

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 4**

[Docket No. FDA-2008-N-0424]

RIN 0910-AF82

**Postmarketing Safety Reporting for Combination Products; Extension of Comment Period**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is extending to January 29, 2009, the comment period for the proposed rule that appeared in the *Federal Register* of October 1, 2009. In the proposed rule, FDA requested comments on postmarketing safety reporting requirements for combination products. The agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

**DATES:** The comment period for the proposed rule published October 1, 2009 (74 FR 50744), is extended. Submit written or electronic comments by January 29, 2010.

**ADDRESSES:** You may submit comments, identified by Docket No. FDA-2008-N-0424 and/or RIN number 0910-AF82, by any of the following methods:

*Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

*Written Submissions*

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

*Instructions:* All submissions received must include the agency name and docket number and Regulatory Information Number (RIN) for this

rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** John Barlow Weiner, Office of Combination Products (HFG-3), Food and Drug Administration, 15800 Crabbs Branch Way, suite 200, Rockville, MD 20855, 301-427-1934.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the *Federal Register* of October 1, 2009 (74 FR 50744), FDA published a proposed rule with a 90-day comment period to request comments on postmarketing safety reporting requirements for combination products. Comments on the proposed rule will inform FDA's rulemaking to establish regulations for postmarketing safety reporting for combination products.

The agency has received requests for a 30-day extension of the comment period for the proposed rule. Each request conveyed concern that the current 90-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule.

FDA has considered the requests and is extending the comment period for the proposed rule for 30 days, until January 29, 2010. The agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

**II. Request for Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on 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.

Dated: December 7, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

[FR Doc. E9-29493 Filed 12-10-09; 8:45 am]

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**DEPARTMENT OF VETERANS AFFAIRS**

**38 CFR Part 3**

RIN 2900-AN46

**Notice of Information and Evidence Necessary To Substantiate Claim**

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Proposed rule.

**SUMMARY:** The Department of Veterans Affairs (VA) proposes to amend its regulations regarding VA's duty to notify a claimant of the information and evidence necessary to substantiate a claim. The purpose of this amendment is to implement the Veterans' Benefits Improvement Act of 2008, which requires the Secretary of Veterans Affairs to prescribe in regulations requirements relating to the content of notice to be provided to claimants for veterans benefits, including different content for notice based on the type of claim filed, the type of benefits or services sought under the claim, and the general information and evidence required to substantiate the basic elements of each type of claim.

**DATES:** Comments must be received by VA on or before February 9, 2010.

**ADDRESSES:** Written comments may be submitted through

[www.Regulations.gov](http://www.Regulations.gov); by mail or hand-delivery to Director, Regulations Management (02REG), Department of Veterans Affairs, 810 Vermont Ave., NW., Room 1068, Washington, DC 20420; or by fax to (202) 273-9026.

(This is not a toll free number). Comments should indicate that they are submitted in response to "RIN 2900-AN46—Notice of Information and Evidence to Substantiate Claim." 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) 461-4902 for an appointment. (This is not a toll free number). 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:** Thomas J. Kniffen, Chief, Regulations

Staff (211D), Compensation and Pension Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461-9725. (This is not a toll-free number.)

**SUPPLEMENTARY INFORMATION:** This proposed rule is necessary to implement the Veterans' Benefits Improvement Act of 2008, Public Law 110-389, 122 Stat. 4145, 4147. Section 101(a)(1) of the Act redesignated former 38 U.S.C. 5103(a) as 38 U.S.C. 5103(a)(1) but made no change to its language. 122 Stat. 4147. Section 5103(a)(1) continues to require VA to notify a claimant for veterans benefits of the information and evidence not previously provided to the Department that is necessary to substantiate a claim and of the respective responsibilities of VA and the claimant in obtaining various portions of the evidence. The United States Court of Appeals for the Federal Circuit (Federal Circuit) has held that section 5103(a)(1) "on its face does not address the level of required detail" in the notice provided and "must be interpreted as requiring only generic notice at the outset." *Wilson v. Mansfield*, 506 F.3d 1055, 1059-60 (Fed. Cir. 2007). The Federal Circuit explained that "generic notice", refers to notice that "identifies" the information and evidence necessary to substantiate the particular type of claim being asserted" by a claimant. *Id.* In *Angel Vazquez-Flores v. Eric K. Shinseki, Secretary of Veterans Affairs*, and *Michael R. Schultz v. Eric K. Shinseki, Secretary of Veterans Affairs*, Nos. 2008-7150 & 2008-7115, 2009 WL 2835434, \*6 (Fed. Cir. Sept. 4, 2009), the Federal Circuit stated that the term "particular type of claim" refers to the type of claim filed, e.g., claim for service connection or an increased rating. See also *Wilson*, 506 F.3d at 1059-60; *Paralyzed Veterans of Am. v. Secretary of Veterans Affairs*, 345 F.3d 1334, 1347 (Fed. Cir. 2003).

Section 101(a)(2) of Public Law 110-389 amends 38 U.S.C. 5103(a) by adding subsection (a)(2), requiring the Secretary of Veterans Affairs to prescribe in regulations requirements relating to the content of notice to be provided under section 5103(a). VA's regulations must specify "different contents" for notice based on the type of claim filed (e.g., original claims, reopened claims, claims for increase), must provide that the contents of the notice be appropriate to the type of benefits or services sought under the claim, and must specify the "general information and evidence required to substantiate the basic elements" of each type of claim. Public Law 110-389, 122 Stat. 4147. Section

101(b) of Public Law 110-389, 112 Stat. 4147, specifies that the regulations will apply to notice provided to claimants on or after the effective date of such regulations. However, the statute does not specify the types of "information and evidence" that would be required for any type of claim, nor does it limit VA's authority to determine what types of information and evidence are necessary for that purpose.

VA is proposing to amend current 38 CFR 3.159 so that it would pertain only to VA's duty to notify a claimant upon receipt of an application for veterans benefits, as required by 38 U.S.C. 5102 and 5103. Therefore, § 3.159(a)(1) and (2), (c), (d), (e), (f), and (g), which pertain to VA's duty to assist in developing claims under 38 U.S.C. 5103A, rather than the duty to notify under section 5103, would be redesignated as new § 3.167(a) through (e). We have made one substantive amendment to current § 3.159(d)(3) which will be redesignated as new § 3.167(c)(1). We are eliminating lack of veteran status as a basis upon which VA will refrain from or discontinue assistance under section 5103A in new section 3.167(c)(1) because the United States Court of Appeals for Veterans Claims (Veterans Court) held in *Gardner v. Shinseki*, 22 Vet. App. 415, 421 (2009), that VA has a duty to assist a person who files a claim for veterans benefits alleging that he or she is a veteran even if the person has not demonstrated veteran status.

VA provides the following assistance to develop a claimant's status as a veteran. Sections III through V of VA Form 21-526, Veteran's Application for Compensation and/or Pension, ask a veteran to provide information about his or her military service and to attach an original or certified copy of the claimant's DD214, Certification of Release or Discharge from Active Duty. As part of the initial screening process, VA conducts a routine check of the application and accompanying documents to determine whether the claimant has provided sufficient information to verify the character of discharge from military service and the claimed service. If the information provided is not sufficient to verify the claimed service or to establish the claimant's status as a "veteran," VA assists the claimant by requesting military records and other relevant records, as explained in § 3.167(b)(1)-(3) of this rulemaking, which is a recodification of current § 3.159(c)(1)-(3). VA discontinues its assistance if the Department determines that the claimant's service does not satisfy the requirements of title 38, United States

Code, or the claimant does not submit essential information missing from the application that VA has requested. Also, VA will not provide assistance if no reasonable possibility exists that such assistance would aid in substantiating the claimant's status as a veteran, e.g., the claimant's DD214 shows that the claimant received a dishonorable discharge from service.

Current § 3.159(a)(4) defines "event" for purposes of current § 3.159(c)(4)(ii), which pertains to VA's duty to assist. However, the term is also relevant with regard to the notice VA must provide regarding the elements necessary to substantiate a claim for service connection. We are therefore retaining the definition without substantive amendment as new § 3.159(a)(5) and also redesignating it without substantive amendment as proposed new § 3.167(a)(3).

In addition to current § 3.159(a)(4), VA would retain in amended § 3.159 another definition in current § 3.159(a) that pertains to VA's duty to notify. The current definition of "[s]ubstantially complete application" in § 3.159(a)(3) would be redesignated in new § 3.159(a)(1) and we would additionally define the term to include an application "identifying" pertinent information. Proposed new § 3.159(a)(2) would define "[T]ype of claim filed" to mean "an original claim, claim to reopen a prior final decision on a claim, or a claim for increase in benefits." This regulatory definition incorporates 38 U.S.C. 5103(a)(2)(B)(i) identifying "an original claim, claim for reopening a prior decision on a claim, [and] a claim for an increase in benefits" as the three types of claims for which VA must specify different contents.

VA would state in § 3.159(a)(3) that "[t]ype of benefit sought" refers to "the general nature of the benefits sought, such as disability compensation, increased compensation, dependency and indemnity compensation, and pension." The definition would not include "specific disabilities, theories of entitlement, or other case-specific facts." Section 5103(a)(1) itself makes clear that the requisite notice must be provided soon after VA receives the complete or substantially complete application. At the juncture in the claims process at which VA must comply with 38 U.S.C. 5103(a)(1), VA is unable to provide notice that accounts for specific disabilities, theories of entitlement, or particular facts. VA solicits case-specific information and evidence by sending development letters to claimants as part of the Department's duty to assist in obtaining

evidence to substantiate claims as required by 38 U.S.C. 5103A.

VA would redesignate without change the definition of “[i]nformation” in current § 3.159(a)(5) as proposed new § 3.159(a)(4).

VA would redesignate without substantive amendment current § 3.159(f) as proposed new § 3.159(b), which would state that, for purposes of the notice requirements in §§ 3.159 through 3.166, notice to the claimant means notice to the claimant or his or her fiduciary, if any, as well as to his or her representative, if any.

VA would redesignate without amendment current § 3.159(b)(2) as proposed new § 3.159(c), describing the notice that VA would provide upon receipt of an incomplete application.

Proposed new § 3.159(d) would address the notice VA would provide upon receipt of a complete or substantially complete application, as required by 38 U.S.C. 5103(a)(1). Proposed new § 3.159(d)(1) describes the purpose of the notice required by 38 U.S.C. 5103(a)(1). Consistent with the plain language of 38 U.S.C. 5103(a)(1), which is unchanged by Public Law 110–389 and section 101(a)(2) of the Act, § 3.159(d)(1) would explain that, upon receipt of a complete or substantially complete application, VA “will provide a claimant with notice of the general information and types of evidence that could be used by VA in deciding the type of claim filed for the type of benefit sought.” The first and second sentences of this paragraph would generally restate 38 U.S.C. 5103(a)(2)(B)(ii) and (iii).

The third sentence of proposed § 3.159(d)(1) would state that “VA generally will not \* \* \* identify specific evidence necessary to substantiate an individual claimant’s case.” As the Federal Circuit explained in *Vazquez-Flores*, 38 U.S.C. 5103(a)(1) does not require veteran-specific notice. 2009 WL 2835434, \*6; *see also Wilson*, 506 F.3d at 1059–60. In addition, because VA provides notice under section 5103(a) at an early stage in the claim, VA can provide notice of the general types of evidence that would be needed to substantiate the claim for the type of benefit sought, but generally cannot at that stage identify specific items of evidence that may prove necessary in each individual case once the facts and arguments have been developed pursuant to VA’s duty to assist. Further, any attempt to identify specific items of evidence would not only be potentially speculative, but would often require highly detailed and complex notice to account for the

variety of facts and arguments that may be raised as the claim is developed.

The report of the Senate Veterans’ Affairs Committee on S. 3023, which was enacted as Public Law 110–389, noted that IBM Global Business Services found “the current [VA notice] letter to be ‘long and complex, containing a great deal of legal language that can be confusing to veterans when trying to understand the process for completing their disability claim.’” S. Rep. 110–449, at 8–9 (2008). IBM recommended that VA revise the notice letter “to be shorter and more transparent,” a conclusion that the Senate committee appeared to endorse. *Id.* at 9–10. VA formed a work group and, consistent with the recommendations, VA revised notice letters provided to claimants for compensation, pension, and death benefits to make the letters shorter and more specific. We believe that VA notice will be more easily read and understood by claimants if VA provides short, succinct notice about the information and evidence necessary to substantiate the type of claim filed and benefit sought at the initial stages of a claim and defers case-specific letters to the development stage of the claim. *Id.* at 78 (letter from Secretary of Veterans Affairs James B. Peake, M.D., dated July 8, 2008). VA currently receives more than 800,000 claims annually, most of which require VA to provide section 5103(a)(1) notice. *Id.* By providing generic rather than case-specific notice, the Department is able to respond quickly to a claimant’s application for benefits, thereby commencing the claims-adjudication process. *Id.* Case-specific notice, by contrast, is not administratively feasible and would only delay the process without appreciably furthering development of the information and evidence necessary to substantiate the claim.

Consistent with proposed new § 3.159(d)(1), we would explain in the proposed new § 3.159(d)(2)(i) that VA will notify a claimant of the general type of information and evidence that is necessary to substantiate entitlement for the type of veterans benefits for which a claim was filed. *Vazquez-Flores*, 2009 WL 2835434, \*6; *Wilson*, 506 F.3d at 1058–60.

Proposed new § 3.159(d)(2)(ii) and (iii) would explain how VA’s notice will delineate the parties’ respective obligations under 38 U.S.C. 5103(a)(1) to obtain the information or evidence necessary to substantiate a claim. As set forth in § 3.159(d)(2)(ii), VA will notify a claimant that VA will obtain records that a claimant adequately identifies and authorizes VA to obtain from any Federal agency or from any other entity

or person and will provide a medical examination or obtain a medical opinion if necessary to decide the claim.

Proposed new § 3.159(d)(2)(i)(A) and (B) would state that VA will notify a claimant of the claimant’s obligation to provide VA with enough information to identify and locate the records, including the person or entity holding the records, the approximate time frame covered by the records, and, in the case of medical-treatment records, the condition for which treatment was provided and, if necessary, to authorize the release to VA of existing records in a form acceptable to the person or entity holding the records.

Proposed new § 3.159(d)(3) would explain the circumstances under which VA will not provide notice under 38 U.S.C. 5301(a)(1). This is a restatement of current § 3.159(b)(3), with one additional circumstance. In proposed new § 3.159(d)(3)(i), we would state that VA will not provide notice if the claim can be granted when the initial application is filed. In such cases, there is no need to delay award of the benefit by issuing notice and waiting at least 30 days for a response from the claimant because VA already has the information and evidence necessary to grant the claim.

Proposed new § 3.159(d)(4) would provide the time period within which a claimant must provide the information and evidence requested by VA. Proposed new § 3.159(d)(4)(i) and (ii) would redesignate the last three sentences of current § 3.159(b)(1).

We propose to redesignate current §§ 3.160 and 3.161 as §§ 3.170 and 3.171 respectively.

Proposed new § 3.160 would provide the content of the notice that VA will provide upon receipt of an original claim for disability compensation. Paragraph (a)(1) would explain that, if a veteran alleges disability resulting from active duty, VA will notify the veteran that information and evidence of the following is necessary to substantiate the claim: (1) A current disability, which is established by medical treatment records, medical opinions, and evidence from non-medical persons about persistent and recurrent symptoms of disability they have observed; (2) inservice incurrence or aggravation of an injury or disease, symptoms that were noted during service and that persisted until diagnosis of an injury or disease causing the symptoms, or an event in service capable of causing injury or disease, which is established by medical treatment records, medical opinions, and, in the case of certain symptoms or inservice events, evidence from non-

medical persons; and (3) a relationship between the inservice disease, injury, symptoms, or event and the veteran's current disability, which is generally established by medical treatment records, medical opinions, or by use of a legal presumption that the disability is related to a particular type of military service, such as detention as a prisoner of war, participation in a radiation-risk activity, or service in Vietnam or the Southwest Asia theater of operations during the Gulf War. Subsection (a)(1) would also explain that information and evidence must show the extent of current disability, which may be based on medical treatment records, medical opinions, statements from the veteran's employer about how the disability affects the veteran's ability to work and from other people about how the veteran's symptoms affect the veteran.

VA would not provide notice of the information and evidence necessary to establish the claimant's status as a veteran. VA Form 21-526, Veteran's Application for Compensation and/or Pension, solicits from a veteran information that enables VA to verify the veteran's service and character of discharge, and, under its duty to assist with claim development, VA requests the records necessary to verify the veteran's service and character of discharge from the military service departments. "Service department findings are binding on VA for purposes of establishing service in the U.S. Armed Forces." *Spencer v. West*, 13 Vet. App. 376, 380 (2000) (quoting *Duro v. Derwinski*, 2 Vet. App. 530, 532 (1992)); 38 CFR 3.203. Therefore, in most cases, there is no need to notify a claimant of the information and evidence necessary to substantiate veteran status and VA instead tailors the notice provided to the type of benefit sought.

VA also would not provide notice regarding the information and evidence necessary to substantiate an effective date for an award of benefits. We recognize that the Veterans Court has held that VA must provide notice under 38 U.S.C. 5103(a)(1) as to all elements of a claim, including "downstream elements" such as establishing entitlement to an effective date. *Dingess v. Nicholson*, 19 Vet. App. 473, 484 (2006), *aff'd per curiam*, Nos. 2006-7247 & 2006-7312, 2007 WL 1686737 (Fed. Cir. June 5, 2007). However, we believe that, at the initial stage of a claim when section 5103(a)(1) notice must be provided, notice of the information and evidence necessary to establish an effective date for an award of benefits "may be misleading and confusing" to the claimant. S. Rep. 110-

449, at 10. For example, it may lead the claimant to assume that service connection has been conceded and that the issue on which evidence must be submitted relates to the effective date. *Id.*

Further, there is generally no need to notify claimants of the need to submit evidence relating to the effective dates of VA awards. The determination of an effective date of an award is governed by statute and there generally is no evidence that a claimant can submit to substantiate a particular effective date. Pursuant to 38 U.S.C. 5110, the effective date of an award in most circumstances is based upon the date of the claim for benefits, the date of separation from service, the date of a veteran's death, or the date a disability arose or worsened. The date of the claim will be a matter of record before VA sends notice under section 5103(a)(1). The other events upon which an effective date may be based generally will be established by the same evidence that VA obtains or requests the claimant to submit for purposes of establishing entitlement to the benefit sought. As noted above, VA routinely obtains verification of service from the service department, as needed, upon receipt of a complete application providing the necessary information. Further, at the time VA grants disability or death benefits and the issue of effective date therefore arises, VA will necessarily have obtained, pursuant to its notice under section 5103(a)(1) and its duty to assist under section 5103A, evidence documenting the date of the veteran's death (in death benefit claims) or medical evidence concerning the diagnosis, treatment, and history of the veteran's disability (in disability benefit cases). There will seldom be circumstances where additional evidence would be relevant with respect to the issue of effective date. However, in the event that additional evidence would be relevant at the stage of proceedings in which VA assigns an effective date, it may be addressed in the notices relevant to that stage of proceedings, including notices of decisions and statements of the case.

As explained in § 3.160(a)(2), VA will notify a claimant who files a claim alleging disability based on active duty for training that information and evidence of the following is necessary to show service connection for the disability: (1) A current disability, which is established by medical treatment records, medical opinions, and evidence from non-medical persons about persistent and recurrent symptoms of disability they have observed; (2) disability during active duty for training from a disease or injury

that was incurred or aggravated in line of duty, symptoms that were noted during active duty for training and that persisted until diagnosis of an injury or disease causing the symptoms, or an event during such training capable of causing injury or disease, which is generally established by medical treatment records, medical opinions and competent non-medical evidence based on personal observations; and (3) a relationship between the current disability and the disability suffered during active duty for training, which is generally established by medical treatment records or medical opinions. Subsection (a)(2) would also explain that the information and evidence must show the extent of the claimant's current disability, which may be based on medical treatment records, medical opinions, statements from the veteran's employer about how the disability affects the claimant's ability to work and from other people about how the claimant's symptoms affect the claimant.

Section 3.160(a)(3) would state that VA will notify a claimant who files a claim based on inactive duty training that the following information and evidence is necessary to substantiate the claim: (1) A current disability, which is established by medical treatment records, medical opinions, and evidence from non-medical persons about persistent and recurrent symptoms of disability they have observed; (2) disability during inactive duty training from an injury that was incurred or aggravated during such training or an acute myocardial infarction, cardiac arrest, or cerebrovascular accident during such training, which is generally established by medical treatment records or medical opinions; and (3) a relationship between the claimant's current disability and the disability suffered during inactive duty training. Subsection (a)(3) would also explain that the information and evidence must show the extent of current disability, which may be based on medical treatment records, medical opinions, statements from the claimant's employer about how the disability affects the claimant's ability to work and from other people about how the claimant's symptoms affect the claimant.

Section 3.160(b) would explain that, if a veteran files a claim alleging disability caused or aggravated by a service-connected disability, VA will notify the veteran that information and evidence of the following is necessary to substantiate the claim: (1) The veteran has a disability in addition to the service-connected disability, which is established by medical treatment

records, medical opinions, and evidence from non-medical persons about persistent and recurrent symptoms of disability they have observed; (2) a relationship between the additional disability and a service-connected disability, which is generally established by medical treatment records and medical opinions; and (3) the extent of current disability, which may be based on medical treatment records, medical opinions, statements from the veteran's employer about how the disability affects the veteran's ability to work and from other people about how the veteran's symptoms affect the veteran.

Section 3.160(c) would describe the notice that VA will provide upon receipt of an application for disability caused by VA treatment, vocational rehabilitation, or compensated work therapy. Section 3.160(c) would explain that VA will notify the veteran that information and evidence of the following is necessary to substantiate the claim: (1) An additional physical or mental disability or an aggravation of an existing injury or disease, which is established by medical treatment records, medical opinions, and evidence from non-medical persons about persistent and recurrent symptoms of disability they have observed; (2) the veteran's additional disability or aggravation of an existing injury or disease was caused by VA hospital care, medical or surgical treatment or examination, VA training or rehabilitation services, or participation in VA's compensated work therapy program, which is generally established by medical treatment records and medical opinions; (3) the additional disability or aggravation caused by VA hospital care, medical or surgical treatment or examination was the direct result of VA fault (carelessness, negligence, lack of proper skill, or error in judgment) or was the direct result of an event not reasonably foreseeable (*i.e.*, not an ordinary risk of the services provided); and (4) the extent of current additional disability, which may be based on medical treatment records, medical opinions, statements from the veteran's employer about how the disability affects the veteran's ability to work and from other people about how the veteran's symptoms affect the veteran.

Section 3.161 would explain the notice that VA will provide upon receipt of an application seeking increased disability compensation. Section 3.161(a) would state that VA will notify a claimant the following information and evidence is necessary to substantiate a claim for an increased

schedular rating: (1) An increase in the extent of the claimant's service-connected disability, which is based on medical treatment records, medical opinions, and statements from non-medical persons about persistent and recurrent symptoms of disability they have observed; and (2) the extent of current disability, which may be based on medical treatment records, medical opinions, statements from the veteran's employer about how the disability affects the veteran's ability to work and from other people about how the veteran's symptoms affect the veteran. VA will notify a claimant that VA will assign a rating for the disability from 0 to 100 percent under the VA Schedule for Rating Disabilities.

Consistent with proposed new § 3.159(d)(1), VA will not provide case-specific notice in increased-rating claims regarding the relevant rating criteria under diagnostic codes (DC) that are applicable to rating the current extent of a claimant's disability for the following reasons. First, as the Federal Circuit has explained, 38 U.S.C. 5103(a)(1) is satisfied by generic notice regarding an increased-rating claim rather than veteran-specific notice regarding the DCs applicable to a particular veteran's claim. *Vazquez-Flores*, 2009 WL 2835434, \*6, \*10; *Wilson*, 506 F.3d at 1059–60; *Paralyzed Veterans*, 345 F.3d at 1347. We note as well that section 101(a) of the Veterans' Benefits Improvement Act of 2008 retained section 5103(a) as subsection (a)(1) and made no amendment to the provision. Thus, the unamended text of 38 U.S.C. 5103(a)(1) does not require that VA provide case-specific notice of potentially applicable DCs.

Second, notifying the claimant to submit evidence that their disability has increased in severity generally will put the claimant on notice to submit or direct VA's attention to all evidence that potentially may bear upon the severity of the disability. Third, many provisions in VA's rating schedule necessarily contain detailed medical criteria that would not be useful to claimants. A notice conveying extensive and often technical regulatory criteria will likely be long and complex, containing a great deal of medical language that can be confusing for the average reader, thereby diminishing its usefulness. *See* S. Rep. 110–449, at 8–9. Generic notice, on the other hand, will be more readily understandable and useful to claimants. *Id.* at 78. Fourth, it is VA's policy to assign a rating under the DC that most closely reflects the features of the current disability as shown by the medical evidence. This may require consideration of several potentially

applicable DCs containing different criteria. Providing notice of the criteria under a single DC, such as that previously used in a particular case, may be misleading and may dissuade claimants from submitting all evidence bearing upon the current severity of their disabilities. At the same time, a notice conveying the requirements of several potentially applicable DCs, many of which may ultimately prove inapplicable upon development of the claim, may be confusing the claimant and may create unrealistic expectations. Fifth, providing notice tailored to the specific DCs potentially applicable to each claim requires time-consuming review in each case by VA employees in order to identify potentially applicable DCs based on the facts previously of record. The time devoted to such review would divert resources from the development and adjudication of claims and, for the reasons stated above, generally would not make VA's notices more helpful to claimants. By providing generic notice, VA will be able to focus its resources on adjudicating the more than 800,000 claims filed annually. *Id.*

We recognize that the Senate Veterans' Affairs Committee report on Public Law 110–389 urges VA to codify in regulations the holding of *Vazquez-Flores v. Peake*, 22 Vet. App. 91 (2008), *vacated*, No. 2008–7150, 2009 WL 2835434 (Fed. Cir. Sept. 4, 2009), in which the Veterans Court held that 38 U.S.C. 5103(a)(1) requires VA to provide case-specific notice in increased-rating claims regarding the relevant DC criteria applicable to a claim. S. Rep. 110–449, at 11–12. However, VA believes, and the Federal Circuit concurs, that the Veterans Court's interpretation of section 5103(a)(1) does not accurately reflect the plain language of the statute and does not appropriately defer to VA's interpretation of the statute as reflected in former 38 CFR 3.159(b). *Vazquez-Flores*, 2009 WL 2835434, \*6. In accordance with the provisions of Public Law 110–389 directing VA to prescribe regulations governing the content of VA notices under section 5103(a)(1), we propose to clarify our interpretation of the statute, consistent with the Federal Circuit's guidance in *Vazquez-Flores* and *Wilson*. With all due respect to the views expressed in the Committee report, such statements do not carry the force of law, particularly where they do not illuminate the meaning of the statutory terms, but merely express expectations that were not themselves reflected in the statute as passed. *See Strickland v. Commissioner, Maine Dep't of Human Servs.*, 48 F.3d 12, 19 (1st Cir. 1995). We

note that there was no mention of *Vazquez-Flores* during deliberations by the House of Representatives on Public Law 110–389. 154 Cong. Rec. H9387–H9405 (daily ed. Sept. 24, 2008). It is well established that expressions of expectations in isolated committee reports do not have the force of law, nor do they express the intent of Congress. See *Strickland*, 48 F.3d at 19 (declining to rely on legislative history comprised of “one paragraph in one report of one of the two chambers that passed the law”); *Scalise v. Thornburgh*, 891 F.2d 640, 645 (7th Cir. 1989) (“An expression of an ‘expectation’ by one committee of the House \* \* \* does not establish congressional intent”); cf. *Lincoln v. Vigil*, 508 U.S. 182, 193 (1993) (“Congress may always circumscribe agency discretion to allocate resources by putting restrictions in the operative statutes (though not \* \* \* just in the legislative history).”). In addition, section 101(b) of Public Law 110–389 authorizes the Secretary of Veterans Affairs to prescribe regulations regarding the content of the notices that the Department will provide. The fact that Public Law 110–389 itself contains no language circumscribing in any way the Secretary’s discretion to promulgate such regulations also leads us to conclude the “expectation” expressed in the Senate Committee report is not dispositive as to the notice that VA must provide upon receipt of a claim for an increased rating.

Section 3.161(b) explains the notice that VA would provide upon receipt of an application for a rating of total disability based on individual unemployability. The notice would state that the information and evidence generally must establish that a veteran is unable to secure and follow substantial gainful employment because of a service-connected disability rated at least 60 percent disabling or more than one service-connected disability with one disability rated at 40 percent or more and a combined rating of at least 70 percent, but that VA will consider all evidence showing that the veteran is unemployable even if these ratings are not met. This determination may be based on medical treatment records, medical opinions, statements from the veteran’s employer about how the disability affects the veteran and the veteran’s ability to work, and statements from other people about how the veteran’s symptoms affect the veteran.

Section 3.161(c) would state that VA will notify a claimant that, to substantiate a claim for temporary total disability due to hospitalization, the information and evidence must show that the veteran was hospitalized for

treatment for a service-connected disability in a VA hospital or an approved hospital for more than 21 days or was hospitalized for observation for a service-connected disability at VA expense for more than 21 days. This is based on medical treatment records.

Section 3.161(d) would state that VA would notify a claimant that to substantiate a claim for temporary total disability due to surgery or other treatment the information and evidence must show that the veteran received surgery at a VA or other approved hospital or outpatient facility for a service-connected disability and that the surgery required convalescence for at least 1 month or resulted in severe postoperative residuals (such as incompletely healed surgical wounds, stumps of recent amputations, therapeutic immobilizations, house confinement, or required use of a wheelchair or crutches), or that the veteran received treatment at a VA or other approved hospital or outpatient facility that resulted in immobilization by cast, without surgery, of at least one major joint. This is based on medical treatment records.

Section 3.161(e) would state that VA would notify a claimant that to substantiate a claim for increased compensation because of the need for aid and attendance or bedridden status, medical treatment records, medical opinions, and competent non-medical evidence based on personal observations must show that the veteran requires the aid of another person to perform personal functions required in everyday living, such as bathing, feeding, or adjustment of prosthetics, or must remain in bed due to his or her disability or disabilities based on medical necessity and not based on a prescription of bed rest for purposes of convalescence or cure. VA also requires medical treatment records and medical reports showing that the veteran’s need for aid and attendance or confinement to bed is a result of a service-connected disability.

In § 3.161(f), VA would state that, upon receipt of a claim for increased compensation based on being permanently housebound, VA will notify the claimant that the information and evidence must show that the veteran has a totally disabling service-connected disability. This may be based on medical treatment records, medical opinions, statements from the veteran’s employer about how the disability affects the veteran’s ability to work, and statements from other people about how the veteran’s symptoms affect the veteran. The information and evidence must also show that the veteran is

substantially confined to the veteran’s house, ward or clinical areas if institutionalized, or immediate premises due to a service-connected disability or disabilities. This is established by medical treatment records, medical opinions, and statements from non-medical people about how the disability affects the veteran and the veteran’s ability to function.

Section 3.162 would explain the notice that VA would provide when a veteran files a claim for improved pension or increased pension. Section 3.162(a) would state that, if VA receives a claim for improved pension, VA will notify the claimant that the information and evidence must show the veteran served during a period of war.

In addition, VA will notify the claimant that the information and evidence must show that the veteran is 65 years of age or older, or alternatively, that the veteran is permanently and totally disabled due to a nonservice-connected disability, which means that the veteran is a patient in a nursing home for long-term care, receiving social security disability benefits; unemployable due to a disability reasonably certain to continue through the veteran’s lifetime; or suffering from a disability that is reasonably certain to continue through the veteran’s lifetime and would make it impossible for the average person to follow a substantially gainful occupation; or suffering from a disease or disorder that VA believes justifies a determination that people who have the disease or disorder are permanently and totally disabled. This may be established by Social Security Administration records or medical treatment records, medical opinions, statements from the veteran’s employer about how the disability affects the veteran and the veteran’s ability to work, and statements from other people about how the veteran’s symptoms affect the veteran. VA will also notify the claimant that the information and evidence must show that the claimant’s annual income and net worth do not exceed certain limits.

For reasons similar to those explained above concerning proposed § 3.160, we do not propose to provide notice of the criteria governing effective dates as part of the notice under section 5103(a)(1). By statute, the effective date of pension awards generally will be governed by the date of the application or by other facts that would necessarily be established by the evidence upon which the pension award is based. There ordinarily would be no other evidence relating solely to effective dates that would be necessary to substantiate a claim. However, in the event that

additional evidence would be relevant in a particular case at the stage of proceedings in which VA assigns an effective date, it may be addressed in the notices relevant to that stage of proceedings.

Section 3.162(b) would explain the notice that VA will provide upon receipt of a claim for increased pension. VA will notify the claimant that medical treatment records, medical opinions, and competent non-medical evidence based on personal observations must show that the claimant is in need of regular aid and attendance or is permanently housebound or, alternatively, the information and evidence must show that there has been a change in the claimant's income or net worth. A claimant is in need of regular aid and attendance if the claimant: (1) Has 5/200 visual acuity or less in both eyes; (2) has concentric contraction of the visual field to 5 degrees or less in both eyes; (3) is a patient in a nursing home because of mental or physical incapacity; or (4) requires the aid of another person in order to perform personal functions of everyday living, such as bathing, feeding, or adjusting a prosthetic device. A claimant is permanently housebound if the claimant is substantially confined to the claimant's house or immediate premises, or ward or clinical areas if institutionalized, because of a disability or disabilities and it is reasonably certain that the disability or disabilities will not improve during the claimant's lifetime.

Section 3.163 would explain the notice that VA will provide upon receipt of a claim for benefits from a veteran's survivor. In addition to notice regarding the type of claim filed by a veteran's survivor, VA will also notify the claimant of the information and evidence necessary to substantiate a claim for accrued benefits because the claimant may be entitled to benefits that were due and unpaid the veteran at death.

As set forth in § 3.163(a)(1), VA will notify a survivor who files a claim for dependency and indemnity compensation (DIC) based on a death related to active duty that the information and evidence must show that: (1) The veteran died during active duty; (2) VA awarded the veteran service connection for a disease or injury and medical evidence shows that the disease or injury caused or contributed to the veteran's death; or (3) the veteran had a disease or injury that was incurred or aggravated during active duty or was caused by an event during active duty, as shown by medical evidence, competent non-medical

evidence based on personal observations, and use of applicable legal presumptions, and medical evidence shows that the disease or injury caused or contributed to the veteran's death.

We recognize that, in *Hupp v. Nicholson*, 21 Vet. App. 342, 352–53 (2007), the Veterans Court held that notice in the context of a DIC claim “must include (1) A statement of the conditions, if any, for which a veteran was service connected at the time of his or [her] death; (2) an explanation of the evidence and information required to substantiate a DIC claim based on a previously service-connected condition; and (3) an explanation of the evidence and information required to substantiate a DIC claim based on a condition not yet service-connected.” The proposed rule would include the latter two components, but not the first. As explained above, the Federal Circuit stated in *Vazquez-Flores*, 2009 WL 2835434, \*6, \*10, and *Wilson*, 506 F.3d at 1059, 1062, that the language in current section 5103(a)(1) requires generic notice tailored to the type of claim filed rather than veteran-specific notice. The notice required by *Hupp*, which was decided before *Vazquez-Flores* and *Wilson*, is not generic but rather would entail a review of the veteran's claim file to determine whether VA previously granted service connection for a veteran's disability.

In VA's judgment and experience, the generic notice described in § 3.163(a) would explain to a claimant the information and evidence necessary to substantiate a DIC claim based on a previously service-connected disability as well as a claim based on a disability that was not previously service connected. DIC claimants are members of the veteran's immediate family and generally will know or can easily determine whether the veteran was granted service connection for any conditions. Moreover, VA will already have that information and will consider it in developing and deciding the claim. DIC claimants will not need to submit evidence of such awards. Additionally, the fact that VA previously awarded the veteran service connection for certain conditions would not preclude a DIC claimant from establishing service connection for a different condition that caused the veteran's death. Recitation of the veteran's previously service-connected conditions, which may have no bearing upon the DIC claim, is not necessary in order to notify the claimant of the information and evidence VA needs to substantiate the claim. Requiring such notices tailored to the specific facts of each DIC claim would

impose unnecessary burdens and delays in VA's claim processing.

Section 3.163(a)(2) would explain that VA will notify a survivor who files a claim for DIC based on a death related to active duty for training that the information and evidence must show one of the following: (1) That the veteran died during active duty for training; (2) that VA had granted the veteran service connection for a disease or injury and medical evidence shows that the service-connected disease or injury caused or contributed to the veteran's death; or (3) that the veteran was disabled during active duty for training due to a disease or injury incurred in the line of duty, as shown by medical evidence and competent non-medical evidence based on personal observation, and medical evidence shows that the disease or injury caused or contributed to the veteran's death.

Section 3.163(a)(3) would explain that VA will notify a survivor who files a claim for DIC based on a death related to inactive duty training that the information and evidence must show that the veteran: (1) Died during inactive duty training due to an injury incurred or aggravated in line of duty or an acute myocardial infarction, cardiac arrest or cerebrovascular accident during such training, as shown by medical evidence and competent non-medical evidence based on personal observations; or (2) had a disability that was due to an injury incurred or aggravated during inactive duty training or an acute myocardial infarction, cardiac arrest, or cerebrovascular accident during such training, as shown by medical evidence and competent non-medical evidence based on personal observations, and medical evidence shows that the injury, acute myocardial infarction, cardiac arrest, or cerebrovascular accident caused or contributed to the veteran's death.

Section 3.163(a)(4) would explain that VA will notify a survivor who files a claim for DIC that, if the veteran did not die from a service-connected disability, DIC is payable if the veteran was receiving compensation from VA for a service-connected disability that was rated totally disabling. The veteran must have received, or been entitled to receive, compensation for at least 10 years immediately before death; at least 5 years immediately preceding death and continuously since the veteran's release from active duty; or at least 1 year immediately preceding death, if the veteran was a former prisoner of war who died after September 30, 1999.

Section 3.163(a)(5) would set forth the notice that VA would provide upon

receipt of a claim for DIC based upon a veteran's death caused by VA treatment, vocational rehabilitation or compensated work therapy. VA would notify the claimant that generally the medical treatment records and medical opinions must show that the veteran's death was caused by VA hospital care, medical or surgical treatment or examination, VA training or rehabilitation services, or participation in VA's compensated work therapy program. The evidence also must show that veteran's death, which was caused by VA hospital care, medical or surgical treatment or examination, was the direct result of VA fault (carelessness, negligence, lack of proper skill, or error in judgment) or was the direct result of an event not reasonably foreseeable (*i.e.*, not an ordinary risk of the services provided). VA would notify the claimant that this requirement does not apply to claims based on VA training or rehabilitation services or compensated work therapy.

In § 3.163(b), VA would explain the notice that will be provided upon receipt of a claim for supplemental DIC for a veteran's child or parent. Section 3.163(b)(1) would state that, upon the receipt of a claim for supplemental DIC for a veteran's child, VA will provide notice that medical treatment records and medical opinions must show that the child, before his or her 18th birthday, became permanently incapable of self-support due to a mental or physical disability.

Section 3.163(b)(2) would state that, upon receipt of a claim for supplemental DIC for a veteran's parent, VA will provide notice that medical treatment records and medical opinions must show that the parent has corrected visual acuity of 5/200 or less, in both eyes, or concentric contraction of the visual field to 5 degrees or less; or is a patient in a nursing home because of mental or physical incapacity; or requires the aid of another person in order to perform personal functions required in everyday living, such as bathing, feeding, and dressing.

Section 3.163(c) would explain that, when VA receives a claim for improved pension from a veteran's surviving spouse or child, VA will notify the claimant that the information and evidence must show that the veteran served: (1) For ninety days or more during a period of war; (2) for ninety consecutive days, at least one of which was during a period of war; (3) for any length of time during a period of war and was discharged or released for a service-connected disability; or (4) for any length of time during a period of war and at the time of death was

receiving or was entitled to receive VA compensation or service department retirement pay for a service-connected disability. The notice would further explain that the information and evidence must show that the claimant's annual income and net worth do not exceed certain limits.

Section 3.163(d) would explain that, when VA receives a claim for increased pension from a veteran's surviving spouse, VA would provide notice that to substantiate the claim, medical treatment records, medical opinions, and competent non-medical evidence based on personal observations must show that the claimant is in need of regular aid and attendance or permanently housebound and would provide notice of the criteria for establishing need for regular aid and attendance or permanent housebound status. The notice would explain that a claimant is in need of regular aid and attendance if the claimant: (1) Has 5/200 visual acuity or less in both eyes; (2) has concentric contraction of the visual field to 5 degrees or less in both eyes; (3) is a patient in a nursing home because of mental or physical incapacity; or (4) requires the aid of another person in order to perform personal functions of everyday living, such as bathing, feeding, or adjusting a prosthetic device. The notice would further explain that a claimant is permanently housebound if the claimant is substantially confined to the claimant's house or immediate premises because of a disability or disabilities and it is reasonably certain that the disability or disabilities will not improve during the claimant's lifetime.

Section 3.163(e) would explain that, when VA receives a claim for accrued benefits and survivor benefits, VA would provide notice that to substantiate a claim for accrued benefits, the information and evidence must show that the benefits were awarded to the individual by a VA rating or decision before the individual died, or evidence in VA's possession on or before the date of the individual's death, even if such evidence was not physically located in the VA claims folder on or before the date of death, shows that the individual had applied for and was entitled to the benefits. VA would also notify the claimant that accrued benefits are paid to the following persons in the following order of priority: (1) Veteran's surviving spouse; (2) veteran's children (in equal shares); and (3) veteran's surviving dependent parents (in equal shares) or the surviving dependent parent if only one is living.

Proposed new § 3.164 would explain the notice that VA will provide upon

receipt of an application for specially adapted housing, special home adaptation grant, allowance for an automobile or automobile adaptive equipment, clothing allowance, and monetary allowances for certain children provided under chapter 18 of title 38, United States Code.

Section 3.164(a) would explain that, upon receipt of an application for specially adapted housing, VA would notify the claimant that medical treatment records and medical opinions must show that the veteran or servicemember on active duty is permanently and totally disabled due to one of the following: (1) Loss, or loss of use, of both lower extremities requiring the use of braces, crutches, canes, or a wheelchair to move from place to place; (2) blindness in both eyes so that the veteran can see only light, together with the loss, or loss of use of one lower extremity; (3) loss, or loss of use, of one lower extremity, together with a disease or injury that affects the veteran's balance or ability to move forward and requires the use of braces, crutches, canes, or a wheelchair in order to move from place to place; (4) loss, or loss of use, of one lower extremity, together with loss or loss of use of one upper extremity that affects the veteran's balance or ability to move forward and requires the use of braces, crutches, canes, or a wheelchair in order to move from place to place; (5) loss, or loss of use, of both upper extremities that prevents the veteran from using the arms at or above the elbows; or (6) severe burn injury. The notice would further explain that the information and evidence must show that the veteran or servicemember suffered the disability as a result of an injury, disease, or event in line of duty in the active military, naval or air service, or as the result of VA hospital care, medical or surgical treatment or examination under circumstances involving VA carelessness, negligence, lack of proper skill or error in judgment or an event not reasonably foreseeable, or as the result of VA training or rehabilitation services or participation in VA's compensated work therapy program.

Section 3.164(b) would explain that upon receipt of a claim for a special home adaptation grant, VA would notify the claimant that medical treatment records and medical opinions must show that the veteran or servicemember on active duty is permanently and totally disabled due to a service-connected disability resulting from blindness in both eyes with 5/200 visual acuity or less; anatomical loss or loss of use of both hands; or severe burn injury. The notice would further explain that

the information and evidence must establish that the veteran or servicemember suffered the disability as a result of an injury, disease, or event in line of duty in the active military, naval or air service, or as the result of VA hospital care, medical or surgical treatment or examination under circumstances involving VA carelessness, negligence, lack of proper skill or error in judgment or an event not reasonably foreseeable, or as the result of VA training or rehabilitation services or participation in VA's compensated work therapy program.

Section 3.164(c) would explain the notice that VA would give a claimant for an automobile allowance and/or adaptive equipment. VA would notify a claimant for an automobile allowance and adaptive equipment that medical treatment records and medical opinions must show that a veteran is entitled to compensation as a result of, or a servicemember on active duty is disabled due to the loss, or permanent loss of use, of at least a foot or a hand or permanent impairment of vision in both eyes, resulting in vision of 20/200 or less in the better eye with glasses or vision of 20/200 or better, if there is a severe defect in peripheral vision. The notice would further explain that the information and evidence must establish that the veteran or servicemember suffered the disability as a result of an injury, disease, or event in line of duty in the active military, naval or air service, or as a result of VA hospital care, medical or surgical treatment or examination under circumstances involving VA carelessness, negligence, lack of proper skill or error in judgment or an event not reasonably foreseeable, or as a result of VA training or rehabilitation services or participation in VA's compensated work therapy program.

Further, VA would notify a claimant for adaptive equipment that such a claim may also be substantiated by information and evidence showing that a veteran is entitled to compensation for ankylosis of at least one knee or one hip. The information and evidence must show that the veteran suffered the disability as a result of an injury, disease, or event in line of duty in the active military, naval or air service, or as a result of VA hospital care, medical or surgical treatment or examination under circumstances involving VA carelessness, negligence, lack of proper skill or error in judgment or an event not reasonably foreseeable, or as a result of VA training or rehabilitation services or participation in VA's compensated work therapy program.

Section 3.164(d) would explain the notice that VA will provide upon receipt of an application for a clothing allowance. VA would notify a claimant that the information and evidence must show that the veteran suffered a disability as a result of an injury, disease, or event in line of duty in the active military, naval or air service, or as a result of VA hospital care, medical or surgical treatment or examination under circumstances involving VA carelessness, negligence, lack of proper skill or error in judgment or an event not reasonably foreseeable, or as a result of VA training or rehabilitation services or participation in VA's compensated work therapy program. VA would also notify the claimant that a VA examination or hospital report or an examination report from a government or private facility must show that the veteran wears or uses a prosthetic or orthopedic appliance because the qualifying disability tends to wear out or tear the veteran's clothes, or the veteran uses prescription medication for a skin condition which is due to a qualifying disability and the medication causes irreparable damage to the veteran's outer garments.

Section 3.164(e) would explain the notice that VA will provide upon receipt of an application for a monetary allowance for an individual with spina bifida born to a Vietnam veteran. VA will notify a claimant that the information and evidence must show that: (1) The individual's biological father or mother is or was a veteran who performed active military, naval, or air service in the Republic of Vietnam during the period beginning on January 9, 1962, and ending on May 7, 1975, including service in the waters offshore and service in other locations if the conditions of service involved duty or visitation in the Republic of Vietnam, and (2) the individual was conceived on or after the date on which the veteran first served in the Republic of Vietnam. VA would notify the claimant that this is based on evidence such as service department records and a birth certificate, church record of baptism, affidavit or certified statement from a physician or midwife present during the birth, or notarized copy of a Bible or other family record containing reference to the birth and medical treatment records and medical opinions showing that the individual has any form or manifestation of spina bifida except spina bifida occulta.

VA would also notify the claimant that VA will examine the nature and severity of the individual's disability due to spina bifida and assign an evaluation of Level 1 to Level 3 by

comparing the individual's symptoms to the criteria in § 3.814 of title 38, Code of Federal Regulations, and that this is based on medical treatment records and reports and statements from the individual's employer and other people about how the disability affects the individual's ability to work and function.

Section 3.164(f) would explain the notice that VA will provide upon receipt of an application for a monetary allowance for an individual with certain birth defects born to a female Vietnam veteran. VA will notify a claimant that the information and evidence must show that: (1) The individual's biological mother is or was a veteran who performed active military, naval, or air service in the Republic of Vietnam during the period beginning on February 28, 1961, and ending on May 7, 1975, including service in the waters offshore and service in other locations if the conditions of service involved duty or visitation in the Republic of Vietnam; and (2) the individual was conceived on or after the date on which the veteran first served in the Republic of Vietnam. VA would notify the claimant that this is based on evidence such as service department records and a birth certificate, church record of baptism, affidavit or certified statement from a physician or midwife present during the birth, or notarized copy of a Bible or other family record containing reference to the birth and medical treatment records and medical opinions showing that the individual has a covered birth defect.

VA would also notify the claimant that VA will examine the nature and severity of the individual's disability to the birth defect(s) and assign an evaluation of Level 1 to Level 3 by comparing the individual's symptoms to the criteria in § 3.815 of title 38, Code of Federal Regulations, and that this is based on medical treatment records and reports and statements from the individual's employer and other people about how the disability affects the individual's ability to work and function.

Proposed new § 3.165 would explain the notice that VA will provide upon receipt of an application to reopen a previously denied claim based on new and material evidence. In *Kent v. Nicholson*, 20 Vet. App. 1, 9 (2006), the Veterans Court stated that "VA must inform a claimant seeking to reopen a previously and finally disallowed claim of the unique character of evidence that must be presented" because "[t]he terms 'new' and 'material' have specific, technical meanings that are not commonly known to VA claimants."

Therefore, in addition to the notice described in §§ 3.160 through 3.164 regarding the type of benefit sought, VA will notify a claimant that “new” and “material” evidence is evidence not previously submitted to VA, that by itself or when considered with previous evidence of record, relates to an unestablished fact necessary to substantiate the claim and raises a reasonable possibility of substantiating the claim. However, we recognize that the Veterans Court also stated in *Kent*, 20 Vet. App. at 10, that, upon receipt of a claim to reopen, VA must “look at the bases for the denial in the prior decision and \* \* \* [provide] a notice letter that describe[s] what evidence would be necessary to substantiate th[e] element or elements \* \* \* that were found insufficient in the previous denial.” This holding in *Kent*, which requires VA to provide case-specific notice upon receipt of a claim to reopen, is inconsistent with the subsequent Federal Circuit decisions in *Vazquez-Flores* and *Wilson*, holding that section 5103(a)(1) is satisfied by “generic notice,” *i.e.*, notice that “identif[ies] the information and evidence necessary to substantiate the particular type of claim being asserted” by a claimant and rejecting the argument that the statute requires specific notice of missing evidence with respect to a particular claim. 2009 WL 2835434, \*6, \*10; 506 F.3d at 1059–60. VA will therefore not provide such case-specific notice to a claimant who has filed an application to reopen a previously denied claim. Pursuant to 38 U.S.C. 5104(b) and 7104(d)(1), if VA denies a claim, it must provide the claimant a written statement of the reasons for the denial and of the evidence considered. Accordingly, the type of notice to be provided under proposed § 3.165 will be sufficient to inform claimants as to the types of evidence needed to reopen a claim in view of the information previously provided to the claimants.

In allowing VA to provide generic rather than case-specific notice upon receipt of a claim to reopen, proposed new § 3.165 would promote the efficiency of the veterans’ benefit adjudication process. VA currently receives approximately 800,000 claims annually, most of which require VA to provide notice under 38 U.S.C. 5103(a)(1). The type of notice that would be provided by VA upon receipt of a claim to reopen would allow the Department to respond quickly with notice that is easily understood by a claimant. The type of notice required by the Veterans Court in *Kent*, by contrast, imposes administrative burdens that, in

VA’s view, are not required by section 5103(a)(1) and that would result in undue delays in VA claims processing.

We explain in § 3.166 that VA will provide notice of the evidence and information necessary to substantiate a claim for any other benefit governed by part 3 of title 38, Code of Federal Regulations, consistent with the statutory and regulatory eligibility criteria for the benefit sought.

#### **Paperwork Reduction Act of 1995**

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

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

#### **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 Executive Order classifies 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 proposed rule have

been examined and it has been determined to be a significant regulatory action under Executive Order 12866 because it may raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

#### **Regulatory Flexibility Act**

The Secretary hereby certifies that this proposed regulatory amendment would 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 proposed amendment would not directly affect any small entities. Only individuals could be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), this proposed amendment is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

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

The Catalog of Federal Domestic Assistance numbers and titles for this program are 64.100, Automobiles and Adaptive Equipment for Certain Disabled Veterans and Members of the Armed Forces; 64.101, Burial Expenses Allowance for Veterans; 64.104, 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, and 64.110, Veterans Dependency and Indemnity Compensation for Service Connected Death.

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

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

Approved: September 29, 2009.

**John R. Gingrich,**

*Chief of Staff, Department of Veterans Affairs.*

For the reasons set forth 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. Revise § 3.159 to read as follows:

**§ 3.159 Notice to claimants of required information and evidence.**

(a) *Definitions.* For purposes of §§ 3.159 through 3.166, the following definitions apply.

(1) *Substantially complete application* means an application containing or identifying the claimant's name; his or her relationship to the veteran, if applicable; sufficient service information for VA to verify the claimed service, if applicable; the benefit claimed and any medical condition(s) on which it is based; the claimant's signature; and in claims for nonservice-connected disability or death pension and parents' dependency and indemnity compensation, a statement of income.

(2) *Type of claim filed* means an original claim, claim to reopen a prior final decision on a claim, or a claim for increase in benefits.

(3) *Type of benefit sought* means the general nature of the benefits sought, such as disability compensation, increased compensation, dependency and indemnity compensation, and pension, rather than the specific disabilities, theories of entitlement, or other case-specific facts.

(4) *Information* means non-evidentiary facts, such as the claimant's Social Security number or address; the name and military unit of a person who served with the veteran; or the name and address of a medical care provider who may have evidence pertinent to the claim.

(5) *Event* means one or more incidents associated with places, types, and circumstances of service giving rise to disability.

(Authority: 38 U.S.C. 5103(a)(1) and (2))

(b) For the purpose of the notice requirements in §§ 3.159 through 3.166, notice to the claimant means notice to the claimant or his or her fiduciary, if any, as well as to his or her representative, if any.

(Authority: 38 U.S.C. 5102(b), 5103(a)(1))

(c) *Notice of incomplete application.* If VA receives an incomplete application for benefits, it will notify the claimant of the information necessary to complete the application and will defer assistance until the claimant submits this information.

(Authority: 38 U.S.C. 5103(a)(1) and (2))

(d) *Notice of required information and evidence—(1) Purpose.* When VA receives a complete or substantially complete application for benefits, the Department will provide a claimant with notice of the general information and types of evidence that could be used by VA in deciding the type of claim filed for the type of benefit

sought. This notice is intended to assist claimants in determining what types of information and evidence available to them may assist in substantiating their claims. VA generally will not, in this notice, identify specific evidence necessary to substantiate an individual claimant's case.

(Authority: 38 U.S.C. 5103(a)(1) and (2))

(2) *Content of notice.* When VA receives a complete or substantially complete application for benefits, it will notify a claimant of—

(i) the general information and evidence that is necessary to substantiate entitlement for the type of claim filed and benefit sought as set forth in §§ 3.160 through 3.166.

(ii) VA's obligation to—

(A) Obtain relevant records that the claimant adequately identifies and authorizes VA to obtain from any Federal agency, including the Department of Defense, Social Security Administration and VA medical centers, or from any other entity or person; and

(B) Provide a medical examination or obtain a medical opinion if necessary to decide a claim for disability compensation; and

(iii) The claimant's obligation to—

(A) Provide VA with enough information to identify and locate the existing records, including the person, company, agency, or other custodian holding the records; the approximate time frame covered by the records; and, in the case of medical treatment records, the condition for which treatment was provided; and

(B) Authorize, if necessary, the release to VA of existing records in a form acceptable to the person, company, agency, or other custodian holding the records.

(Authority: 38 U.S.C. 5103(a)(1) and (2))

(3) *Circumstances under which VA will not provide notice.* VA will not provide notice under §§ 3.159 through 3.166 if:

(i) The claim can be granted when the initial application is filed;

(ii) The claimant has filed a notice of disagreement, unless the notice provided by VA prior to receipt of the notice of disagreement does not comply with this section; or

(iii) As a matter of law, the claimant is not entitled to the benefit sought.

(Authority: 38 U.S.C. 5103(a)(1) and (2))

(4) *Time to respond.*

(i) A claimant must provide the information and evidence necessary to substantiate a claim that VA notifies a claimant to provide within 1 year of the date of the notice. If the information and evidence is not received by VA within

1 year, VA cannot pay or provide any benefits based on the application.

(ii) If the claimant has not responded to VA's request for information or evidence within 30 days, VA may decide the claim prior to the expiration of the 1-year period based on all the information and evidence contained in the file, including information and evidence it has obtained on behalf of the claimant and any VA medical examinations or medical opinions. If VA does so, however, and the claimant subsequently provides the information and evidence within 1 year of the date of the request, VA must readjudicate the claim.

(Authority: 38 U.S.C. 5103(a)(1) and (2) and (b))

3. Redesignate §§ 3.160 and 3.161 as §§ 3.170 and 3.171 respectively.

4. Add new §§ 3.160 through 3.167 to read as follows:

Sec.

3.160 Notice upon receipt of application for disability compensation.

3.161 Notice upon receipt of application for increased disability compensation.

3.162 Notice upon receipt of application for improved pension.

3.163 Notice upon receipt of application for survivor benefits.

3.164 Notice upon receipt of application for special benefits.

3.165 Notice upon receipt of claim to reopen based on new and material evidence.

3.166 Notice upon receipt of claim for other benefits governed by part 3.

3.167 VA's duty to assist claimants in obtaining evidence.

**§ 3.160 Notice upon receipt of application for disability compensation.**

(a) *Compensation for service-connected disability.* VA will notify a claimant that information and evidence of the following is necessary to substantiate an original or reopened claim for service connection for a veteran's disability:

(1) *Active Duty.* (i) *Existence of a disability.* The veteran has a current physical or mental disability. This is established by medical treatment records, medical opinions, and evidence from non-medical persons about persistent and recurrent symptoms of disability they have observed.

(ii) *Inservice incurrence or aggravation.* Medical treatment records, medical opinions, and, in certain circumstances, evidence from non-medical persons show that the veteran had—

(A) An injury or disease that was incurred or aggravated in service;

(B) Symptoms that were noted during service or during an applicable presumptive period and that persisted

until diagnosis of an injury or disease causing the symptoms; or

(C) An event in service capable of causing injury or disease.

(iii) *Relationship between the current disability and an injury, disease, symptoms, or event during military service.* There is a relationship between the veteran's inservice disease, injury, symptoms, or event and the current disability, which is generally established by medical treatment records, medical opinions, or by use of a legal presumption that the disability is related to a particular type of military service, such as detention as a prisoner of war, participation in a radiation-risk activity, or service in Vietnam or the Southwest Asia theater of operations during the Gulf War.

(iv) *Extent of disability.* VA will examine the nature, duration, and severity of the veteran's symptoms and assign a disability rating from 0 percent to 100 percent by comparing the symptoms to the criteria in the VA Schedule for Rating Disabilities found in title 38, Code of Federal Regulations. This may be based on medical treatment records, medical opinions, statements from the veteran's employer about how the veteran's symptoms affect the veteran's ability to work and from other people about how the veteran's symptoms affect the veteran.

(2) *Active Duty for Training.* (i) *Existence of a disability.* The claimant has a current physical or mental disability. This is established by medical treatment records, medical opinions, and evidence from non-medical persons about persistent and recurrent symptoms of disability they have observed.

(ii) *Disability during active duty for training.* The claimant was disabled during active duty for training from—

(A) A disease or injury that was incurred or aggravated in line of duty, which is generally established by medical treatment records and medical opinions;

(B) Symptoms that were noted during active duty for training and that persisted until diagnosis of an injury or disease causing the symptoms, which is established by medical treatment records, medical opinions and competent non-medical evidence based on personal observations; or

(C) An event during active duty for training capable of causing injury or disease.

(iii) *Relationship between the current disability and disability during active duty for training.* The claimant's current disability is due to the disability suffered during active duty for training.

This is generally established by medical treatment records and medical opinions.

(iv) *Extent of disability.* VA will examine the nature, duration, and severity of the claimant's symptoms and assign a disability rating from 0 percent to 100 percent by comparing the symptoms to the criteria in the VA Schedule for Rating Disabilities found in title 38, Code of Federal Regulations. This may be based on medical treatment records, medical opinions, statements from the veteran's employer about how the disability affects the claimant's ability to work, and statements from other people about how the claimant's symptoms affect the claimant.

(3) *Inactive Duty Training.* (i) *Existence of a disability.* The claimant has a current physical or mental disability. This is established by medical treatment records, medical opinions, and evidence from non-medical persons about persistent and recurrent symptoms of disability they have observed.

(ii) *Disability during inactive duty training.* Medical treatment records, medical opinions, and competent non-medical evidence based on personal observations show that the claimant was disabled during inactive duty training from—

(A) An injury incurred or aggravated during inactive duty training;

(B) An acute myocardial infarction;

(C) A cardiac arrest; or

(D) A cerebrovascular accident.

(iii) *Relationship between the current disability and disability during inactive duty for training.* The claimant's current disability is due to the disability suffered during inactive duty training. This is generally established by medical treatment records, medical opinions, and competent non-medical evidence based on personal observations.

(iv) *Extent of disability.* VA will examine the nature, duration, and severity of the claimant's symptoms and assign a disability rating from 0 percent to 100 percent by comparing the symptoms to the criteria in the VA Schedule for Rating Disabilities found in title 38, Code of Federal Regulations. This may be based on medical treatment records, medical opinions, statements from the claimant's employer about how the disability affects the claimant's ability to work, and statements from other people about how the claimant's symptoms affect the claimant.

(b) *Compensation for Disability Caused or Aggravated by Service-Connected Disability (Secondary Service Connection)*—(1) *Existence of additional disability.* The veteran has a current physical or mental disability in addition to the veteran's service-connected

disability. This is established by medical treatment records, medical opinions, and evidence from non-medical persons about persistent and recurrent symptoms of disability they have observed.

(2) *Relationship between the additional disability and a service-connected disability.* The veteran's additional disability is related to the veteran's service-connected disability. This is generally established by medical treatment records and medical opinions.

(3) *Extent of disability.* VA will examine the nature, duration, and severity of the veteran's symptoms and assign a disability rating from 0 percent to 100 percent by comparing the symptoms to the criteria in the VA Schedule for Rating Disabilities found in title 38, Code of Federal Regulations. This may be based on medical treatment records, medical opinions, statements from the veteran's employer about how the additional disability affects the veteran's ability to work, and statements from other people about how the veteran's symptoms affect the veteran.

(c) *Disability caused by VA treatment, vocational rehabilitation, or compensated work therapy*—(1) *Existence of an additional disability or aggravation of existing injury or disease.* The veteran has an additional physical or mental disability or an aggravation of an existing injury or disease. This is established by medical treatment records, medical opinions, and evidence from non-medical persons about persistent and recurrent symptoms of disability they have observed.

(2) *Relationship between the additional disability or aggravation and VA treatment, VA vocational rehabilitation, or compensated work therapy.* The veteran's additional disability or aggravation of an existing injury or disease was caused by VA hospital care, medical or surgical treatment or examination, VA training or rehabilitation services, or participation in VA's compensated work therapy program. This is generally established by medical treatment records and medical opinions.

(3) *VA fault.* The additional disability or aggravation caused by VA hospital care, medical or surgical treatment or examination was the direct result of VA fault (carelessness, negligence, lack of proper skill, or error in judgment) or was the direct result of an event not reasonably foreseeable (*i.e.*, not an ordinary risk of the services provided). This requirement does not apply to claims based on VA training or rehabilitation services or compensated work therapy.

(4) *Extent of disability.* VA will examine the nature, duration, and severity of the veteran's symptoms and assign a disability rating from 0 percent to 100 percent by comparing the symptoms to the criteria in the VA Schedule for Rating Disabilities found in title 38, Code of Federal Regulations. This may be based on medical treatment records, medical opinions, statements from the veteran's employer about how the additional disability affects the veteran's ability to work, and statements from other people about how the veteran's symptoms affect the veteran.

(Authority: 38 U.S.C. 5103(a)(1) and (2))

**§ 3.161 Notice upon receipt of application for increased disability compensation.**

VA will notify a claimant that information and evidence of the following is necessary to substantiate the following types of claims for increased disability compensation:

(a) *Increased schedular rating for a service-connected disability—(1) Increase in extent of service-connected disability.* The veteran's service-connected disability has gotten worse or increased in severity. This is based on medical treatment records, medical opinions, and statements from non-medical persons about persistent and recurrent symptoms of disability they have observed.

(2) *Current extent of disability.* VA will examine evidence regarding the nature, duration, and severity of the veteran's symptoms and assign a disability rating from 0 percent to 100 percent by comparing the veteran's current symptoms to the criteria in the VA Schedule for Rating Disabilities found in title 38, Code of Federal Regulations. This may be based on medical treatment records, medical opinions, statements from the veteran's employer about how the additional disability affects the veteran's ability to work, and statements from other people about how the veteran's symptoms affect the veteran.

(b) *Total Disability Rating for Individual Unemployability.* VA will examine the evidence to determine whether a veteran is unable to secure and follow substantial gainful employment because of a service-connected disability rated at least 60 percent disabling or more than one service-connected disability with one disability rated at 40 percent or more and a combined rating of at least 70 percent, or whether the veteran is unemployable due to service-connected disability even if these ratings are not met. This may be based on medical treatment records, medical opinions, statements from the veteran's employer

about how the disability affects the veteran and the veteran's ability to work, and statements from other people about how the veteran's symptoms affect the veteran.

(c) *Temporary total disability due to hospitalization.* The veteran was hospitalized for treatment for a service-connected disability in a VA hospital or an approved hospital for more than 21 days or was hospitalized for observation for a service-connected disability at VA expense for more than 21 days. This is based on medical treatment records.

(d) *Temporary total disability due to surgery or other treatment.* The veteran received surgery at a VA or other approved hospital or outpatient facility for a service-connected disability and the surgery required convalescence for at least 1 month or resulted in severe postoperative residuals (such as incompletely healed surgical wounds, stumps of recent amputations, therapeutic immobilizations, house confinement, or required use of a wheelchair or crutches), or the veteran received treatment at a VA or other approved hospital or outpatient facility that resulted in immobilization by cast, without surgery, of at least one major joint. This is based on medical treatment records, particularly on reports of hospital discharge or release from outpatient treatment.

(e) *Aid and attendance or bedridden.* The information and evidence must show that, as a result of a service-connected disability, the veteran is in need of aid and attendance or confined to bed.

(1) *Need for aid and attendance or confinement.* The veteran requires the aid of another person to perform personal functions required in everyday living, such as bathing, feeding, or adjustment of prosthetics, or must remain in bed due to his or her disability or disabilities based on medical necessity and not based on a prescription of bed rest for purposes of convalescence or cure. This is shown by medical treatment records, medical opinions, and competent non-medical evidence based on personal observations.

(2) *Relationship between service-connected disability and need for aid and attendance or confinement.* The veteran's need for aid and attendance or confinement to bed is a result of a service-connected disability. This is shown by medical treatment records and medical opinions.

(f) *Permanently housebound—(1) Totally disabling service-connected disability.* The veteran has a totally disabling service-connected disability. This may be based on medical treatment

records, medical opinions, statements from the veteran's employer about how the disability affects the veteran's ability to work, and statements from other people about how the veteran's symptoms affect the veteran.

(2) *Nature of Confinement.* The veteran is substantially confined to the veteran's house, ward or clinical areas if institutionalized, or immediate premises. This is established by medical treatment records and medical opinions.

(3) *Relationship between confinement and service-connected disability.* The veteran's confinement is a result of service-connected disability or disabilities, which are reasonably certain to remain throughout the veteran's lifetime. This is generally established by medical treatment records and medical opinions.

(Authority: 38 U.S.C. 5103(a)(1) and (2))

**§ 3.162 Notice upon receipt of application for improved pension.**

VA will notify a claimant that information and evidence of the following is necessary to substantiate a claim for improved pension or increased pension:

(a) *Improved pension.* VA will notify a claimant that information and evidence of the following is necessary to substantiate a claim for improved pension—

(1) The veteran served during a period of war.

(2) The veteran is 65 years of age or older or permanently and totally disabled due to a nonservice-connected disability, which is shown by Social Security Administration records or medical treatment records, medical opinions, statements from the veteran's employer about how the disability affects the claimant and the veteran's ability to work, and statements from other people about how the veteran's symptoms affect the veteran. Permanently and totally disabled means that the veteran is:

(i) A patient in a nursing home for long-term care;

(ii) Receiving social security disability benefits;

(iii) Unemployable due to a disability reasonably certain to continue through the veteran's lifetime;

(iv) Suffering from a disability that is reasonably certain to continue through the veteran's lifetime and would make it impossible for the average person to follow a substantially gainful occupation; or

(v) Suffering from a disease or disorder that VA believes justifies a determination that people who have the disease or disorder are permanently and totally disabled.

(3) The claimant's annual income and net worth do not exceed certain limits.

(b) *Increased pension.* VA will notify a claimant that medical treatment records, medical opinions, and competent non-medical evidence based on personal observations must show that the claimant is in need of regular aid and attendance or is permanently housebound or, alternatively, the information and evidence must show that there is a change in the claimant's income or net worth.

(1) A claimant is in need of regular aid and attendance if the claimant—

(i) Has 5/200 visual acuity or less in both eyes;

(ii) Has concentric contraction of the visual field to 5 degrees or less in both eyes;

(iii) Is a patient in a nursing home because of mental or physical incapacity; or

(iv) Requires the aid of another person in order to perform personal functions of everyday living, such as bathing, feeding, or adjusting a prosthetic device.

(2) A claimant is permanently housebound if the claimant is substantially confined to the claimant's house or immediate premises, or ward or clinical area if institutionalized, because of a disability or disabilities and it is reasonably certain that the disability or disabilities will not improve during the claimant's lifetime.

(Authority: 38 U.S.C. 5103(a)(1) and (2))

### § 3.163 Notice upon receipt of application for survivor benefits.

VA will notify a claimant that information and evidence of the following is necessary to substantiate the following types of claims for survivor benefits and, in addition to the notice described in paragraphs (a) through (d) of this section, as applicable, VA will also provide each applicant for survivor benefits the notice described in paragraph (e) of this section:

(a) *Dependency and indemnity compensation—(1) Death related to active duty.* VA will notify the claimant that the information and evidence must show any of the following in order to substantiate a claim for dependency and indemnity compensation for death related to active duty:

(i) The veteran died while on active duty;

(ii) VA had granted the veteran service connection for a disease or injury and medical evidence shows that the service-connected disease or injury caused or contributed to the veteran's death; or

(iii) The veteran had a disease or injury that was incurred or aggravated

during active duty or was caused by an event during active duty, as shown by medical evidence, competent non-medical evidence based on personal observations, and use of applicable legal presumptions, and medical evidence shows that the disease or injury caused or contributed to the veteran's death.

(2) *Death related to active duty for training.* VA will notify the claimant that the information and evidence must show the following in order to substantiate a claim for dependency and indemnity compensation for death related to active duty for training:

(i) The veteran died during active duty for training;

(ii) VA had granted the veteran service connection for a disease or injury and medical evidence shows that the service-connected disease or injury caused or contributed to the veteran's death; or

(iii) The veteran was disabled during active duty for training due to a disease or injury incurred in the line of duty, as shown by medical evidence and competent non-medical evidence based on personal observation, and medical evidence shows that the disease or injury caused or contributed to the veteran's death.

(3) *Death related to inactive duty training.* VA will notify the claimant that the information and evidence must show the following in order to substantiate a claim for dependency and indemnity compensation for death related to inactive duty training:

(i) The veteran died during inactive duty training due to an injury incurred or aggravated in line of duty or an acute myocardial infarction, cardiac arrest or cerebrovascular accident during such training, as shown by medical evidence and competent non-medical evidence based on personal observations; or

(ii) The veteran had a disability that was due to an injury incurred or aggravated during inactive duty training or an acute myocardial infarction, cardiac arrest, or cerebrovascular accident during such training, as shown by medical evidence and competent non-medical evidence based on personal observations, and medical evidence shows that the injury, acute myocardial infarction, cardiac arrest, or cerebrovascular accident caused or contributed to the veteran's death.

(4) *Death from nonservice-connected disability.* In addition to providing notice under paragraphs (a)(1), (a)(2), or (a)(3) of this section as appropriate based on the veteran's service, VA will notify claimants for dependency and indemnity compensation that, if the veteran did not die from a service-connected disability, dependency and

indemnity compensation is payable if the information and evidence shows that the veteran was receiving or was entitled to receive compensation from VA for a service-connected disability that was rated totally disabling for—

(i) At least 10 years immediately preceding death;

(ii) At least 5 years immediately preceding death and continuing since the veteran's release from active duty; or

(iii) At least 1 year immediately preceding death, if the veteran was a former prisoner of war who died after September 30, 1999.

(5) *Death caused by VA treatment, vocational rehabilitation, or compensated work therapy.* VA will notify the claimant that the information and evidence must show the following in order to substantiate a claim for dependency and indemnity compensation for death caused by VA treatment, vocational rehabilitation or compensated work therapy:

(i) The veteran's death was caused by VA hospital care, medical or surgical treatment or examination, VA training or rehabilitation services, or participation in VA's compensated work therapy program. This is generally established by medical treatment records and medical opinions.

(ii) The veteran's death caused by VA hospital care, medical or surgical treatment or examination was the direct result of VA fault (carelessness, negligence, lack of proper skill, or error in judgment) or was the direct result of an event not reasonably foreseeable (*i.e.*, not an ordinary risk of the services provided). This requirement does not apply to claims based on VA training or rehabilitation services or compensated work therapy.

(b) *Supplemental dependency and indemnity compensation.* VA will notify the claimant that the following evidence is needed to substantiate a claim for supplemental dependency and indemnity compensation:

(1) *For a child.* Medical treatment records and medical opinions must show that a veteran's child, before his or her 18th birthday, became permanently incapable of self-support due to a mental or physical disability.

(2) *For parents.* Medical treatment records and medical opinions must show that a veteran's parent is in need of the aid and attendance, which means that the parent—

(i) Has corrected visual acuity of 5/200 or less, in both eyes, or concentric contraction of the visual field to 5 degrees or less; or

(ii) Is a patient in a nursing home because of mental or physical incapacity; or

(iii) Requires the aid of another person in order to perform personal functions required in everyday living, such as bathing, feeding, and dressing.

(c) *Improved pension for veteran's surviving spouse or child.* VA will notify a veteran's surviving spouse or child claiming improved pension that information and evidence of the following is needed to substantiate the claim:

(1) The veteran served in the active military, naval, or air service—

(i) For ninety days or more during a period of war;

(ii) For ninety consecutive days, at least one of which was during a period of war;

(iii) For any length of time during a period of war and was discharged or released from such service for a service-connected disability; or

(iv) For any length of time during a period of war and at the time of death was receiving or was entitled to receive VA disability compensation or service department retirement pay for a service-connected disability; and

(2) The claimant's annual income and net worth do not exceed certain limits.

(d) *Increased pension for veteran's surviving spouse.* VA will notify a veteran's surviving spouse claiming increased pension that information and evidence of the following is needed to substantiate the claim:

(1) Medical treatment records, medical opinions, and competent non-medical evidence based on personal observations must show that the surviving spouse is—

(i) In need of regular aid and attendance, which means the surviving spouse—

(A) Has visual acuity of 5/200 or less in both eyes;

(B) Has concentric contraction of the visual field to 5 degrees or less in both eyes;

(C) Is a patient in a nursing home because of mental or physical incapacity; or

(D) Requires the aid of another person in order to perform personal functions of everyday living, such as bathing, feeding, or adjusting a prosthetic device.

(2) Permanently housebound, which means that the surviving spouse is substantially confined to the house or immediate premises because of a disability or disabilities and it is reasonably certain that the disability or disabilities will not improve during the claimant's lifetime.

(e) *Accrued benefits.* VA will notify a claimant for accrued benefits and a claimant for survivor benefits that the following information and evidence is

necessary to substantiate a claim for periodic monetary VA benefits that were due, but not paid to, an individual before the individual's death.

(1) The benefits were awarded to the individual by a VA rating or decision before the individual died; or

(2) Evidence in VA's possession on or before the date of the individual's death, even if such evidence was not physically located in the VA claims folder on or before the date of death, shows that the individual had applied for and was entitled to the benefits.

(3) Accrued benefits are paid to the following persons in the following order of priority:

(i) Veteran's surviving spouse.

(ii) Veteran's children (in equal shares).

(iii) Veteran's surviving dependent parents (in equal shares) or the surviving dependent parent if only one is living.

(Authority: 38 U.S.C. 5103(a)(1) and (2))

### § 3.164 Notice upon receipt of application for special benefits.

VA will notify a claimant that the following information and evidence is necessary to substantiate the claims for special benefits.

(a) *Specially Adapted Housing.* For purposes of a claim for specially adapted housing—

(1) *Permanent and total disability.* Medical treatment records and medical opinions must show that the veteran or servicemember on active duty has a permanent disability resulting from—

(i) Loss, or loss of use, of both lower extremities requiring the use of braces, crutches, canes, or a wheelchair to move from place to place;

(ii) Blindness in both eyes so that the veteran can see only light, together with the loss, or loss of use of one lower extremity;

(iii) Loss, or loss of use, of one lower extremity, together with a disease or injury that affects the veteran's balance or ability to move forward and requires the use of braces, crutches, canes, or a wheelchair in order to move from place to place;

(iv) Loss, or loss of use, of one lower extremity, together with loss or loss of use of one upper extremity that affects the veteran's balance or ability to move forward and requires the use of braces, crutches, canes, or a wheelchair in order to move from place to place;

(v) Loss, or loss of use, of both upper extremities that prevents the veteran from using the arms at or above the elbows; or

(vi) Severe burn injury.

(2) *Cause of disability.* Medical treatment records, medical opinions, or

use of a legal presumption that the disability is related to a particular type of military service, such as detention as a prisoner of war, participation in a radiation-risk activity, or service in Vietnam or the Southwest Asia theater of operations during the Gulf War show that the veteran or servicemember suffered the disability as a result of—

(i) An injury, disease, or event in line of duty in the active military, naval or air service; or

(ii) VA hospital care, medical or surgical treatment or examination under circumstances involving VA carelessness, negligence, lack of proper skill or error in judgment or an event not reasonably foreseeable, or

(iii) VA training or rehabilitation services or participation in VA's compensated work therapy program.

(b) *Special Home Adaptation Grant.* For purposes of a claim for a special home adaptation grant—

(1) *Nature of disability.* Medical treatment records and medical opinions must show that the veteran or servicemember on active duty has a permanent disability resulting from—

(i) Blindness in both eyes with 5/200 visual acuity or less;

(ii) Anatomical loss or loss of use of both hands; or

(iii) Severe burn injury.

(2) *Cause of disability.* Information and evidence must show that the veteran or servicemember suffered the disability as a result of—

(i) An injury, disease, or event in line of duty in the active military, naval or air service;

(ii) VA hospital care, medical or surgical treatment or examination under circumstances involving VA carelessness, negligence, lack of proper skill or error in judgment or an event not reasonably foreseeable; or

(iii) VA training or rehabilitation services or participation in VA's compensated work therapy program.

(c) *Allowance for Automobile or Adaptive Equipment.* For purposes of a claim for an automobile allowance or adaptive equipment—(1) *Eligibility for Automobile allowance and adaptive equipment.* (i) *Nature of Disability.* Medical treatment records and medical opinions must show that the veteran is entitled to compensation for, or

servicemember on active duty has, a current disability resulting from—

(A) The loss, or permanent loss of use, of at least a foot or a hand; or

(B) Permanent impairment of vision in both eyes, resulting in vision of 20/200 or less in the better eye with glasses or vision of 20/200 or better, if there is a severe defect in peripheral vision.

(ii) *Cause of disability.* Information and evidence must show that the

veteran or servicemember suffered the disability as a result of—

(A) An injury, disease, or event in line of duty in the active military, naval or air service;

(B) VA hospital care, medical or surgical treatment or examination under circumstances involving VA carelessness, negligence, or lack of proper skill or judgment or an event not reasonably foreseeable; or

(C) VA training or rehabilitation services or participation in VA's compensated work therapy program.

(2) *Eligibility for adaptive equipment only.* (i) *Nature of disability.* Medical treatment records and medical opinions must show that the veteran has a disability resulting from ankylosis of at least one knee or one hip.

(ii) *Cause of disability.* Information and evidence must show that the veteran suffered the disability as a result of—

(A) An injury, disease, or event in line of duty in the active military, naval or air service;

(B) VA hospital care, medical or surgical treatment or examination under circumstances involving VA carelessness, negligence, or lack of proper skill or error in judgment or an event not reasonably foreseeable; or

(C) VA training or rehabilitation services or participation in VA's compensated work therapy program.

(d) *Clothing Allowance.* For purposes of a claim for a clothing allowance—

(1) Information and evidence must show that the veteran suffered a disability as a result of—

(i) An injury, disease, or event in line of duty in the active military, naval or air service;

(ii) VA hospital care, medical or surgical treatment or examination under circumstances involving VA carelessness, negligence, lack of proper skill or error in judgment or an event not reasonably foreseeable; or

(iii) VA training or rehabilitation services or participation in VA's compensated work therapy program; and

(2) The veteran wears or uses a prosthetic or orthopedic appliance because the qualifying disability that tends to wear out or tear the veteran's clothing, or the veteran uses prescription medication for a skin condition which is due to a qualifying disability and the medication causes irreparable damage to the veteran's outer garments. This is based on a VA examination or hospital report or an examination report from a government or private facility.

(e) *Monetary allowance for individuals with spina bifida born to*

*Vietnam veterans.* For purposes of a claim for a monetary allowance for an individual with spina bifida born to a Vietnam veteran—

(1) *Eligible individual.* A monetary allowance is payable to or for an individual, regardless of age or marital status if evidence such as service department records and a birth certificate, church record of baptism, affidavit or certified statement from a physician or midwife present during the individual's birth, or notarized copy of a Bible or other family record containing reference to the birth shows that—

(i) The individual's biological father or mother is or was a veteran who performed active military, naval, or air service in the Republic of Vietnam during the period beginning on January 9, 1962, and ending on May 7, 1975, including service in the waters offshore and service in other locations if the conditions of service involved duty or visitation in the Republic of Vietnam; and

(ii) The individual was conceived on or after the date on which the veteran first served in the Republic of Vietnam.

(2) *Spina bifida.* Medical treatment records and medical opinions must show that the individual has any form or manifestation of spina bifida except spina bifida occulta.

(3) *Extent of current disability.* VA will examine the nature and severity of the individual's disability due to spina bifida and assign an evaluation of Level 1 to Level 3 by comparing the individual's symptoms to the criteria in § 3.814. This may be based on medical treatment records and reports and statements from the individual's employer and other people about how the disability affects the individual's ability to work and function.

(f) *Monetary allowance for individuals with certain birth defects born to female Vietnam veterans.* For purposes of a claim for a monetary allowance for an individual with certain birth defects born to a female Vietnam veteran—

(1) *Eligible individual.* A monetary allowance is payable to or for an individual, regardless of age or marital status if evidence such as service department records and a birth certificate, church record of baptism, affidavit or certified statement from a physician or midwife present during the individual's birth, or notarized copy of a Bible or other family record containing reference to the birth shows that—

(i) The individual's biological mother is or was a veteran who performed active military, naval, or air service in the Republic of Vietnam during the period beginning February 28, 1961, and ending on May 7, 1975, including

service in the waters offshore and service in other locations if the conditions of service involved duty or visitation in the Republic of Vietnam; and

(ii) The individual was conceived on or after the date on which the veteran first served in the Republic of Vietnam.

(2) *Covered birth defect.* Medical treatment records and medical opinions must show that the individual has any birth defect(s) identified by VA as a birth defect that is associated with service of women Vietnam veterans in the Republic of Vietnam during the Vietnam era.

(3) *Extent of current disability.* VA will examine the nature and severity of the individual's disability due to the birth defect(s) and assign an evaluation of Level 0 to Level 4 by comparing the individual's symptoms to the criteria in § 3.815. This may be based on medical treatment records and reports and statements from the individual's employer and other people about how the disability affects the individual's ability to work and function.

(Authority: 38 U.S.C. 5103(a)(1) and (2))

**§ 3.165 Notice upon receipt of claim to reopen based on new and material evidence.**

VA will provide notice that the following information and evidence is necessary to reopen a previously denied claim as provided in § 3.156 in addition to the notice described in §§ 3.159 through 3.164.

(a) New evidence is existing evidence not previously submitted to VA.

(b) Material evidence is existing evidence that, by itself or when considered with previous evidence of record, relates to an unestablished fact necessary to substantiate the claim.

(c) To be new and material, evidence must raise a reasonable possibility of substantiating the claim.

(Authority: 38 U.S.C. 5103(a)(1) and (2))

**§ 3.166 Notice upon receipt of claim for other benefits governed by part 3.**

Subject to § 3.159, if VA receives a claim for any benefit governed by part 3 of this title that is not otherwise addressed in §§ 3.160 through 3.164, VA will provide notice appropriate to the type of benefit sought describing the evidence and information necessary to substantiate the claim. Such notice shall be consistent with the statutory and regulatory eligibility criteria for the benefit.

(Authority: 38 U.S.C. 5103(a)(1) and (2))

**§ 3.167 VA's duty to assist claimants in obtaining evidence.**

(a) *Definitions.* For purposes of this section, the following definitions apply:

(1) *Competent medical evidence* means evidence provided by a person who is qualified through education, training, or experience to offer medical diagnoses, statements, or opinions. Competent medical evidence may also mean statements conveying sound medical principles found in medical treatises. It would also include statements contained in authoritative writings such as medical and scientific articles and research reports or analyses.

(2) *Competent lay evidence* means any evidence not requiring that the proponent have specialized education, training, or experience. Lay evidence is competent if it is provided by a person who has knowledge of facts or circumstances and conveys matters that can be observed and described by a lay person.

(3) *Event* means one or more incidents associated with places, types, and circumstances of service giving rise to disability.

(b) Upon receipt of a substantially complete application for benefits, VA will make reasonable efforts to help a claimant obtain evidence necessary to substantiate the claim. In addition, VA will give the assistance described in paragraphs (b)(1), (b)(2), and (b)(3) of this section to an individual attempting to reopen a finally decided claim. VA will not pay any fees charged by a custodian to provide records requested.

(1) *Obtaining records not in the custody of a Federal department or agency.* VA will make reasonable efforts to obtain relevant records not in the custody of a Federal department or agency, to include records from State or local governments, private medical care providers, current or former employers, and other non-Federal governmental sources. Such reasonable efforts will generally consist of an initial request for the records and, if the records are not received, at least one follow-up request. A follow-up request is not required if a response to the initial request indicates that the records sought do not exist or that a follow-up request for the records would be futile. If VA receives information showing that subsequent requests to this or another custodian could result in obtaining the records sought, then reasonable efforts will include an initial request and, if the records are not received, at least one follow-up request to the new source or an additional request to the original source.

(i) The claimant must cooperate fully with VA's reasonable efforts to obtain

relevant records from non-Federal agency or department custodians. The claimant must provide enough information to identify and locate the existing records, including the person, company, agency, or other custodian holding the records; the approximate time frame covered by the records; and, in the case of medical treatment records, the condition for which treatment was provided.

(ii) If necessary, the claimant must authorize the release of existing records in a form acceptable to the person, company, agency, or other custodian holding the records.

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

(2) *Obtaining records in the custody of a Federal department or agency.* VA will make as many requests as are necessary to obtain relevant records from a Federal department or agency. These records include but are not limited to military records, including service medical records; medical and other records from VA medical facilities; records from non-VA facilities providing examination or treatment at VA expense; and records from other Federal agencies, such as the Social Security Administration. VA will end its efforts to obtain records from a Federal department or agency only if VA concludes that the records sought do not exist or that further efforts to obtain those records would be futile. Cases in which VA may conclude that no further efforts are required include those in which the Federal department or agency advises VA that the requested records do not exist or the custodian does not have them.

(i) The claimant must cooperate fully with VA's reasonable efforts to obtain relevant records from Federal agency or department custodians. If requested by VA, the claimant must provide enough information to identify and locate the existing records, including the custodian or agency holding the records; the approximate time frame covered by the records; and, in the case of medical treatment records, the condition for which treatment was provided. In the case of records requested to corroborate a claimed stressful event in service, the claimant must provide information sufficient for the records custodian to conduct a search of the corroborative records.

(ii) If necessary, the claimant must authorize the release of existing records in a form acceptable to the custodian or agency holding the records.

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

(3) *Obtaining records in compensation claims.* In a claim for

disability compensation, VA will make efforts to obtain the claimant's service medical records, if relevant to the claim; other relevant records pertaining to the claimant's active military, naval or air service that are held or maintained by a governmental entity; VA medical records or records of examination or treatment at non-VA facilities authorized by VA; and any other relevant records held by any Federal department or agency. The claimant must provide enough information to identify and locate the existing records including the custodian or agency holding the records; the approximate time frame covered by the records; and, in the case of medical treatment records, the condition for which treatment was provided.

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

(4) *Providing medical examinations or obtaining medical opinions.*

(i) In a claim for disability compensation, VA will provide a medical examination or obtain a medical opinion based upon a review of the evidence of record if VA determines it is necessary to decide the claim. A medical examination or medical opinion is necessary if the information and evidence of record does not contain sufficient competent medical evidence to decide the claim, but:

(A) Contains competent lay or medical evidence of a current diagnosed disability or persistent or recurrent symptoms of disability;

(B) Establishes that the veteran suffered an event, injury or disease in service, or has a disease or symptoms of a disease listed in §§ 3.309, 3.313, 3.316, and 3.317 manifesting during an applicable presumptive period provided the claimant has the required service or triggering event to qualify for that presumption; and

(C) Indicates that the claimed disability or symptoms may be associated with the established event, injury, or disease in service or with another service-connected disability.

(ii) Paragraph (b)(4)(i)(C) of this section could be satisfied by competent evidence showing post-service treatment for a condition, or other possible association with military service.

(iii) Paragraph (b)(4) of this section applies to a claim to reopen a finally adjudicated claim only if new and material evidence is presented or secured.

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

(c) *Circumstances where VA will refrain from or discontinue providing assistance.* VA will refrain from

providing assistance in obtaining evidence for a claim if the substantially complete application for benefits indicates that there is no reasonable possibility that any assistance VA would provide to the claimant would substantiate the claim. VA will discontinue providing assistance in obtaining evidence for a claim if the evidence obtained indicates that there is no reasonable possibility that further assistance would substantiate the claim. Circumstances in which VA will refrain from or discontinue providing assistance in obtaining evidence include, but are not limited to:

(1) The claimant's ineligibility for the benefit sought because of lack of qualifying service or other lack of legal eligibility;

(2) Claims that are inherently incredible or clearly lack merit; and

(3) An application requesting a benefit to which the claimant is not entitled as a matter of law.

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

(d) *Duty to notify claimant of inability to obtain records.*

(1) If VA makes reasonable efforts to obtain relevant non-Federal records but is unable to obtain them, or after continued efforts to obtain Federal records concludes that it is reasonably certain they do not exist or further efforts to obtain them would be futile, VA will provide the claimant with oral or written notice of that fact. VA will make a record of any oral notice conveyed to the claimant. For non-Federal records requests, VA may provide the notice at the same time it makes its final attempt to obtain the relevant records. In either case, the notice must contain the following information:

(i) The identity of the records VA was unable to obtain;

(ii) An explanation of the efforts VA made to obtain the records;

(iii) A description of any further action VA will take regarding the claim, including, but not limited to, notice that VA will decide the claim based on the evidence of record unless the claimant submits the records VA was unable to obtain; and

(iv) A notice that the claimant is ultimately responsible for providing the evidence.

(2) If VA becomes aware of the existence of relevant records before deciding the claim, VA will notify the claimant of the records and request that the claimant provide a release for the records. If the claimant does not provide any necessary release of the relevant records that VA is unable to obtain, VA

will request that the claimant obtain the records and provide them to VA.

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

(e) 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))

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 82

[EPA-HQ-OAR-2009-0566; FRL-9091-6]

RIN-2060-AP59

### Protection of Stratospheric Ozone: Allocation of Essential Use Allowances for Calendar Year 2010

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

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to allocate essential use allowances for import and production of Class I ozone-depleting substances (ODSs) for calendar year 2010. Essential use allowances enable a person to obtain controlled Class I ODSs through an exemption to the regulatory ban on the production and import of these chemicals, which became effective as of January 1, 1996. EPA allocates essential use allowances for production or import of a specific quantity of Class I substances solely for the designated essential purpose. The proposed allocation in this action is 30.0 metric tons (MT) of chlorofluorocarbons (CFCs) for use in metered dose inhalers (MDIs) for 2010.

**DATES:** Written comments on this proposed rule must be received by the EPA Docket on or before January 11, 2010, unless a public hearing is requested. Comments must then be received on or before 30 days following the public hearing. Any party requesting a public hearing must notify the contact listed below under **FOR FURTHER INFORMATION CONTACT** by 5 p.m. Eastern Standard Time on December 16, 2009. If a hearing is held, it will take place on December 28, 2009 at EPA headquarters in Washington, DC. EPA will post a notice on our Web site (<http://www.epa.gov/ozone/strathome.html>) announcing further information on the hearing if it is requested.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2009-0566, by one of the following methods:

- <http://www.regulations.gov>: Follow the on-line instructions for submitting comments.

- *E-mail:* [A-and-R-docket@epa.gov](mailto:A-and-R-docket@epa.gov).

- *Fax:* 202-566-9744.

- *Mail:* Air Docket, Environmental Protection Agency, Mailcode 2822T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

- *Hand Delivery or Courier:* Deliver your comments to: EPA Air Docket, EPA West, 1301 Constitution Avenue, NW., Room 3334, Mail Code 2822T, Washington, DC 20460. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

*Instructions:* Direct your comments to Docket ID No. EPA-HQ-OAR-2009-0566. EPA's policy is that all comments received by the docket will be included in the public docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information through <http://www.regulations.gov> or e-mail that you consider to be CBI or otherwise protected. If you would like the Agency to consider comments that include CBI, EPA recommends that you submit the comments to the docket that exclude the CBI portion but that you provide a complete version of your comments, including the CBI, to the person listed under **FOR FURTHER INFORMATION CONTACT** below. The <http://www.regulations.gov> Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through <http://www.regulations.gov> your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of