding service connection for TBI and the severity of the secondary condition in relation to the TBI rating. This commenter states that ''the rule only provides for a service connection for [TBI] that do not have the necessary medical documentation to be assessed under the new section proposed if there are also secondary illnesses that may warrant a rating greater than under the new rule.'' He further asserts that ''[T]his could result in veterans receiving a lower schedular rating and subsequent reduction in category grouping for treatment of their illness than previously received.''

VA does not believe that this rulemaking could result in a lower disability rating for any veteran. This rule does not govern how VA determines the degree of disability caused by any service-connected illness, but only provides a mechanism for establishing service connection for certain illnesses. If a veteran were already service connected for one of the five illnesses listed in the rule, then this rule would have no impact on his or her status or rating. Regarding prior claims for service connection of a TBI, this rule would have no impact on those either. This rule does not alter the requirement to first prove that a TBI is service connected in order for VA to consider

what conditions may be service connected as secondary to that TBI.

Comment Suggesting Inclusion of Acquired Brain Injuries

One commenter urged VA to include all acquired brain injuries in the coverage of this rule, such as damage caused by anoxia or hypoxia when the body is subjected to blast or pressure waves following an explosion. The IOM noted at page 14 of its report that TBI can be caused not only by a blow or by jolt to the head or penetrating head injury, but also by exposure to an external energy source. VA agrees with that observation, and we did not limit the scope of this rulemaking to only TBI incurred as a result of a blow to the head. Acquired brain injuries that meet the criteria for service-connected TBI would be covered by this rule. Acquired brain injuries that are not categorized as TBI were not studied in the IOM report and are outside of the scope of this rulemaking. We make no change based on this comment.

Comments Regarding Specific Conditions Secondarily Service-Connected to TBI

1. Parkinsonism and Parkinson's Disease

We received two comments urging VA to amend proposed paragraph (d)(1)(i), that states that parkinsonism shall be held to be the proximate result of service-connected moderate or severe TBI, in the absence of clear evidence to the contrary. One commenter urged VA to clearly indicate that Parkinson's disease is included in the definition of parkinsonism. In support, the commenter cites the definition of parkinsonism found on VA's Parkinson's Disease Research, Education, and Clinical Centers (PADRECC) Web site, which can be interpreted to exclude Parkinson's disease from that definition. In addition, the commenter cited definitions of parkinsonism found on the Web sites of the Michael J. Fox Foundation and the National Parkinson's Foundation.

Another commenter referred to an earlier IOM report, Veterans and Agent Orange: Update 2008. Institute of Medicine of the National Academies, Veterans and Agent Orange: Update 2008, The National Academies Press (Washington, DC, 2009); available online at *http://www.nap.edu/openbook.php?record-id=12662&page=515* (accessed June 24, 2013) (hereinafter ''Veterans and Agent Orange: Update 2008''). The commenter asserts that parkinsonism and other similar diseases are not the same disease as Parkinson's disease, citing the IOM's statement in that earlier report that ''[Parkinson's disease] must be distinguished from a variety of parkinsonian syndromes, including drug-induced parkinsonism and neurodegenerative diseases, such as multiple systems atrophy, which have parkinsonian features combined with other abnormalities.'' Veterans and Agent Orange: Update 2008, 515–16.

The commenter is correct in the assertion that Parkinson's disease is not the same as parkinsonism. The earlier report that the commenter is referring to—Veterans and Agent Orange: Update 2008—evaluated the correlation between Parkinson's disease and certain herbicide exposures. In Veterans and Agent Orange: Update 2008, the IOM specifically limited its study to the relationship between herbicide exposure and Parkinson's disease and cautioned readers, as the commenter correctly noted, that Parkinson's disease ''must be distinguished from a variety of parkinsonian syndromes, including drug-induced parkinsonism and neurodegenerative diseases.'' Agent Orange: Update 2008 at 515–16. The IOM included this caution because it wanted to be clear that it was not evaluating the correlation between parkinsonism and certain herbicide exposure; rather, its evaluation was explicitly limited to correlations between certain herbicide exposure and Parkinson's disease. Veterans and Agent Orange: Update 2008 was the subject of an earlier VA rulemaking in which VA amended 38 CFR 3.309(e) to establish presumptive service connection for Parkinson's disease based on exposure to certain herbicide agents. 38 CFR 3.309(e); *see* Diseases Associated with Exposure to Certain Herbicide Agents (Hairy Cell Leukemia and Other Chronic B-Cell Leukemias, Parkinson's Disease and Ischemic Heart Disease), 75 FR 53202–53204 (Aug. 31, 2010); *see also* Diseases Associated with Exposure to Certain Herbicide Agents (Hairy Cell Leukemia and Other Chronic B-Cell Leukemias, Parkinson's Disease and Ischemic Heart Disease), 75 FR 14391–14392 (Mar. 25, 2010). Based on the limited scope of the IOM report, VA amended § 3.309(e) to only include Parkinson's disease while clarifying in its Final Rule that ''Parkinson's disease'' does not include parkinsonism because the IOM report specifically did not opine regarding parkinsonism. In the Final Rule, VA stated, ''Update 2008 only evaluated the correlation between certain herbicide exposures and Parkinson's disease. Parkinsonism, and other similar diseases, is not the same disease as Parkinson's disease''.

On page 246 of the IOM report at issue in this rulemaking—Gulf War and Health, Volume 7: Long-Term Consequences of Traumatic Brain Injury—the IOM clearly affirms the commenter's assertion that parkinsonism is not the same as Parkinson's disease. The IOM notes that although Parkinson's disease is the primary underlying cause of parkinsonism ''other factors have been associated with [parkinsonism].'' The IOM committee clearly considered Parkinson's disease to be the primary underlying cause of parkinsonism, and symptoms of Parkinson's disease to be within the constellation of symptoms that comprise parkinsonism and we agree with that assessment. In essence, Parkinson's disease is a form of parkinsonism; therefore, all Parkinson's disease is parkinsonism. However, the reverse relationship is not true: not all parkinsonism is Parkinson's disease. Therefore, it is not contradictory for VA to include Parkinson's disease as a part of parkinsonism in this rulemaking while maintaining that Parkinson's disease does not include parkinsonism with regard to 38 CFR 3.309(e). Furthermore, in the present report, the IOM evaluated parkinsonism while in Veterans and Agent Orange: Update 2008 referred to by the commenter the IOM limited its evaluation only to Parkinson's disease; therefore, VA is justified in using the broader term ''parkinsonism'' in § 3.310(d)(i) while maintaining the use of the more limited term ''Parkinson's disease'' in § 3.309(e). However, VA understands that, due to the limited scope of the term ''Parkinson's disease'' in 38 CFR 3.309(e), there exists the potential for confusion concerning the scope of the term ''parkinsonism'' as used in 38 CFR 3.310(d)(i). Therefore, we are adding '', including Parkinson's disease,'' following Parkinsonism in paragraph (d)(1)(i) to provide clarity.

Numerous commenters urged ''VA to continue to review research to assess whether it supports extending eligibility for these benefits to veterans who experience any TBI, not just those classified as moderate or severe.'' One commenter specifically urged VA to amend paragraph (d)(1)(i) to include veterans with parkinsonism following mild TBI with loss of consciousness (LOC). The commenter relied on the two primary studies considered by the IOM. In one of the cited studies, the authors examined a history of TBI as a risk factor for Parkinson's Disease (PD) in a case–control study. Bower JH, et. al., ''Head trauma preceding PD: A case-

control study,'' Neurology, 60(10):1610–1615 (2012). Mild head trauma was defined in this study as the absence of skull fracture and an LOC or post-traumatic amnesia lasting less than 30 minutes. The authors considered the association between PD and a history of mild TBI with LOC, moderate TBI, or severe TBI and found a significant association. The reported data did not further differentiate between mild TBI with LOC, moderate TBI, or severe TBI, so it is unclear how many of the identified patients had mild TBI with LOC. The authors noted that the ''results suggest an association between head trauma and the later development of [Parkinson's disease] that varies with severity.'' The IOM noted several possible study limitations.

In the second study, the authors conducted a case-control study of 93 male twin pairs discordant for Parkinson's disease, identified through the National Academy of Science's World War II veteran twins cohort. Goldman SM, et al, ''Head Injury and Parkinson's Disease Risk in Twins,'' Annals of Neurology, 60(1):65–72 (2006). The authors concluded that there was an association between TBI and parkinsonism, and an increased risk of Parkinson's disease in patients that had TBI with LOC or post-traumatic amnesia. They found no significant association between duration of LOC and Parkinson's disease.

The IOM concluded that there is ''limited/suggestive evidence of an association'' between mild TBI with LOC and parkinsonism, which means that ''[e]vidence is suggestive of an association between TBI and a specific health outcome in human studies but is limited because chance, bias, and confounding could not be ruled out with reasonable confidence.'' Based on our independent review and analysis of these two research studies, we agree with the IOM's conclusion. In the Bower study, there was insufficient differentiation of data to determine how many subjects had mild TBI with LOC, and the study has limited utility for our purposes because of broad confidence intervals and the possibility that mild TBI could not be identified based solely on a review of the medical records. The Goldman study concluded solely that there was an increased risk of Parkinson's disease in patients that had TBI with LOC or post-traumatic amnesia and no association between duration of LOC and Parkinson's disease. VA does not believe that the available scientific evidence warrants expanding the list of conditions in paragraph (d)(1)(i) to include mild TBI with LOC, and so we make no changes based on this comment.

2. Seizures

One commenter asserted that we misquoted study results regarding when seizures occur following a TBI. The commenter asserted that the study stated that seizures may occur at any time following a TBI. In the proposed rule at paragraph (d)(1)(ii), we stated that unprovoked seizures following moderate or severe TBI shall be held to be the proximate result of the service-connected TBI, in the absence of clear evidence to the contrary. We placed no limitation on when the unprovoked seizure must manifest during the veteran's life, and so we make no change based on this comment.

3. Dementias

Two commenters recommended amending paragraph (d)(1)(iii) to remove any time limit on when dementias must manifest in order for the establishment of service connection secondary to TBI to apply. Dementias are very common, with many patients without a history of TBI over the age of 60 being diagnosed annually with dementia. Given the prevalence of the condition in the general population, VA believes it appropriate to require development of dementia within a certain time period following a TBI for this rulemaking to apply. The available medical research indicates that TBI increases the risk of dementia and accelerates the timeline for developing that condition. In cases where dementia develops more than 15 years after a TBI, the link between the two conditions becomes less clear as the intervening time period becomes more attenuated. We make no changes to the rulemaking as a result of these comments.

One commenter recommended that the definition of dementia in paragraph (d)(1)(iii) be amended to include frontotemporal dementia and dementia with Lewy bodies. VA agrees. The research studies cited in support of this recommendation are persuasive and consistent with the body of research considered by the IOM. In addition, VA has continued to review the definition of dementia in this rulemaking and has determined that post-traumatic dementia should be removed from the definition. Post-traumatic dementia is not a recognized ICD–9 diagnosis, and including the condition in this rulemaking could result in confusion, uncertainty, and inconsistent application of the establishment of service connection secondary to TBI. We are, therefore, revising the regulation at (d)(1)(iii) to read, ''Dementias of the following types: Presenile dementia of the Alzheimer type, frontotemporal dementia, and dementia with Lewy bodies, if manifest within 15 years following moderate or severe TBI.'' This change is not intended to suggest that dementia noted by a physician as being ''post-traumatic'' or otherwise related to a TBI would be outside the scope of this rule. Rather, it reflects that clinicians generally do not use that term as a diagnostic classification and are not required to do so for purposes of this rule. The purpose of this change is to ensure that the text of the rule accurately reflects recognized diagnostic categories and will, therefore, be easier to apply.

One commenter urged VA to continue to review research on the relationship between Alzheimer's disease and TBI and to emphasize the importance of early diagnosis of Alzheimer's disease. While matters of medical research and treatment are outside the scope of this rulemaking, we will continue to review the emerging research literature on TBI and dementia. In addition, we will continue our efforts to improve dementia recognition, diagnosis, and care.

4. Depression

The proposed rule suggested that VA establish service connection secondary to TBI for depression if manifest within 3 years of the incurrence of a moderate or severe TBI or within 12 months of the incurrence of a mild TBI. One commenter stated that we misquoted study results and that there was no limitation on when the depression manifests following a TBI. It is unclear whether the commenter meant that VA had misquoted the IOM report itself or the research studies referenced in that report.

As a preliminary matter, we note that the proposed rule concerning secondary service connection for depression does not preclude a claim for direct service connection of depression, or a claim for service connection of depression secondary to TBI under § 3.310(a) for a condition that manifests outside the prescribed time periods. Paragraph (d)(2) provides that if a claim does not meet either the time of manifestation or severity of TBI, or both, VA will develop and decide the claim under generally applicable principles of service connection without regard to these rules concerning secondary service connection.

Moreover, we believe that the scientific literature supports the proposed rule's time and severity limitations for depression. The IOM

reviewed four primary and five secondary studies of major depression manifesting following TBI. The studies showed a higher rate of major depression 6 months or more after TBI when compared to appropriate comparison groups. For example, one 2004 study showed that in the first year after a moderate to severe TBI, 49% of the patients had evidence of psychiatric illnesses compared with 34% in the mild-TBI group and 18% in the comparison group. Fann JR, et. al., ''Psychiatric illness following traumatic brain injury in an adult health maintenance organization population,'' Archives of General Psychiatry, 61(1):53–61 (2004). The authors found the risk of psychiatric illness to be greatest in the period 6 to 12 months after the TBI and the risk was higher for moderate or severe TBI than for mild TBI. For depression that is first manifest after this identified period of significant increased risk, the available studies provide no reliable basis for concluding as a general matter that the depression is linked to the TBI rather than other causes. In such cases, we believe it is necessary to evaluate the medical evidence concerning the particular veteran's illness, under ordinary procedures, to determine whether the depression is related to TBI or is otherwise service connected. We, therefore, make no change based on this comment.

One commenter stated that paragraph (d)(1)(iv) should be amended to either exclude depression if manifested within 12 months of mild TBI, or to include only those veterans with mild TBI diagnosed on the basis of LOC, not on the basis of altered mental state. The commenter believes that there is not sufficient evidence to assume that mild TBI diagnosed on the basis of altered mental status is the proximate cause of depression that develops within 12 months post-injury. The IOM concluded that there was sufficient evidence of an association between TBI (mild, moderate, and severe) and depression based on its review of four primary and five secondary studies. In making a distinction between mild TBI with LOC and mild TBI diagnosed based on altered mental status, the commenter relies on a recent study of mild TBI in US soldiers that saw a high level of combat during a year-long deployment in Iraq. Hoge CW, et. al., ''Mild traumatic brain injury in U.S. soldiers returning from Iraq,'' New England Journal of Medicine, 358(5):453–463) (2008). This research was also considered by the IOM. In this study, soldiers were given a questionnaire which included questions regarding TBI. Soldiers were deemed to have mild TBI if they answered yes to any of three questions about losing consciousness, being dazed or confused, or not recalling the injury. Answers to these questions were used to form two subgroups within the mild-TBI group to determine whether LOC or altered mental status was a strong predictor of various conditions, including depression. A total of 124 soldiers were identified with mild TBI with LOC, and 260 soldiers were identified with mild TBI and altered mental status. This is the only study identified by the IOM that distinguished between how mild TBI was diagnosed, whether because of LOC or altered mental state. Limitations of this study include the fact that the researchers relied on information self-reported by study participants, and the study included only a small number of soldiers who were identified as having mild TBI.

In contrast, the greater preponderance of studies upon which the IOM based its findings showed that groups with TBI (mild, moderate, or severe) had higher rates of major depression 6 months or longer after TBI than did appropriate comparison and control groups. As noted by the commenter, these studies (as with Hoge and colleagues) also had limitations. The limitations identified in these studies include a lack of differentiation in severity of TBI in one study, and another study being conducted on the general population rather than solely veterans. However, the results of these research studies viewed as a whole support the IOM's conclusion that led to the conclusion that there is sufficient evidence of an association between TBI and depression. VA has reviewed the supporting research, as well as the IOM's analysis, and accepts the committee's conclusion. VA has determined that the proper course of action is to include all levels of severity of TBI in the rulemaking regarding depression. While the research relied on by the commenter is intriguing and suggestive, given the limitations in the study and the absence of any follow up studies confirming the results, we do not believe the data at this time is strong enough to justify a decision to limit the scope of this rulemaking.

5. Diseases of Hormone Deficiency

The proposed rule suggested that VA establish procedures for establishing secondary service connection for ''Diseases of hormone deficiency that result from hypothalamo-pituitary changes if manifest within 12 months of moderate or severe TBI.'' VA received one comment asking us to clarify which hormone deficiencies or disorders will be presumed to be the proximate result of service-connected TBI in the absence of clear evidence to the contrary. The IOM noted at page 227 of its report that clinical data suggest that TBI can lead to acute and chronic hypopituitarism as a result of hypothalamo-pituitary changes. (Hypopituitarism is the decreased secretion of one or more of the eight hormones normally produced by the pituitary gland).

The IOM identified eight primary studies and four secondary studies that assessed the relationship between various endocrine disorders and TBI. The studies, viewed together, evaluate the possible relationship between TBI and deficiencies in hormones produced in both the anterior and posterior pituitary gland. Based on these studies, the IOM concluded that there is sufficient evidence of an association between moderate or severe TBI and endocrine dysfunction, particularly hypopituitarism. VA agrees with that conclusion. The scientific evidence supports a finding that moderate or severe TBI can produce changes in the pituitary gland and hypothalamus that can lead to pituitary hormone deficiencies, i.e., hypopituitarism. We believe it is unnecessary to list in the regulation the various diseases of hormone deficiency that result from hypothalamo-pituitary changes. There are various mechanisms by which a TBI may cause the hypothalamus and/or the pituitary gland to malfunction. Describing them individually would not add any clarity for the reader and would make the regulation more technical and difficult to read, understand, and apply. Further, although current research supports a finding that some diseases of hormone deficiency are associated with TBI, this does not preclude the possibility that future research could find an association between TBI and other diseases of hormone deficiency that result from hypothalamo-pituitary changes. Listing specific diseases here would limit VA's ability to make determinations based on the most current peer reviewed research, and would require VA to continually update this rule based on that research. We, therefore, decline to make any changes based on this comment.

Other Comments

Other commenters asked for VA to include additional focuses in this rulemaking, such as extending eligibility to veterans overexposed to radiation and suffering from Parkinson's disease, extending benefits to veterans with sealed service records, providing

name-brand prescription medication to veterans with Parkinson's disease, supporting funding for Parkinson's research, and improving rural veterans' access to hospitals. As previously stated, this rulemaking focuses on the secondary service-connected conditions that are a proximate result of TBI; therefore, these comments are outside the scope of this rulemaking.

Numerous comments requested additional research. VA agrees that further research on the health effects of TBI is warranted and we note that VA/DoD have recently invested $62.2 million to begin a research consortium ''Chronic Effects of Neurotrauma Consortium—CENC'' to study the chronic effects of TBI.

Paperwork Reduction Act

This final rule contains no provisions constituting a collection of information under the Paperwork Reduction Act (44 U.S.C. 3501–3521).

Regulatory Flexibility Act

The Secretary of Veterans Affairs hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601–612). This final rule will directly affect only individuals and will not affect any small entities. Only VA beneficiaries could be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Executive Orders 13563 and 12866

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, when regulatory action is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a ''significant regulatory action,'' requiring review by the Office of Management and Budget (OMB), unless OMB waives such review, as ''any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.''

The economic, interagency, budgetary, legal, and policy implications of this final rule have been examined, and it has been determined to be a significant regulatory action under the Executive Order 12866. VA's impact analysis can be found as a supporting document at *http://www.regulations.gov,* usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's Web site at *http://www1.va.gov/orpm/,* by following the link for ''VA Regulations Published.''

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any year. This final rule will have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance Numbers and Titles

The Catalog of Federal Domestic Assistance program numbers and titles for this final rule are 64.109, Veterans Compensation for Service-Connected Disability, and 64.110, Veterans Dependency and Indemnity Compensation for Service-Connected Death.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Jose D. Riojas, Chief of Staff, Department of Veterans Affairs, approved this document on August 23, 2013, for publication.

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Disability benefits, Health care, Veterans, Vietnam.

Dated: December 12, 2013.

William F. Russo,

Deputy Director, Regulation Policy and Management, Office of the General Counsel, Department of Veterans Affairs.

For the reasons set out in the preamble, VA amends 38 CFR part 3 as follows:

PART 3—ADJUDICATION

■ 1. The authority citation for part 3, subpart A continues to read as follows:

Authority: 38 U.S.C. 501(a), unless otherwise noted.

■ 2. Amend § 3.310 by adding paragraph (d), to read as follows:

§ 3.310 Disabilities that are proximately due to, or aggravated by, service-connected disease or injury.

* * * * *

(d) *Traumatic brain injury.* (1) In a veteran who has a service-connected traumatic brain injury, the following shall be held to be the proximate result of the service-connected traumatic brain injury (TBI), in the absence of clear evidence to the contrary:

(i) Parkinsonism, including Parkinson's disease, following moderate or severe TBI;

(ii) Unprovoked seizures following moderate or severe TBI;

(iii) Dementias of the following types: presenile dementia of the Alzheimer type, frontotemporal dementia, and dementia with Lewy bodies, if manifest within 15 years following moderate or severe TBI;

(iv) Depression if manifest within 3 years of moderate or severe TBI, or within 12 months of mild TBI; or

(v) Diseases of hormone deficiency that result from hypothalamo-pituitary changes if manifest within 12 months of moderate or severe TBI.

(2) Neither the severity levels nor the time limits in paragraph (d)(1) of this section preclude a finding of service connection for conditions shown by evidence to be proximately due to service-connected TBI. If a claim does not meet the requirements of paragraph (d)(1) with respect to the time of manifestation or the severity of the TBI, or both, VA will develop and decide the claim under generally applicable principles of service connection without regard to paragraph (d)(1).

(3)(i) For purposes of this section VA will use the following table for determining the severity of a TBI:

Mild	Moderate	Severe
Normal structural imaging LOC = 0–30 min	Normal or abnormal structural imaging LOC > 30 min and < 24 hours	Normal or abnormal structural imaging. LOC > 24 hrs.
AOC = a moment up to 24 hrs	AOC > 24 hours. Severity based on other criteria.	
PTA = 0–1 day GCS = 13–15	PTA > 1 and < 7 days GCS = 9–12	PTA > 7 days. GCS = 3–8.

Note: The factors considered are:

Structural imaging of the brain.

LOC—Loss of consciousness.

AOC—Alteration of consciousness/mental state.

PTA—Post-traumatic amnesia.

GCS—Glasgow Coma Scale. (For purposes of injury stratification, the Glasgow Coma Scale is measured at or after 24 hours.)

(ii) The determination of the severity level under this paragraph is based on the TBI symptoms at the time of injury or shortly thereafter, rather than the current level of functioning. VA will not require that the TBI meet all the criteria listed under a certain severity level in order to classify the TBI at that severity level. If a TBI meets the criteria in more than one category of severity, then VA will rank the TBI at the highest level in which a criterion is met, except where the qualifying criterion is the same at both levels.

(Authority: 38 U.S.C. 501, 1110 and 1131)

[FR Doc. 2013–29911 Filed 12–16–13; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2010–0141; FRL–9904–14–Region–3]

Approval and Promulgation of Air Quality Implementation Plans; Delaware; Attainment Plan for the Philadelphia-Wilmington, Pennsylvania-New Jersey-Delaware Nonattainment Area for the 1997 Annual Fine Particulate Matter Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving a State Implementation Plan (SIP) revision submitted by the State of Delaware. The SIP revision (also referred to herein as ''the attainment plan'') demonstrates Delaware's attainment of the 1997 annual fine particulate matter ($PM_{2.5}$) national ambient air quality standard (NAAQS) (the 1997 $PM_{2.5}$ NAAQS) for the Philadelphia-Wilmington, Pennsylvania-New Jersey-Delaware (PA-NJ-DE) nonattainment area (Philadelphia Area). The SIP revision includes Delaware's attainment demonstration for the Philadelphia Area and motor vehicle emission budgets (MVEBs) used for transportation conformity purposes for New Castle County, Delaware. The attainment plan also includes an analysis of reasonably available control measures (RACM) and reasonably available control technology (RACT), a base year emissions inventory, and contingency measures. This action is being taken in accordance with the Clean Air Act (CAA).

DATES: This final rule is effective on January 16, 2014.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2010–0141. All documents in the docket are listed in the *www.regulations.gov* Web site. Although listed in the electronic docket, some information is not publicly available, i.e., confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Delaware Department of Natural Resources and Environmental Control, 89 Kings Highway, P.O. Box 1401, Dover, Delaware 19903.

FOR FURTHER INFORMATION CONTACT: Rose Quinto, (215) 814–2182, or by email at *quinto.rose@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

By letter dated April 3, 2008, Delaware submitted the SIP revision at issue to EPA. By letter dated April 25, 2012, Delaware submitted revisions to the portion of the SIP revision relating to the MVEBs. The April 25, 2012 MVEBs revised submittal replaced the previously submitted 2009 MVEBs with a budget that is based on the Motor Vehicle Emissions Simulator (MOVES) model and included MVEBs for 2012. On November 19, 2012 (77 FR 69399), EPA published a notice of proposed rulemaking seeking comment on EPA's proposed approval of this SIP revision, including the portion relating to the 2009 and 2012 MVEBs for transportation conformity purposes for New Castle County, Delaware (hereinafter referred to as ''the NPR''). In response to the NPR, EPA received a single comment dated November 30, 2012. A summary of the November 30, 2012 comment and EPA's response is provided in Section III (Summary of Public Comment and EPA Response) of this final rulemaking action.

On March 4, 2013, EPA took final rulemaking action on the portion of the attainment plan relating to the base year emissions inventory. *See* 78 FR 10420. As a result of this March 2013 final rulemaking action, no further action needs to be taken on such portion of the April 3, 2008 SIP revision. Therefore, this final rulemaking action relates to the remaining portions of the attainment plan, including: (1) An attainment demonstration for the Delaware portion of the Philadelphia Area; (2) 2009 and 2012 MVEBs used for transportation conformity purposes for New Castle County, Delaware; (3) an analysis of RACM and RACT; and, (4) contingency measures.

On September 19, 2013 (78 FR 57473), EPA published a supplemental NPR that revised and expanded the basis for proposing approval of Delaware's attainment plan for the 1997 annual $PM_{2.5}$ NAAQS in light of the developments since EPA issued its initial proposal on November 19, 2012 (hereinafter referred to as ''the supplemental NPR''). Principally, the supplemental NPR addressed the potential effects of a January 4, 2013 decision of the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit Court) remanding to EPA two final rules implementing the 1997 $PM_{2.5}$ NAAQS. In the supplemental NPR, EPA also revised its proposed approval of Delaware's