Dated: January 18, 1995.

W.P. Leahy,

Rear Admiral, U.S. Coast Guard Commander, Seventh Coast Guard District.

[FR Doc. 95–2650 Filed 2–2–95; 8:45 am]

BILLING CODE 4910–14–M

DEPARTMENT OF EDUCATION

34 CFR Parts 74 and 75

Administration of Grants and Agreements With Institutions of Higher Education, Hospitals, and other Non-Profit Organizations; Direct Grant Programs

AGENCY: Department of Education.

ACTION: Final regulations.

SUMMARY: The Secretary amends 34 CFR parts 74 and 75 to add the Office of Management and Budget (OMB) control numbers to certain sections of the regulations. Those sections contain information collection requirements approved by OMB. The Secretary takes this action to inform the public that these requirements have been approved.

EFFECTIVE DATE: These regulations are effective on February 3, 1995.

FOR FURTHER INFORMATION CONTACT: Greg Vick, U. S. Department of Education, 600 Independence Avenue, S.W., Room 3636, Regional Office Building 3, Washington, D.C. 20202. Telephone (202) 708–8199. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: On June 10, 1994, final regulations for Direct Grant Programs (part 75) were published in the **Federal Register** at 59 FR 30258, and on July 6, 1994, final regulations for the Administration of Grants and Agreements with Institutions of Higher Education, Hospitals, and other Non-Profit Organizations (part 74) were published in the **Federal Register** at 59 FR 34722. Compliance with information collection requirements in 34 CFR 74.12, 74.21, 74.25, 74.34, 74.44, 74.45, 74.46, 74.47, 74.51, 74.52, 74.53, 74.71, 74.72, 75.118 and 75.590 was delayed until those requirements were approved by OMB under the Paperwork Reduction Act of 1980. OMB approved the information collection requirements in the regulations for part 75 on June 3, 1994 and for part 74 on July 12, 1994.

Waiver of Proposed Rulemaking

In accordance with the Administrative Procedure Act (5 U.S.C. 553), it is the practice of the Secretary to offer interested parties the opportunity to comment on proposed regulations. However, the publication of OMB control numbers is purely technical and does not establish substantive policy. Therefore, the Secretary has determined under 5 U.S.C. 553(b)(B), that proposed rulemaking is unnecessary and contrary to the public interest and that a delayed effective date is not required under 5 U.S.C. 553(d)(3).

List of Subjects

34 CFR Part 74

Administrative practice and procedure, Education Department, Grant programs-education, Grant administration, Hospitals, Institutions of higher education, Non-profit organizations, Reporting and recordkeeping requirements.

34 CFR Part 75

Education Department, Discretionary grant programs, Continuation funding, Grant administration, Reporting and recordkeeping requirements, Performance reports, Unobligated funds.

Dated: January 27, 1995.

Donald R. Wurtz,

Chief Financial Officer.

The Secretary amends Parts 74 and 75 of Title 34 of the Code of Federal Regulations as follows:

PART 74—ADMINISTRATION OF GRANTS AND AGREEMENTS WITH INSTITUTIONS OF HIGHER EDUCATION, HOSPITALS, AND OTHER NON-PROFIT ORGANIZATIONS

1. The authority citation for part 74 continues to read as follows:

Authority: 20 U.S.C. 1221e–3(a)(1) and 3474; OMB Circular A–110, unless otherwise noted.

2. Sections 74.12, 74.21, 74.25, 74.34, 74.44, 74.45, 74.46, 74.47, 74.51, 74.52, 74.53, 74.71, and 74.72 are amended by adding the OMB control number at the end of these sections to read as follows: ''(Approved by the Office of Management and Budget under control number 1880–0513)''

PART 75—DIRECT GRANT PROGRAMS

3. The authority citation for part 75 continues to read as follows:

Authority: 20 US.C. 1221e-3(a)(1) and 3474, unless otherwise noted.

§ 75.118 [Amended]

§ 75.599 [Amended]

4. Sections 75.118 and 75.590 are amended by adding the OMB control number at the end of these sections to read as follows: ''(Approved by the Office of Management and Budget under control number 1875–0102)''

[FR Doc. 95–2659 Filed 2–2–95; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900–AH35

Compensation for Certain Undiagnosed Illnesses

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends the Department of Veterans Affairs (VA) adjudication regulations to authorize compensation for disabilities resulting from the undiagnosed illnesses of Persian Gulf veterans. This amendment provides the necessary regulatory framework to allow the Secretary to pay compensation under the authority granted by the Persian Gulf War Veterans' Benefits Act.

EFFECTIVE DATE: November 2, 1994, the effective date of Title I of Public Law 103–446.

FOR FURTHER INFORMATION CONTACT: Steven Thornberry, Consultant, Regulations Staff, Compensation and Pension Service, Veterans Benefits Administration, 810 Vermont Avenue, NW, Washington, DC 20420, telephone (202) 273–7210.

SUPPLEMENTARY INFORMATION: ''The Persian Gulf War Veterans' Benefits Act,'' Title I of Public Law 103–446, authorizes the Secretary of Veterans Affairs to compensate any Persian Gulf veteran suffering from a chronic disability resulting from an undiagnosed illness or combination of undiagnosed illnesses that became manifest either during active duty in the Southwest Asia theater of operations during the Persian Gulf War or to a degree of 10 percent or more within a presumptive period following such service, as determined by the Secretary. On December 8, 1994, VA published a proposed rule to implement the statute (59 FR 63283–85). We requested that comments to the proposed rule be submitted on or before January 9, 1995. We received 10 comments.

We had proposed that, for the purposes of § 3.317, a disability resulting from an undiagnosed illness would be considered chronic if it had existed for 6 months or more. One commenter recommended that VA consider disabilities subject to

intermittent periods of improvement and worsening over a 6-month period as chronic.

VA agrees that including this concept in the rule will promote clarity and ensure that the criteria for chronicity are consistently applied. Therefore, we have revised § 3.317(a) as the commenter suggested.

Another commenter recommended that the rule specify the point from which VA would measure chronicity, i.e., forward from the date symptoms were first reported or backward from date of claim.

The 6-month period of chronicity will be measured from the earliest date the symptoms of the disability became manifest, whether as reported and documented during the course of a medical examination or as established by other, non-medical evidence. In order to ensure proper understanding, we have revised § 3.317(a) to clarify this issue.

Another commenter objected to defining a chronic disease as one which has existed for at least 6 months and suggested that chronicity be determined on the basis of clinical and laboratory findings and application of the criteria for a showing of chronic diseases in 38 CFR 3.303(b).

VA does not agree. The criteria of § 3.303(b) require a combination of manifestations sufficient to identify the disease entity and sufficient observation to establish chronicity at the time. So long as we are dealing with a known disease whose clinical course is familiar, those criteria are appropriate. In our judgment, however, they are not appropriate for dealing with an undiagnosed illness, which cannot be associated with a known disease process and the clinical course of which cannot be predicted. In these cases, it is essential to establish an objective indicator of chronicity to ensure that the same standard will be applied in every case. Therefore, we have adopted 6 months, a period commonly accepted within the medical community for that purpose, as the standard for determining chronicity.

One commenter recommended that the regulation include a statement that objective indications of disability mean both ''signs'' in the medical sense and non-medical indicators capable of independent verification, as VA stated in the preamble to the proposed rule.

We agree with the commenter's recommendation and have amended § 3.317(a) accordingly.

Another commenter suggested that the regulation explicitly state how many ''signs or symptoms'' of undiagnosed illness must be present for a veteran to be eligible for compensation under § 3.317. The commenter stated that it appears that VA would accept even a single symptom as sufficient to qualify.

The commenter is correct in assuming that a single symptom or sign may be sufficient to establish entitlement under § 3.317, provided it is determined to be the result of an undiagnosed illness. This was intended by our proposed § 3.317(a)(1): ''* * * objective indications of chronic disability * * * manifested by *one or more* signs and symptoms * * *'' (emphasis added). However, as further clarification, we have amended the words ''signs and symptoms'' to read ''signs or symptoms.''

The proposed regulation, as required by the statute, contained a list of 13 categories of signs and symptoms which might be manifestations of undiagnosed illnesses. One commenter said that it was not clear why VA considered some of the 13 signs and symptoms listed at § 3.317(b) undiagnosable. As an example, the commenter referred to fatigue lasting longer than 6 months as having a known diagnosis, already recognized by VA, of chronic fatigue syndrome (CFS).

The signs and symptoms listed at § 3.317(b) represent possible manifestations of undiagnosed illnesses. However, the commenter's implication that a medically verifiable sign of an illness constitutes a diagnosis of a specific disease is not correct. A ''disease'' is manifested by a characteristic set of symptoms and signs (*Dorland's Illustrated Medical Dictionary*, 27th ed.). A single sign or symptom may be among the characteristic signs and symptoms of more than one disease, depending on any other signs and symptoms with which it appears. Many Persian Gulf veterans, however, have come forward with signs and symptoms which are not characteristic of any known disease.

The commenter's assertion that fatigue lasting longer than 6 months by itself equates to CFS is also incorrect. VA has adopted criteria for CFS similar to those contained in guidelines published by the U.S. Department of Health and Human Services (HHS), which require a combination of several major and minor criteria to establish a diagnosis of CFS (see the **Federal Register** of November 29, 1994, 59 FR 60901). The major criteria include fatigue so severe as to reduce daily activities below 50 percent of the usual, pre-illness level for at least 6 months. Fatigue of a lesser severity, which does not last for 6 months, or which is not accompanied by the major or minor criteria recognized by VA, would not support a diagnosis of CFS. If that fatigue does not fall among the characteristic signs and symptoms of another disease, it certainly might indicate the presence of an undiagnosed illness.

This same commenter stated that VA has a working definition of ''Persian Gulf Syndrome'' that lists many of the 13 signs and symptoms listed at § 3.317(b) and wondered why this ''syndrome'' is not cited in that paragraph.

''Persian Gulf Syndrome'' is not a disease entity currently recognized by VA or commonly accepted within the medical community. VA has, in fact, been unable to establish a single ''working definition,'' and any working definition, by its very nature, would not find a firm basis in the current scientific and medical evidence and, in our judgment, should not be used to establish entitlement under the provisions of this rule. The purpose of this rule making is not to define by regulation what the medical community has yet to identify or define, but rather to establish criteria for paying compensation to Persian Gulf veterans suffering from chronic disabilities resulting from undiagnosed illnesses.

One commenter recommended that § 3.317(b) specify that other signs and symptoms might qualify as possible manifestations of undiagnosed illness.

The list at § 3.317(b) is simply a guideline presenting the symptoms and signs which have been encountered in over 17,000 completed and analyzed examinations of participants in VA's Persian Gulf Health Registry. The categories are broad and encompass a wide range of conditions and complaints. Section 3.317(b) itself clearly indicates that this list is not exclusive, and we do not believe that revising the language would make the point any clearer.

Another commenter stated that many Persian Gulf veterans also complained of hair loss and memory loss and requested that VA clarify whether these conditions are encompassed by the 13 listed categories.

Hair loss is included within the category ''signs and symptoms involving skin'' (§ 3.317(b)(2)), and memory loss is included within the category ''neuropsychological signs or symptoms'' (§ 3.317(b)(7)). This is consistent with current VA rating procedures, and we see no need to make the list more specific, since any attempts to expand the list and make it exclusive might inadvertently omit conditions that could be manifestations of undiagnosed illnesses.

One commenter recommended that VA alter the wording of proposed § 3.317(a)(3) (§ 3.317(a)(4) in the final rule), which provides that VA will evaluate chronic disabilities of undiagnosed illnesses using the criteria of VA's Rating Schedule for a disease or injury in which ''the functions affected, anatomical localization, and symptomatology are similar,'' to read ''the functions affected, anatomical localization, *or* symptomatology.''

Since we intend to allow rating specialists enough flexibility to rate as accurately and fairly as possible, we have amended the language as the commenter suggested.

This same commenter also recommended that VA develop full rating criteria specific to the undiagnosed illnesses of Persian Gulf veterans, and covering the full range of physiological and psychological disabilities being reported.

Although Persian Gulf veterans have reported that they are suffering from a variety of signs and symptoms, the scientific and medical communities have been unable to identify a single disease process and, in fact, have suggested that more than one disease category may be involved. Our purpose in this rule making is to authorize compensation for the *disabilities* resulting from the undiagnosed illnesses, and, in our judgment, the criteria in the Rating Schedule are adequate to evaluate any disabilities which may arise.

One commenter recommended that VA revise § 3.317 to specify that service connection may be recognized for aggravation of a preexisting undiagnosed illness during service in the Southwest Asia theater of operations or during the presumptive period.

VA does not agree. In enacting Public Law 103–446, Congress authorized VA to compensate Persian Gulf veterans who suffer chronic disabilities resulting from undiagnosed illnesses that became manifest during active service in the Southwest Asia theater of operations or within a presumptive period thereafter, as determined by the Secretary. It would exceed the Secretary's statutory authority to compensate for aggravation of disabilities resulting from preexisting undiagnosed illnesses. Furthermore, since the course of an undiagnosed illness cannot be predicted, it would be impossible to determine whether an increase in disability was due to the natural progress of the illness or to aggravation during service.

The proposed regulation contained provisions prohibiting payment of compensation where affirmative evidence establishes that an undiagnosed illness was not incurred during active service in the Persian Gulf (§ 3.317(c)(1)), and where affirmative evidence establishes that an undiagnosed illness is the result of a supervening condition or event that occurred following the veteran's most recent departure from the Southwest Asia theater of operations and the onset of the illness (§ 3.317(c)(2)). One commenter stated that § 3.317(c)(1) was redundant and unnecessary in light of § 3.317(c)(2).

VA does not agree. The prohibition contained in § 3.317(c)(2) applies whether the illness was alleged to have occurred during service in the Southwest Asia theater of operations or during the presumptive period thereafter. However, since Public Law 103–446 did not contemplate eligibility by reason of aggravation of a pre-existing undiagnosed illness, the provisions of § 3.317(c)(1) are necessary to ensure that entitlement to compensation is properly established.

One commenter stated that the ''affirmative evidence'' standard for determining that an undiagnosed illness was the result of a supervening condition or event does not equate to any standard known in law but is rather an arbitrary standard established by VA. The commenter suggested substituting the recognized legal standard of ''clear and convincing evidence.''

VA does not agree. In fact, the standard of ''affirmative evidence'' is long established in the statutes and regulations governing VA benefits. It is used in 38 U.S.C. 1113 to define the type of evidence sufficient to rebut a presumption of service connection. Congress again adopted the term at 38 U.S.C. 1116(a)(3), which provides that a veteran who served in the Republic of Vietnam during the Vietnam era and has one of the presumptive diseases related to herbicide exposure will be presumed to have been exposed to herbicides ''unless there is affirmative evidence'' to the contrary. Under 38 CFR 3.307(d), affirmative evidence accepted to rebut a presumption of service connection, although not requiring a conclusive showing, must, nonetheless, be competent to indicate the time of existence or inception of a disease and must support a conclusion that a disease was not incurred in service. We believe that this standard is both reasonable for determining whether a claimed undiagnosed illness is the result of a supervening condition and consistent with standards that VA applies to presumption for diagnosed conditions.

One commenter recommended that the regulation define the term ''known clinical diagnosis'' in order to specify the criteria to be applied in determining whether a condition qualifies as an undiagnosed illness.

VA does not agree. The concept of what constitutes a ''known clinical diagnosis'' is not such a matter of uncertainty within the medical community as the commenter has implied. Examining physicians routinely determine whether or not an illness is part of a disease process that follows a particular clinical course which can be generally predicted. If the physician is unable to attribute a disability to such a known clinical diagnosis, he or she would routinely include a statement to that effect on the examination report. In the event of conflicting findings, it would be incumbent upon VA to resolve the issue on the basis of all medical evidence of record.

Another commenter believed that the requirement for a finding of undiagnosed illness is outside currently accepted standards of medical practice and that physicians should not be required to make a diagnosis of an ''undefined non-disease.''

The regulation does not require that physicians make such a diagnosis. Physicians should simply record all noted signs and reported symptoms, document all clinical findings, and provide a diagnosis where possible. If the signs and symptoms are not characteristic of a known clinical diagnosis, the physician should so indicate. This conforms with the usual standards of medical practice.

The proposed regulation provided that VA shall pay compensation to a Persian Gulf veteran who exhibits objective indications of chronic disability resulting from an undiagnosed illness or combination of illnesses as manifested by one of the 13 signs and symptoms listed at § 3.317(b). One commenter stated that objective verification of symptoms by an examining physician would be impossible, since most of the 13 signs and symptoms are subjective. He predicted that many veterans would not present with objective signs perceptible to examining physicians and that, therefore, examinations would be judged inadequate or claims would be denied for a lack of objective evidence. Another commenter recommended that VA omit the word ''objective.''

VA does not agree. Some veterans may present with purely subjective symptoms, which, nonetheless, establish the basis for a valid claim under the provisions of this rule. We believe, however, that it is not only fair but also in keeping with Congressional intent to require some objective

indication of the presence of a chronic *disability* attributable to an undiagnosed illness before awarding compensation. In the House of Representatives report on H.R. 4386, an earlier version of Persian Gulf legislation, the Committee on Veterans' Affairs stated its intention ''that there must be some objective indication or showing of the disability which is observable by a person other than the veteran, or for which medical treatment has been sought.'' (House Report # 103–669, p. 7.) Similarly, at a September 14, 1994, hearing on the Senate Committee on Veterans' Affairs, Senator Rockefeller, then Chairman of the Committee, stated that in introducing S. 2330, an earlier Senate version of the legislation, it was his intention that compensation be paid in situations where a veteran ''has symptoms that can be verified by objective tests that show that the [veteran] is not well.'' (S. Hrg. 103–829, p. 3.)

Ordinarily, an objective indication is established through medical findings, i.e., ''signs'' in the medical sense of evidence perceptible to an examining physician. However, we also will consider non-medical indications which can be independently observed or verified, such as time lost from work, evidence that a veteran has sought medical treatment for his or her symptoms, evidence affirming changes in the veteran's appearance, physical abilities, and mental or emotional attitude, etc. Lay statements from individuals who establish that they are able from personal experience to make their observations or statements will be considered as evidence when VA determines whether the veteran is suffering from an undiagnosed illness.

Two commenters suggested that where the previously undiagnosed illness of a veteran is subsequently diagnosed, compensation under § 3.317 should continue until a decision on eligibility under other statutory or regulatory provisions has been reached.

Once the illness in a particular case has been diagnosed and a veteran is no longer entitled to compensation under the provisions of § 3.317, the provisions of § 3.500(y) require termination of compensation as of the last day of the month in which 60 days following the final rating decision expires. However, VA will simultaneously begin consideration of potential entitlement under other statutory and regulatory provisions and will initiate any required development for additional evidence. Although the 60-day period of § 3.500(y) is fixed in accordance with the requirements of 38 CFR 3.105(d) and (e), those sections of the regulations also provide for a 60-day predetermination period prior to final rating action in order to safeguard a veteran's due process rights. We believe that a decision on entitlement under other provisions can be made prior to termination or reduction under § 3.500(y).

While the possibility remains that some awards under § 3.317 might be terminated prior to a final determination of entitlement under other provisions, we have no authority to pay compensation in the absence of an actual determination of entitlement. However, if payment is terminated but entitlement is subsequently established on another basis, payments may be made retroactive to the date compensation under the provisions of § 3.317 was terminated.

One commenter recommended that this regulation state that if scientific research eventually establishes that the signs and symptoms of Persian Gulf veterans with undiagnosed illnesses constitute a syndrome which can be attributed to service in the Persian Gulf, the provisions of 38 CFR 3.303(d) will provide a basis for establishing service connection for this syndrome.

VA does not agree. Section 3.303(d) provides that, notwithstanding statutory presumptive periods, service connection may be granted for a disease first diagnosed after discharge from service when all pertinent evidence establishes that the disease was incurred in service. However, so long as medical and scientific research has not established that some or all Persian Gulf veterans with undiagnosed illnesses are in fact suffering from a recognizable disease process attributable to service in the Gulf, any regulatory assumption that research will, in fact, eventually support such a finding would be conjectural and premature.

One commenter remarked that VA, in establishing a presumptive period, seems not to have taken into account either credible scientific and medical evidence or pertinent circumstances regarding the experiences of Persian Gulf veterans and, thus, failed to meet statutory requirements of Public Law 103–446.

VA does not agree. Public Law 103–446 required VA to determine an appropriate presumptive period following a review of the credible scientific and medical evidence and the historical treatment afforded disabilities for which manifestation periods have been established, and taking into account other pertinent circumstances regarding the experiences of veterans of the Persian Gulf War. Although many veterans began to develop unexplained signs and symptoms of illness shortly after their return from the Persian Gulf, there is as yet little or no medical or scientific evidence definitively linking the illnesses with service in the Gulf, and the credible evidence available supports no conclusions regarding etiology or definition of these illnesses. The National Institutes of Health (NIH)-sponsored Technology Assessment Workshop on the Persian Gulf Experience and Health, held in April 1994, concluded that it was not possible to establish a single case definition for the illnesses of Persian Gulf veterans and that, in fact, more than one disease category might be present, with overlapping symptoms and causes. More recently, a report of the Medical Follow-up Agency of the Institute of Medicine (IOM), published in January of this year, endorsed the report of the NIH panel comprized of non-government experts and stated that ''[t]he Gulf War illness phenomenon may prove to be a mixture of several illnesses, or may prove not to be associated with a specific exposure or disease.'' The IOM report further concluded that establishment of a case definition was ''handicapped by the lack of any generally recognized pathognomonic physical signs or laboratory findings, and by uncertainty about whether a specific syndrome exists and, if it does exist, its prevalence among Gulf War veterans. The subjectivity of many of the complaints associated with the Gulf War illness creates serious problems for those seeking to investigate the validity and origins of the illness.'' (Health Consequences of Service During the Persian Gulf War: Initial Findings and Recommendations for Immediate Action, National Academy Press, 1995, p. 26.) Given this uncertainty of available scientific and medical evidence, we felt that a presumptive period could not be established on this basis, and we looked to the other 2 factors, historical treatment and pertinent circumstances, to determine an appropriate period.

For many years Congress has authorized a one-year presumptive period for various chronic diseases, many of which present signs and symptoms similar to those of the undiagnosed illnesses of Persian Gulf veterans (see 38 U.S.C. 1101(3) and 1112(a)). This historical treatment of chronic diseases might indicate that a one-year presumptive period would be warranted for the undiagnosed illnesses of Persian Gulf veterans. We felt, however, that a one-year presumptive period would not meet the particular needs of these veterans, because it was

not immediately apparent when most of them left the Southwest Asia theater of operations that their signs and symptoms, which some believed resulted from exposure to environmental hazards, would present the problems of diagnosis and etiology that remain unresolved today. We believe that two years following service in the Gulf provides an adequate period of time in which all veterans of the hostilities would have become aware of the potential significance of their symptoms and have had an opportunity to present and document health concerns that arose soon after their departure from the Gulf. Certainly by the end of the first 2 years following their return, there were great public awareness of and concern for Persian Gulf veterans with unexplained illnesses that defied diagnosis but seemed to be in some way linked to service in the Persian Gulf.

An additional reason for establishing a 2-year presumptive period rather than a one-year period is that VA did not begin full-scale operation of its Persian Gulf Health Registry until November 1992. Because many Persian Gulf veterans first presented their health concerns in connection with VA's Persian Gulf Health Registry examination, veterans of the actual hostilities, who began to return from the Gulf by mid-1991, did not have this resource available to them within their first year after leaving the Gulf. Within 2 years, however, all veterans of the hostilities would have had this opportunity to document their illnesses. Therefore, we established a 2-year presumptive period running from the date of a veteran's last service in the Southwest Asia theater of operations.

Two commenters recommended that in establishing a presumptive period VA take into account the bases for the longer presumptive periods established for certain diseases associated with radiation and herbicide exposure. One of these same commenters specifically recommended establishing a presumptive period based on the onset of symptoms of ''slow viruses,'' which may take up to 8 years to become manifest.

VA does not agree. Where scientific and medical evidence has concluded that manifestation of a disease may be delayed following exposure to specific substances, such as herbicides or radiation, that evidence might justify establishment of an appropriate presumptive period. However, medical and scientific evidence addressing the latency periods of known diseases cannot form a basis for determining a latency period for undiagnosed illnesses. Longer or open-ended presumptive periods for certain diseases, such as those associated with exposure to radiation or herbicides, were established only following many years of extensive research. For example, to assist in determining what diseases may be associated with exposure to herbicides used in the Republic of Vietnam during the Vietnam era, VA contracted with the National Academy of Sciences (NAS) to do a review of the available scientific and medical literature. The NAS subsequently reviewed 6,420 abstracts of scientific or medical studies and approximately 230 epidemiological studies prior to submitting recommendations. A similar body of medical and scientific evidence addressing the undiagnosed illnesses of Persian Gulf veterans simply does not exist at this time, and what evidence is available supports no conclusions regarding etiology or identification. There is no basis, other than conjecture, for comparing the undiagnosed illnesses of Persian Gulf veterans to the symptoms of slow viruses or to diseases associated with exposure to radiation or herbicides.

Several commenters believed that a 2-year presumptive period was either arbitrary, premature, or too restrictive and, citing the current uncertainty of medical and scientific evidence, recommended presumptive periods ranging from 5 years to open-ended.

Although medical and scientific evidence is accumulating about the various signs and symptoms of Persian Gulf veterans with undiagnosed illnesses, there is little or no evidence definitively linking the illnesses with service in the Gulf, and the credible evidence available supports no conclusions regarding etiology, definition of the undiagnosed illnesses, or latency period, which would justify adopting a longer presumptive period. The commenters offered no other reasonable basis to justify a presumptive period longer than 2 years, and we have not adopted their recommendations.

Six commenters believe that the 2-year presumptive period is inadequate because Persian Gulf veterans were unaware that they would need to document their undiagnosed illnesses. They stated that associating the presumptive period with establishment of the Persian Gulf Health Registry did not give all veterans of the hostilities an adequate opportunity to document their illnesses because availability of the Registry examination was not widely known until mid-1993, nearly 2 years after the first U.S. servicemembers began returning from the Persian Gulf.

The Persian Gulf Registry examination is not the only acceptable means of documenting the presence of an undiagnosed illness. Other types of medical evidence may be used, such as routine VA medical reports, military medical records, and reports from private physicians. We believe that where the illness of a veteran manifested itself to a compensable degree (10 percent or greater), it is very likely either that the veteran would have sought medical treatment or that other, non-medical evidence is available which would document the veteran's signs or symptoms. For example, lay statements from individuals who establish that they are able from personal experience to make their observations or statements concerning the appearance of the signs or symptoms of a veteran's illness may be used to establish entitlement. In fact, many veterans did file claims for compensation within 2 years of leaving the Gulf based on disabilities that they felt may have resulted from exposure to environmental hazards. VA examinations and other medical evidence reflecting complaints of or treatment for these disabilities should provide adequate documentation for the purposes of this regulation. The 2-year presumptive period is not intended to limit the presumption of service connection under § 3.317 to illnesses documented within that time frame. Documentation of the signs and symptoms first made shortly after the presumptive period might establish entitlement if it reasonably supports a conclusion that the illness existed during the 2-year period following a veteran's last service in the Persian Gulf region.

These commenters also stated that many who remained on active duty after service in the Persian Gulf were hesitant to report their ailments for fear of jeopardizing their military careers.

In our judgment, remaining on active duty following service in the Persian Gulf does not necessarily preclude the likelihood that alternative documentation acceptable to VA can be obtained. Although many of these individuals might have been unwilling to seek treatment for their illnesses from military physicians, documentation of treatment from civilian physicians might exist for some. In the event that others chose not to obtain medical treatment of any kind, lay statements, such as those mentioned earlier, may be used to establish entitlement.

These commenters also stated that since many VA and Department of Defense (DOD) physicians have been unwilling to acknowledge that their

illnesses could be related to Persian Gulf service, it is possible that complaints that have been made have gone unreported to VA regional offices in connection with claims for compensation.

When a veteran files a claim for compensation, the regional office of jurisdiction obtains all pertinent VA, military, and private medical records. Whether or not an examining physician agreed with the veteran's belief that his or her illness was the result of service in the Persian Gulf, it is likely that documentation of the complaint exists, since the physician would have been obligated to record it. If the complaint was made within the 2-year presumptive period, that record will serve as documentation to establish potential entitlement to compensation.

Three commenters recommended that VA measure the presumptive period from a date other than the date of a veteran's last service in the Southwest Asia theater of operations. They separately recommended that the presumptive period run from the effective date of Public Law 103–446, the date VA's Persian Gulf Health registry was established, or the date of a veteran's separation from service.

VA does not agree. Since the statute presumes that these health concerns are related to Persian Gulf service, it is reasonable that the presumptive period be measured from the date service in the Gulf ended, and the statute itself specifically indicates that the presumptive period will be so measured. Furthermore, measuring the presumptive period from the last date of Gulf service is consistent with other presumptive periods, such as those for diseases related to radiation or herbicide exposure, which are measured from the last date on which exposure could have occurred. Finally, if the presumptive period were to be measured from the date a veteran was separated from service, veterans who remained on active duty for several years after they left the Persian Gulf would be unfairly advantaged.

Another commenter felt that, where the undiagnosed illnesses of Persian Gulf veterans are eventually diagnosed, the regulation should also allow a 2-year presumptive period for the diagnosed conditions.

VA does not agree. The undiagnosed illness provisions of Public Law 103–446, as implemented by § 3.317, were specifically intended to relieve the unique situation in which certain Persian Gulf War veterans found themselves unable to establish entitlement to VA compensation because their illnesses currently cannot be diagnosed. There is already a well-established statutory and regulatory framework for compensating disabilities resulting from diagnosed diseases, which Congress could have revised if it had chosen to do so. Compensation may be awarded when the evidence establishes that a disease was incurred directly during active duty or that a preexisting disease was aggravated by active duty, so long as any increase in severity was not due to the natural progress of the disease. Compensation may also be paid on a presumptive basis for certain chronic diseases that appear within a statutory presumptive period, generally one year. If the undiagnosed illnesses of Persian Gulf veterans are eventually identified and this current legal framework for compensation proves to be inadequate, that will be an issue for VA and the Congress to consider at that time.

VA wishes to thank the commenters for their thoughtful remarks. The rule is hereby adopted as proposed with the revisions to § 3.317(a) mentioned in the preamble.

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

This final rule has been reviewed by the Office of Management and Budget under the provisions of Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993.

(The Catalog of Federal Domestic Assistance program numbers are 64.109 and 64.110.)

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Health care, Individuals with disabilities, Pensions, Veterans.

Approved: January 25, 1995.

Jesse Brown,

Secretary of Veterans Affairs.

For the reasons set forth in the preamble, 38 CFR Part 3 is amended 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. Section 3.317 is added to read as follows:

§ 3.317 Compensation for certain disabilities due to undiagnosed illnesses.

(a)(1) Except as provided in paragraph (c) of this section, VA shall pay compensation in accordance with chapter 11 of title 38, United States Code, to a Persian Gulf veteran who exhibits objective indications of chronic disability resulting from an illness or combination of illnesses manifested by one or more signs or symptoms such as those listed in paragraph (b) of this section, provided that such disability:

(i) became manifest either during active military, naval, or air service in the Southwest Asia theater of operations during the Persian Gulf War, or to a degree of 10 percent or more not later than two years after the date on which the veteran last performed active military, naval, or air service in the Southwest Asia theater of operations during the Persian Gulf War; and

(ii) by history, physical examination, and laboratory tests cannot be attributed to any known clinical diagnosis.

(2) For purposes of this section, ''objective indications of chronic disability'' include both ''signs,'' in the medical sense of objective evidence perceptible to an examining physician, and other, non-medical indicators that are capable of independent verification.

(3) For purposes of this section, disabilities that have existed for 6 months or more and disabilities that exhibit intermittent episodes of improvement and worsening over a 6-month period will be considered chronic. The 6-month period of chronicity will be measured from the earliest date on which the pertinent evidence establishes that the signs or symptoms of the disability first became manifest.

(4) A chronic disability resulting from an undiagnosed illness referred to in this section shall be rated using evaluation criteria from part 4 of this chapter for a disease or injury in which the functions affected, anatomical localization, or symptomatology are similar.

(5) A disability referred to in this section shall be considered service connected for purposes of all laws of the United States.

(b) For the purposes of paragraph (a)(1) of this section, signs or symptoms which may be manifestations of undiagnosed illness include, but are not limited to:

(1) fatigue

(2) signs or symptoms involving skin

(3) headache
(4) muscle pain
(5) joint pain
(6) neurologic signs or symptoms
(7) neuropsychological signs or symptoms
(8) signs or symptoms involving the respiratory system (upper or lower)
(9) sleep disturbances
(10) gastrointestinal signs or symptoms
(11) cardiovascular signs or symptoms
(12) abnormal weight loss
(13) menstrual disorders.

(c) Compensation shall not be paid under this section:

(1) if there is affirmative evidence that an undiagnosed illness was not incurred during active military, naval, or air service in the Southwest Asia theater of operations during the Persian Gulf War; or

(2) if there is affirmative evidence that an undiagnosed illness was caused by a supervening condition or event that occurred between the veteran's most recent departure from active duty in the Southwest Asia theater of operations during the Persian Gulf War and the onset of the illness; or

(3) if there is affirmative evidence that the illness is the result of the veteran's own willful misconduct or the abuse of alcohol or drugs.

(d) For purposes of this section:

(1) the term ''Persian Gulf veteran'' means a veteran who served on active military, naval, or air service in the Southwest Asia theater of operations during the Persian Gulf War.

(2) the Southwest Asia theater of operations includes Iraq, Kuwait, Saudi Arabia, the neutral zone between Iraq and Saudi Arabia, Bahrain, Qatar, the United Arab Emirates, Oman, the Gulf of Aden, the Gulf of Oman, the Persian Gulf, the Arabian Sea, the Red Sea, and the airspace above these locations.

(Authority: Title I, Pub. L. 103–446; 38 U.S.C. 501(a))

3. Section 3.500 is amended by adding paragraph (y) to read as follows:

§ 3.500 General.

* * * * *

(y) *Compensation for certain disabilities due to undiagnosed illnesses (§§ 3.105; 3.317).* Last day of the month in which the 60-day period following notice to the payee of the final rating action expires. This applies to both reduced evaluations and severance of service connection. (Authority: Pub. L. 103–446; 38 U.S.C. 501(a))

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 270

[FRL–5149–1]

Determination of Point at Which RCRA Subtitle C Jurisdiction Begins for Municipal Waste Combustion Ash at Waste-to-Energy Facilities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of statutory interpretation.

SUMMARY: On May 2, 1994, the Supreme Court issued its decision in *City of Chicago* v. *Environmental Defense Fund, Inc.* 114 S.Ct. 1588 (1994). In so doing, the Court held that, although municipal waste-to-energy (WTE) facilities that burn household wastes alone, or in combination with nonhazardous wastes from industrial and commercial sources, are exempt from regulation as a hazardous waste treatment, storage, or disposal facility under Subtitle C of the Resource Conservation and Recovery Act (RCRA), the ash that they generate is not exempt. The Court, however, did not specify the point at which the ash generated by the WTE facility becomes subject to Subtitle C of RCRA. EPA is responding to numerous requests for resolution of this issue by announcing today that it interprets § 3001(i) of RCRA to first subject the ash generated by a WTE facility to RCRA Subtitle C when it exits the combustion building following the combustion and air pollution control processes.

EFFECTIVE DATE: February 3, 1995.

ADDRESSES: Docket Clerk, OSW (OS–305), Docket No. *95–XA2N–FFFFF,* U.S. Environmental Protection Agency Headquarters, 401 M Street, SW., Washington, DC 20460. The public docket is located in M2616 at EPA Headquarters and is available for viewing from 9:00 a.m. to 4:00 p.m., Monday through Friday, excluding Federal holidays. Appointments may be made by calling (202) 260–9327. Copies cost $0.15/page. Charges under $25.00 are waived.

FOR FURTHER INFORMATION CONTACT: For general information, contact the RCRA/Superfund Hotline, Office of Solid Waste, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC, 20460, (800) 424–9346, TDD (800) 553–7672 (hearing impaired); in the Washington, DC metropolitan area the number is (703) 920–9810, TDD (703) 486–3323.

For more detailed information on specific aspects of this Notice, contact Andrew L. Teplitzky (703–308–7275) or Allen J. Geswein (703–308–7261), Office of Solid Waste (5306W), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

SUPPLEMENTARY INFORMATION:

Preamble Outline

I. Authority

This action interpreting RCRA Section 3001(i) and the hazardous waste regulations in 40 CFR Parts 260–271 is being taken under the authority of sections 2002 and 3001 of the Solid Waste Disposal Act of 1970 as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6912 and 6921).

II. Background

A. Nature of Ash From Waste-to-Energy Facilities

Combustion of municipal solid waste, particularly through WTE facilities, can be an important component of a local government's waste management practices. As of 1993, approximately 207 million tons of municipal solid waste were generated annually in the U.S., 16 percent of which (33 million tons) was combusted. There are approximately 150 municipal waste combustors in the U.S., 80 percent of which are WTE facilities. The remaining 20 percent incinerate waste without recovering energy.

Approximately 25 percent (dry weight) of the waste that is combusted remains as ash, amounting to around eight million tons of municipal waste combustor (MWC) ash generated annually. While the ash may be collected at a number of locations within a WTE facility, it typically is characterized as either ''bottom ash'' or ''fly ash.'' Bottom ash collects at the bottom of the combustion unit and comprises approximately 75–80% of the total ash by weight. Fly ash collects in the air pollution control devices that ''clean'' the gases produced during the combustion of the waste and comprises