

Absorbable Hemostatic Device”; the notice contains an analysis of the paperwork burden for the draft guidance.

#### XIV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### XV. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. General and Plastic Surgery Devices Panel, Transcript, pp. 80–177, July 8, 2002.

2. General and Plastic Surgery Devices Panel, Transcript, July 24, 2003.

#### List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 878 be amended as follows:

#### PART 878—GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for 21 CFR Part 878 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 878.4490 is revised to read as follows:

#### § 878.4490 Absorbable hemostatic device.

(a) *Identification.* An absorbable hemostatic device is an absorbable device that is placed in the body during surgery to produce hemostasis by accelerating the clotting process of blood.

(b) *Classification.* Class II (special controls). The special control for the device is FDA’s “Class II Special Controls Guidance Document: Absorbable Hemostatic Device.” See § 878.1(e) for the availability of this guidance document.

Dated: October 19, 2006.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. E6–18324 Filed 10–30–06; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 1

[REG–124152–06]

RIN 1545–BF73

#### Definition of Taxpayer for Purposes of Section 901 and Related Matters; Correction

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of proposed rulemaking and notice of public hearing; Correction.

**SUMMARY:** This document contains corrections to notice of proposed rulemaking and notice of public hearing that was published in the **Federal Register** on Friday, August 4, 2006 (71 FR 44240) relating to the determination of who is considered to pay a foreign tax for purposes of sections 901 and 903.

#### FOR FURTHER INFORMATION CONTACT:

Bethany A. Ingwalson, (202) 622–3850 (not a toll-free number).

#### SUPPLEMENTARY INFORMATION:

##### Background

The notice of proposed rulemaking and notice of public hearing (REG–124152–06) that is the subject of these corrections are under sections 901 and 903 of the Internal Revenue Code.

##### Need for Correction

As published, the notice of proposed rulemaking and notice of public hearing (REG–124152–06) contains errors that may prove to be misleading and are in need of clarification.

##### Correction of Publication

Accordingly, the notice of proposed rulemaking and notice of public hearing (REG–124152–06) that was the subject of FR Doc. E6–12358 is corrected as follows:

##### § 1.901–2 [Corrected]

1. On page 44246, column 1, § 1.901–2(f)(6), paragraph (i) of *Example 4.*, line 4, the language “county Y. A accrues interest income on the” is corrected to read “country Y. A accrues interest income on the”.

2. On page 44246, column 2, § 1.901–2(f)(6), paragraph (i) of *Example 4.*, first

paragraph of the column, line 1, the language “pay over to country X 10 percent of the” is corrected to read “pay over to country Y 10 percent of the”.

3. On page 44247, column 1, § 1.901–2(f)(6), paragraph (i) of *Example 8.*, the language “tax purposes. New D also has a short U.S.” is corrected to read “tax purposes. “New” D also has a short U.S.”.

4. On page 44247, column 1, § 1.901–2(f)(6), paragraph (ii) of *Example 8.*, line 11, the language “years of terminating D and new D. See” is corrected to read “years of old D and new D. See”.

5. On page 44247, column 1, § 1.901–2(f)(6), paragraph (ii) of *Example 8.*, line 13, the language “allocation of terminating D’s country M taxes” is corrected to read “allocation of old D’s country M taxes”.

6. On page 44247, column 1, § 1.901–2(h), the language “(h) *Effective Date.* Paragraphs (a)” is corrected to read “(h) *Effective date.* Paragraphs (a)”.

**LaNita Van Dyke,**

*Federal Register Liaison, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).*

[FR Doc. E6–18205 Filed 10–30–06; 8:45 am]

**BILLING CODE 4830–01–P**

## DEPARTMENT OF VETERANS AFFAIRS

### 38 CFR Part 3

RIN 2900–AM17

#### Notice and Assistance Requirements

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Proposed rule.

**SUMMARY:** The Department of Veterans Affairs (VA) proposes to amend its regulation governing VA’s duty to provide a claimant with notice of the information and evidence necessary to substantiate a claim and VA’s duty to assist a claimant in obtaining the evidence necessary to substantiate the claim. The purpose of these proposed changes is to clarify when VA has no duty to notify a claimant of how to substantiate a claim for benefits, to make the regulation comply with statutory changes, and to streamline the development of claims.

**DATES:** Comments must be received by VA on or before January 2, 2007.

**ADDRESSES:** Written comments may be submitted through <http://www.Regulations.gov>; by mail or hand-delivery to the Director, Regulations Management (00REG), Department of Veterans Affairs, 810 Vermont Ave.,

NW., Room 1068, Washington, DC 20420; or by fax to (202) 273-9026. Comments should indicate that they are submitted in response to "RIN 2900-AM17—Notice and Assistance Requirements." Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 273-9515 for an appointment. In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at <http://www.Regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:**

Maya Ferrandino, Consultant, Compensation and Pension Service, Policy and Regulations Staff, Veterans Benefits Administration, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 273-7211.

**SUPPLEMENTARY INFORMATION:** Section 3(a) of the Veterans Claims Assistance Act of 2000 (VCAA), Public Law 106-475, 114 Stat. 2096, amended 38 U.S.C. 5103 to impose on VA a duty to provide certain notice to certain claimants applying for veterans' benefits. See 38 U.S.C. 5103(a). Under section 5103(a), upon receipt of a substantially complete application for benefits, VA must "notify the claimant and the claimant's representative, if any, of any information, and any medical or lay evidence, not previously provided to the Secretary that is necessary to substantiate the claim" (section 5103(a) notice). 38 U.S.C. 5103(a). VA implemented section 5103(a) in 38 CFR 3.159, which reflects section 5103(a)'s requirement that VA give the notice upon receipt of a substantially complete application. See 38 CFR 3.159(b)(1). In addition, VA defined "substantially complete application" for purposes of section 5103(a) notice. See 38 CFR 3.159(a)(3). The purpose of this rulemaking is, in part, to clarify when VA has no duty to give section 5103(a) notice.

Long before enactment of the VCAA, VA had defined "application" in 38 CFR 3.1(p). An "application" is "a formal or informal communication in writing requesting a determination of entitlement or evidencing a belief in entitlement, to a benefit." 38 CFR 3.1(p). Because that definition pre-dated the VCAA, it is apparent that it was not issued in implementation of the VCAA. However, experience implementing section 5103(a) has disclosed a potential ambiguity in the regulations, which this rulemaking will clarify. That ambiguity is whether VA's receipt of a notice of

disagreement (NOD) also triggers VA's duty to give section 5103(a) notice because the NOD can be viewed as satisfying the § 3.1(p) definition of "application." We propose to clarify that it does not.

An NOD is the means by which a claimant initiates an appeal of a decision on a claim to the Board of Veterans' Appeals (Board). 38 U.S.C. 7105(a); 38 CFR 20.200. "A written communication from a claimant or his or her representative expressing dissatisfaction or disagreement with an adjudicative determination by the agency of original jurisdiction and a desire to contest the result will constitute [an NOD]." 38 CFR 20.201.

The ambiguity we propose to clarify is whether VA's receipt of an NOD triggers VA's duty to issue section 5103(a) notice. It appears from these regulatory definitions that a single written communication expressing disagreement with a decision of the agency of original jurisdiction could be viewed as constituting both an NOD under § 20.201 and an application under § 3.1(p). (If a single written communication contains language expressing disagreement with a decision of the agency of original jurisdiction as well as language raising a new claim for benefits, section 5103(a) notice would be required in response to the new claim for benefits.) Because the definition in § 3.1(p) is a holdover from before the VCAA and was not intended to govern when VA must give section 5103(a) notice, VA does not view it as dispositive of the question. Furthermore, section 5103(a) does not specify whether VA must issue section 5103(a) notice upon receipt of an NOD. For the reasons we explain below, VA believes that Congress did not intend to require section 5103(a) notice upon VA's receipt of an NOD.

1. Congress intended VA to give section 5103(a) notice at the beginning of the claim process, but an NOD is filed after VA has decided a claim.

VA's claim process begins with the filing of an application. 38 U.S.C. 5101(a); 38 CFR 3.151(a), 3.152(a); *Hensley v. West*, 212 F.3d 1255, 1259 (Fed. Cir. 2000) (discussing claims process before VCAA's enactment). As stated, upon VA's receipt of a complete or substantially complete application, VA provides section 5103(a) notice. The claimant has a year from the date the notice is sent to respond. 38 U.S.C. 5103(b)(1). As we will further discuss, VA may decide the claim within that one-year period, but if the claimant subsequently submits relevant evidence within that one-year period, VA must readjudicate the claim. 38 CFR

3.159(b)(1). After notice of a decision on a claim is sent to the claimant, the claimant has up to one year to file an NOD with that decision. 38 U.S.C. 7105(b)(1); 38 CFR 20.302. Following receipt of an NOD, unless VA can resolve the disagreement through development or review action, VA will issue a statement of the case. 38 U.S.C. 7105(d)(1); 38 CFR 19.26. To perfect the appeal, the appellant has to file a substantive appeal in response to the statement of the case. 38 U.S.C. 7105(a), (d)(3); 38 CFR 20.200, 20.302(b)(1). Following VA's receipt of a substantive appeal, the appeal is certified to the Board.

From the above description of the claim process, it is apparent that, typically, an application starts the claim process and an NOD starts the appeal process after VA has decided a claim. However, the legislative history of the VCAA indicates that Congress intended VA to issue section 5103(a) notice early in the claim process. See S. Rep. No. 106-397, at 22 (2000) ("The Committee bill, in summary, modifies the pertinent statutes to reinstate VA's traditional practice of assisting veterans at the beginning of the claims process."). The VCAA's legislative history indicates that Congress intended the new law to improve the efficiency of the adjudication process and the process by which subsequent claims for rating increases or service connection for additional conditions are handled, by ensuring proper development of the record when the claimant first submits an application for benefits. 146 Cong. Rec. S9211, S9212 (daily ed. Sept. 25, 2000) (statement of Sen. Rockefeller). The drafters wanted claimants to know early in the claim process what was necessary to substantiate their claims. Therefore, the VCAA was drafted to impose on VA the duty to issue section 5103(a) notice early in the claim process.

However, an NOD, which, as stated, is received in response to a decision on a claim and begins the appeal process for a decision on a claim, may fall within the § 3.1(p) definition of claim/application. We find nothing in section 5103(a)'s language or in the legislative history indicating Congressional intent to require VA to give another section 5103(a) notice upon receipt of an NOD.

2. Congress requires VA to issue a statement of the case in response to an NOD, so additional section 5103(a) notice would be redundant.

Upon receipt of an NOD, applicable law requires VA to review and, if necessary, further develop the evidence on the claim for which an NOD was filed. If such development or review

does not resolve the disagreement, VA is required to prepare a statement of the case. The statement of the case in effect provides the claimant and any representative with notice similar to the notice required by section 5103(a). A statement of the case must include a summary of the evidence in the case pertinent to the issue or issues with which disagreement has been expressed and a citation of pertinent laws and regulations that controlled the decision. It also must include a discussion of how these laws and regulations affected the decision on the claim and a summary of the reasons for the decision made on each claim. 38 U.S.C. 7105(d)(1); 38 CFR 19.29. A statement of the case notifies a claimant of the evidence that VA received from the claimant and from other sources, and explains why that evidence dictated the result on that claim. A statement of the case therefore informs a claimant of the evidence needed to substantiate a claim for benefits addressed in the NOD. The requirement to issue a statement of the case could be viewed as being largely superfluous if section 5103(a) were interpreted to require VA to also provide notice under this section upon receipt of an NOD.

3. Giving section 5103(a) notice at the appeal stage of the claim process results in logical inconsistencies in the claim process.

Furthermore, interpreting section 5103(a) to require notice upon receipt of an NOD could result in the VA claim decision becoming final while the claimant still has time to submit the information and evidence necessary to substantiate a claim for benefits addressed in the NOD. Section 5103(b) of title 38, United States Code, provides a claimant one year to submit information or evidence requested in VA's section 5103(a) notice; however, an appellant has sixty days from the date VA mails a statement of the case, or the remainder of the one-year period beginning on the date notification of the determination being appealed is mailed, whichever period ends later, to file a formal or substantive appeal. 38 U.S.C. 7105(d)(3); 38 CFR 20.302(b). Thus, if the claimant does not complete the appeal initiated by the NOD or the Board decides the appeal before one year has elapsed from the date VA gave notice, VA's claim decision could become final while there is still time remaining to submit information and evidence necessary to substantiate a claim for benefits addressed in the NOD. Congress could not have intended such a result in this circumstance.

4. Not requiring section 5103(a) notice upon VA's receipt of an NOD would be

consistent with case law governing such notice.

Besides the reasons given above regarding the intent of Congress, developing case law also supports not requiring section 5103(a) notice upon VA's receipt of an NOD. In *Pelegri v. Principi*, 18 Vet. App. 112, 120 (2004), the United States Court of Appeals for Veterans Claims (CAVC) concluded that VA must provide section 5103(a) notice to a claimant seeking service connection before an initial unfavorable RO decision is made on the claim. The Court of Appeals for the Federal Circuit has agreed. *Mayfield v. Nicholson*, 444 F.3d 1328, 1334 (Fed. Cir. 2006). In *Dingess v. Nicholson*, 19 Vet. App. 473, 489 (2006), the CAVC added that VA must provide section 5103(a) notice to a claimant on the initial-disability rating and effective-date elements of a claim before the initial adjudication on them. Requiring section 5103(a) notice upon VA's receipt of an NOD would not satisfy these requirements because notice given following receipt of an NOD necessarily implies notice given after VA had already decided the claim. Furthermore, because the law requires that VA address the initial disability-rating and effective-date elements of a claim in the notice it gives upon receipt of an application, requiring notice on such elements upon VA's receipt of an NOD would be redundant.

Therefore, for the reasons stated above, we propose to state in a new paragraph, § 3.159(b)(3), that VA does not have a duty to provide the section 5103(a) notice upon receipt of an NOD.

Additionally, we propose to state that the section 5103(a) notice duty does not arise when the claimant is not eligible for the claimed benefit as a matter of law. In such circumstances, for example, in a claim for nonservice-connected disability pension when the claimant has no wartime service, there is no additional information or evidence the claimant could provide or VA could obtain that could substantiate the claim. This regulation would be consistent with the intent of Congress expressed in 38 U.S.C. 5103A(a)(2), which provides that "[t]he Secretary is not required to provide assistance to a claimant under this section if no reasonable possibility exists that such assistance would aid in substantiating the claim."

The legislative history of sections 5103(a) and 5103A(a) supports a conclusion that VA action under section 5103(a) is not required if there is no relevant information or evidence to obtain because the claim is barred as a matter of law. The House Committee on Veterans' Affairs' report on legislation that became the VCAA stated with

regard to the provision that became 38 U.S.C. 5103A(a):

This language \* \* \* recognizes that certain claims, including those that their face seek benefits for ineligible claimants (such as a veteran who seeks pension benefits but lacks wartime service), or claims which have been previously decided on the same evidence can be decided without providing any assistance or obtaining any additional evidence, and authorizes the Secretary to decide those claims without providing any assistance under this subsection.

H.R. Rep. No. 106-781, at 10 (2000), reprinted in 2000 U.S.C.C.A.N. 2006, 2012-13. Accordingly, Congress clearly contemplated that evidentiary development should not be required for claims that are barred as a matter of law.

Our analysis is also supported by the case law of the CAVC. In *Mason v. Principi*, 16 Vet. App. 129, 132 (2002), the CAVC rejected the claimant's contention that service during the 1980 Iran hostage situation constitutes wartime service for purposes of nonservice-connected disability pension pursuant to 38 U.S.C. 1521. The CAVC noted that there was no dispute as to the facts concerning the claimant's service and held that the claimant did not serve on active duty during a "period of war" as defined by 38 U.S.C. 101(11). *Id.* The CAVC further held that the VCAA was not applicable to the claim because the statute, and not the evidence, was dispositive of the claim. *Id.*; see also *Smith v. Gober*, 14 Vet. App. 227, 231-32 (2000) (VCAA does not affect issue of whether pursuit on past due benefits is payable pursuant to Federal statutes), *aff'd*, 281 F.3d 1384 (Fed. Cir. 2002); *Valiao v. Principi*, 17 Vet. App. 229, 232 (2003) ("[w]here the facts averred by a claimant cannot conceivably result in any disposition of the appeal other than affirmance of the Board decision, the case should not be remanded for development [under the VCAA] that could not possibly change the outcome of the decision"). Thus, if a claim cannot be granted because, under undisputed facts, the claimant as a matter of law is not entitled to the benefit sought, it is reasonable to conclude that no section 5103(a) notice to the claimant is required.

Therefore, VA proposes to state in § 3.159(b)(3) that no section 5103(a) notice duty arises "[w]hen, as a matter of law, entitlement to the benefit claimed cannot be established, including, but not limited to, when the claimant is ineligible for the benefit sought due to lack of qualifying service, lack of veteran status, or other lack of legal eligibility."

In addition to revising § 3.159 to ensure that the regulation is clear for

users and consistent with statutory requirements, we propose to amend 38 CFR 3.159(b)(1). First, we propose to remove the third sentence of current § 3.159(b)(1), which states that VA will request the claimant to provide any evidence in the claimant's possession that pertains to the claim. Section 3.159 generally implements the notice and development requirements of sections 5103(a) and 5103A. The three notice requirements in section 5103(a) are currently prescribed in § 3.159(b)(1) as follows: VA will notify the claimant (1) of the information and medical or lay evidence required to substantiate the claim, (2) of which information and evidence, if any, that the claimant is to provide to VA, and (3) of which information and evidence, if any, VA will attempt to obtain on behalf of the claimant. However, the third sentence of current § 3.159(b)(1) is not required by statute and is redundant of the three statutory requirements from the perspective of what the claimant needs to submit to support the claim. As such, it is unnecessary as part of the regulation.

In *Paralyzed Veterans of America v. Secretary of Veterans Affairs*, 345 F.3d 1334 (Fed. Cir. 2003), the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) addressed a specific challenge to the additional regulatory provision in § 3.159 that states that VA will request that the claimant provide any evidence in the claimant's possession that pertains to the claim. The Federal Circuit expressly agreed with VA's rationale that the additional provision merely assists "the claimant by inviting any additional evidence that might help substantiate the claim." *Id.* at 1347. The Federal Circuit found that the additional provision was reasonable and "effectively aimed at ensuring that the claimant makes the best showing possible to support his or her claim." *Id.* at 1348. However, the Federal Circuit stopped short of finding this "additional regulatory provision" to be necessary, especially in light of the other three requirements.

In *Pelegri v. Principi*, 18 Vet. App. 112 (2004), although the content of the section 5103(a) notice was not expressly at issue, the CAVC commented that the regulatory provision stating that VA will request that the claimant provide any evidence in the claimant's possession that pertains to the claim "can be considered a fourth element of the requisite notice" under section 5103(a). *Id.* at 121. However, because a request that the claimant provide any evidence that pertains to the claim is redundant of the notice required by statute from the perspective of what the claimant

needs to submit to support the claim, a claimant will not be prejudiced by deleting this regulatory provision. A claimant who receives a section 5103(a) notice containing the three statutory elements will have received the same information regarding what the claimant needs to submit to support the claim as the claimant would have received had the claimant received a letter containing the three statutory elements and an additional request that the claimant provide any evidence in the claimant's possession that pertains to the claim.

We wish to avoid the possibility that this regulatory provision, intended only to perpetuate VA's long-standing practice to invite a claimant to submit any evidence he or she wants VA to consider, may be misconstrued as a statutory requirement to include specific language in the notices parroting the sentence in the regulation. Therefore, we propose to delete the statement in current § 3.159(b)(1) that VA will also request that the claimant provide any evidence in the claimant's possession that pertains to the claim. To avoid the possibility of similar misunderstandings regarding the nature of this provision and to ensure consistency between the manual and regulatory provisions, we further propose to rescind the provision of paragraph I.1.B.3.b of the Veterans Benefits Administration Adjudication Procedures Manual M21-1MR (VBA Manual M21-1MR), which currently requires ROs to send a letter to the claimant in response to a substantially complete application that "asks the claimant to submit any evidence in his/her possession that pertains to the claim."

Second, for ease of use, we propose to add at the end of the second sentence of current § 3.159(b)(1) the term "notice" in parentheses, to use as a term of art within § 3.159(b)(1). The first two sentences of § 3.159(b)(1) describe the content of the section 5103(a) notice, and rather than repeating the language describing the content of the notice in the rest of § 3.159(b)(1), we propose to use the term "notice" to refer to the notice described in the first two sentences of § 3.159(b)(1).

Third, we propose to remove the fourth sentence of current § 3.159(b)(1). This sentence states: "If VA does not receive the necessary information and evidence requested from the claimant within one year of the date of the notice, VA cannot pay or provide any benefits based on that application." This provision implemented language from section 5103 that was repealed by the Veterans Benefits Act of 2003, Public Law 108-183, section 701(b), 117 Stat.

2670. To ensure consistency with current law and the intent of Congress, we propose to replace this sentence with the following: "The information and evidence that the claimant is informed that the claimant is to provide must be provided within one year of the date of the notice."

Fourth, we propose to amend the fifth sentence of current § 3.159(b)(1), which states that VA may decide the claim if the claimant has not responded to the section 5103(a) notice within 30 days. We propose to provide 45 days as a reasonable period after which VA may decide a claim if no response to the section 5103(a) notice has been received. Therefore, we propose to change the 30-day period in § 3.159(b)(1) to a 45-day period. To ensure consistency between the manual and regulatory provisions, we further propose to rescind the provision of paragraph I.1.B.3.c of the VBA Manual M21-1MR, which currently advises ROs to "inform the claimant that if he/she does not respond to the request for information within 60 days, VA may decide the claim based on all the information and evidence in the file." The 45-day period will provide a claimant with more time to respond to the section 5103(a) notice compared to the 30-day period in § 3.159(b)(1) and, at the same time, will allow VA to adjudicate the claim more expeditiously compared to the 60-day period in the manual provision. It is important to note that, regardless of whether VA decides a claim after the 45-day period, the claimant still has one year from the date of the section 5103(a) notice to submit the requested information and evidence.

Additionally, 38 U.S.C. 5103A(g), "Other assistance not precluded," states, "Nothing in this section shall be construed as precluding the Secretary from providing such other assistance under subsection (a) to a claimant in substantiating a claim as the Secretary considers appropriate." In accordance with section 5103A(g), VA promulgated § 3.159(c), obligating itself to give the assistance described in paragraphs (c)(1), (c)(2), and (c)(3) of § 3.159, relating to assistance with obtaining records, to an individual attempting to reopen a finally decided claim. *See* Duty to Assist, 66 FR 45,620, 45,628 (Aug. 29, 2001). In accordance with VA's intention to issue regulations when the Secretary deems it appropriate to provide the additional assistance in substantiating a claim contemplated in section 5103A(g), *see id.* at 45,629, we propose to add to § 3.159 a new paragraph (g), which states that the authority recognized in subsection (g) of 38 U.S.C. 5103A is reserved to the sole

discretion of the Secretary and will be implemented, when deemed appropriate by the Secretary, through the promulgation of regulations. The main purpose of this provision is to avoid the potential disparate treatment of similarly situated claimants that could arise from inconsistent use in various parts of the agency of open-ended authority to provide "extra" development assistance. Also, this provision is consistent with the Secretary's determination, in the prior rulemaking for § 3.159, of the appropriate level of assistance to be provided individuals based on VA's finite resources and the need to process claims in an efficient manner for the benefit of all veterans.

Last, we propose to clarify another aspect of § 3.159 to state that a medical examination or medical opinion is not necessary to establish a nexus between a current disability and service when a claimant satisfies the chronicity or continuity requirements in 38 CFR 3.303(b). Section 3.303(b) states, in pertinent part, as follows: "With chronic disease shown as such in service (or within the presumptive period under § 3.307) so as to permit a finding of service connection, subsequent manifestations of the same chronic disease at any later date, however remote, are service connected, unless clearly attributable to intercurrent causes \* \* \*. For the showing of chronic disease in service there is required a combination of manifestations sufficient to identify the disease entity, and sufficient observation to establish chronicity at the time, as distinguished from merely isolated findings or a diagnosis including the word 'Chronic.' When the disease identity is established \* \* \*, there is no requirement of evidentiary showing of continuity. Continuity of symptomatology is required only where the condition noted during service (or in the presumptive period) is not, in fact, shown to be chronic or where the diagnosis of chronicity may be legitimately questioned. When the fact of chronicity in service is not adequately supported, then a showing of continuity after discharge is required to support the claim." If the chronicity or continuity requirements are met, there is no need for VA to provide a medical examination or medical opinion to determine whether there is a nexus between a veteran's current disability or death and some disease or symptoms during service. (Of course, a medical examination might be needed for some other reason, such as to determine the current level of disability in a claim for

service connection.) We believe that it would be helpful to claimants, their representatives, and VA staff to explicitly state this within § 3.159(c)(4)(i), which covers medical examinations and medical opinions. We therefore propose to add the following sentence after the first sentence in § 3.159(c)(4)(i): "A medical examination or medical opinion is not necessary to show a link between a veteran's current disability or death and some disease or symptoms during service when the evidence of record already satisfies the chronicity or continuity requirements in § 3.303(b)."

#### **Paperwork Reduction Act**

This document contains no provisions constituting a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

#### **Regulatory Flexibility Act**

The Secretary hereby certifies that this regulatory amendment 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. Only VA beneficiaries could be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), this amendment is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

#### **Executive Order 12866**

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation 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). The Order classifies a rule as a significant regulatory action requiring review by the Office of Management and Budget if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of \$100 million or more; creating a serious inconsistency or interfering with an action of another agency; materially altering the budgetary impact of entitlements or the rights of entitlement recipients; or raising novel legal or policy issues. VA has examined the economic, legal, and policy implications of this proposed rule and has concluded that it is a significant regulatory action because it raises novel legal or policy issues.

#### **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 proposed rule would have no such effect on State, local, and tribal governments, or on the private sector.

#### **Catalog of Federal Domestic Assistance Numbers**

The Catalog of Federal Domestic Assistance program numbers and titles for this proposal are 64.100, Automobiles and Adaptive Equipment for Certain Disabled Veterans and Members of the Armed Forces; 64.101, Burial Expenses Allowance for Veterans; 64.102, Compensation for Service-Connected Deaths for Veterans' Dependents; 64.103, Life Insurance for Veterans; 64.104, Pension for Non-Service-Connected Disability for Veterans; 64.105, Pension to Veterans Surviving Spouses, and Children; 64.106, Specially Adapted Housing for Disabled Veterans; 64.109, Veterans Compensation for Service-Connected Disability; 64.110, Veterans Dependency and Indemnity Compensation for Service-Connected Death; 64.114, Veterans Housing—Guaranteed and Insured Loans; 64.115, Veterans Information and Assistance; 64.116, Vocational Rehabilitation for Disabled Veterans; 64.117, Survivors and Dependents Educational Assistance; 64.118, Veterans Housing—Direct Loans for Certain Disabled Veterans; 64.119, Veterans Housing—Manufactured Home Loans; 64.120, Post-Vietnam Era Veterans' Educational Assistance; 64.124, All-Volunteer Force Educational Assistance; 64.125, Vocational and Educational Counseling for Servicemembers and Veterans; 64.126, Native American Veteran Direct Loan Program; 64.127, Monthly Allowance for Children of Vietnam Veterans Born with Spina Bifida; and 64.128, Vocational Training and Rehabilitation for Vietnam Veterans' Children with Spina Bifida or Other Covered Birth Defects.

#### **List of Subjects in 38 CFR Part 3**

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

Approved: July 25, 2006.

**Gordon H. Mansfield,**

*Deputy Secretary of Veterans Affairs.*

For the reasons set out in the preamble, VA proposes to amend 38 CFR part 3 (subpart A) as follows:

### PART 3—ADJUDICATION

#### Subpart A—Pension, Compensation, and Dependency and Indemnity Compensation

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 § 3.159 as follows:

a. In paragraph (b)(1), at the end of the first sentence after the word “claim”, add the following parenthetical “(hereafter in this paragraph referred to as the “notice”)”.

b. In paragraph (b)(1), at the beginning of the second sentence, add “In the notice,”.

c. In paragraph (b)(1), remove the third sentence.

d. In paragraph (b)(1), remove the fourth sentence and add a new sentence in its place as set forth below.

e. In paragraph (b)(1), remove “request” each place it appears and add, in its place, “notice”.

f. In paragraph (b)(1), remove “30 days” and add, in its place, “45 days”.

g. Add paragraphs (b)(3), and (g).

h. In paragraph (c)(4)(i), at the end of the first sentence, a new sentence is added.

The revisions read as follows:

#### § 3.159 Department of Veterans Affairs assistance in developing claims.

\* \* \* \* \*

(b) \* \* \*

(1) \* \* \* The information and evidence that the claimant is informed that the claimant is to provide must be provided within one year of the date of the notice. \* \* \*

\* \* \* \* \*

(3) VA has no duty to provide the notice described in paragraph (b)(1) of this section at times other than upon its receipt of a complete or substantially complete application. No such duty arises:

(i) Upon receipt of a Notice of Disagreement.

(ii) When, as a matter of law, entitlement to the benefit claimed cannot be established, including, but not limited to, when the claimant is ineligible for the benefit sought due to lack of qualifying service, lack of veteran status, or other lack of legal eligibility.

(Authority: 38 U.S.C. 5103(a), 5103A(a)(2))

(c) \* \* \*

(4) \* \* \*

(i) \* \* \* A medical examination or medical opinion is not necessary to show a link between a veteran’s current disability or death and some disease or symptoms during service when the evidence of record already satisfies the chronicity or continuity requirements in § 3.303(b). \* \* \*

\* \* \* \* \*

(g) The authority recognized in subsection (g) of 38 U.S.C. 5103A is reserved to the sole discretion of the Secretary and will be implemented, when deemed appropriate by the Secretary, through the promulgation of regulations.

(Authority: 38 U.S.C. 5103A(g))

[FR Doc. E6–18180 Filed 10–30–06; 8:45 am]

**BILLING CODE 8320–01–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA–R05–OAR–2006–0539, EPA–R05–OAR–2006–0610; FRL–8224–4]

#### Approval and Promulgation of Air Quality Implementation Plans; Indiana

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to approve requests submitted by the Indiana Department of Environmental Management on December 21, 2005 and June 27, 2006 to revise the Indiana State Implementation Plan (SIP) in two areas: (1) To amend 326 IAC 1–3–4, ambient air quality standards, to provide consistency between state and federal reference conditions for measurements of particulate matter air quality; and (2) to update the references to the Code of Federal Regulations (CFR) from the 2002 edition to the 2004 edition.

In the final rules section of this **Federal Register**, EPA is approving the SIP revision as a direct final rule without prior proposal, because EPA views this as a noncontroversial revision and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If we do not receive any adverse comments in response to these direct final and proposed rules, we do not contemplate taking any further action in relation to this proposed rule. If EPA receives adverse comments, we will withdraw the direct final rule and will respond to all public comments in a subsequent final rule based on this

proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time.

**DATES:** Comments must be received on or before November 30, 2006.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA–R05–OAR–2006–0539, EPA–R05–OAR–2006–0610 by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.

- *E-mail:* [mooney.john@epa.gov](mailto:mooney.john@epa.gov).

- *Fax:* (312)886–5824.

- *Mail:* John M. Mooney, Chief, Criteria Pollutant Section, Air Programs Branch(AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

- *Hand Delivery:* John M. Mooney, Chief, Criteria Pollutant Section, Air Programs Branch(AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m. excluding Federal holidays.

Please see the direct final rule which is located in the Rules section of this **Federal Register** for detailed instructions on how to submit comments.

**FOR FURTHER INFORMATION CONTACT:** Jonathan Nichols, Life Scientist, Criteria Pollutant Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–7942, [nichols.jonathan@epa.gov](mailto:nichols.jonathan@epa.gov).

**SUPPLEMENTARY INFORMATION:** In the Final Rules section of this **Federal Register**, EPA is approving the State’s SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting