requirements of the Federal external review process established under section 2719 of the PHS Act and its implementing regulations. In such a case, the contractor would be responsible for conducting standard and expedited reviews of all adverse benefit determinations and final internal adverse benefit determinations that are eligible for external review as defined by the regulations. Reviews would be conducted in an accurate, efficient, timely, and consistent manner. In conjunction with completing these reviews, the contractor may be tasked with the following functions and responsibilities to support the permanent Federal external appeals process:

- Development, maintenance, distribution, and update of "decision support" protocols;
- Adjudication of external review cases, using established protocols;
- Timely and accurate disposition of all external review cases;
- Collection, consolidation, storage, maintenance, and transmission of information regarding the receipt and disposition of external review cases for the Federal external review process;
- Performance of statistical and data analyses of external review cases to include trend analyses, and compliance with HHS data and reporting requirements including ad-hoc analyses for reports and inquiries from HHS, Congress, and other entities, and for purposes of continuous quality improvement;
- Participation and coordination with other entities (including other IROs) involved in the Federal external review process for quality improvement purposes;
- Communication of external review decisions to claimants and other parties involved in the case;
- Case management and documentation, which may include document imaging to produce a complete electronic case file; and
- Training all critical and qualified staff on all aspects of the external review process.

Accordingly, the Departments of HHS and Labor are seeking to engage formally, in a transparent and participatory manner, with the public on best practices and standards currently used by IROs. Specific questions are set forth below. Comments are invited from all stakeholders on these issues.

Qualified Organizations and Staff

(1) What accreditation standards currently apply to IROs?

(2) What credentialing standards do IROs require for medical and legal reviewers? Is credentialing required or voluntary?

(3) What procedures are currently used by IROs to assure that reviewers do not have conflicts of interest with disputing parties?

(4) What are IROs' current capacity for performing reviews? Does staffing and the time necessary for performing a review differ based on the type of claim (e.g., medical necessity, experimental/investigational treatment, coverage issues, etc.)?

Infrastructure

(5) Please describe the type of data collection systems that IROs currently use to conduct analyses, reporting, and tracking of appeals and grievances.

(6) Are the current data systems available in a secure, 508-compliant, web-based interactive structure?

(7) What telecommunication systems and consumer technical support systems do IROs currently maintain for consumers (*e.g.,* Web sites, 24-hour hotlines, helpdesk, and/or translation services for non-English speakers)?

(8) What is a reasonable amount of time for a contractor to become fully operational (have all systems in place to conduct external reviews) after the date of a contract award? What resources would be necessary?

(9) What considerations must be taken into account to smoothly transition from the current Federal interim external review process to a possible new permanent Federal external review process?

(10) Do IROs currently operate nationally or in limited geographic areas? Would IROs that currently serve local areas be able to expand their service areas to possibly include other geographic areas such as other States? Are there any State and/or local licensing requirements?

(11) Are there any special considerations HHS and/or DOL should be aware of in considering a specialized contract for urgent care appeals or for experimental and investigational treatments? Would such an approach have an impact on coordination?

(12) Please describe the difference in standard operating procedures and resources (time, cost, personnel) for appeals that involve only medical necessity and those that involve both medical necessity and coverage questions.

Data Collection

(13) What data are currently collected by IROs for tracking appeals and conducting analyses?

(14) What steps are taken to ensure confidentiality and security protections of patient information?

Evaluation

(15) Do IROs (or subcontractors) currently conduct evaluations of their operations? Do such evaluations include an assessment of how easy it is for consumers to access and use the external review process in a timely manner? Do evaluations result in quality improvement initiatives? If so, what are some examples of quality improvement initiatives undertaken by IROs?

(16) What specific requirements should be applied to IROs to evaluate progress toward performance goals? What performance goals are the most appropriate?

Signed at Washington, DC, November 10, 2010.

Elizabeth Fowler,

Director of Policy, Office of Consumer Information and Insurance Oversight. Department of Health and Human Services.

Signed at Washington, DC, November 9, 2010.

Phyllis C. Borzi,

Assistant Secretary, Employee Benefits Security Administration Department of Labor.

[FR Doc. 2010–28876 Filed 11–12–10; 11:15 am]

BILLING CODE 4150–29– 4150–65–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900–AN83

Presumptive Service Connection for Diseases Associated With Persian Gulf War Service: Functional Gastrointestinal Disorders

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) is amending its adjudication regulations concerning presumptive service connection for medically unexplained chronic multisymptom illnesses associated with service in the Southwest Asia theater of operations for which there is no record during service. This amendment is necessary to implement a decision of the Secretary of Veterans Affairs that there is a positive association between service in Southwest Asia during certain periods and the subsequent development of functional gastrointestinal disorders (FGIDs), and to clarify that FGIDs fall within the scope of the existing presumption of service connection for medically

unexplained chronic multisymptom illnesses. The intended effect of this amendment is to clarify the presumption of service connection for these illnesses based on service in the Southwest Asia theater of operations during the Persian Gulf War.

DATES: Comments must be received by VA on or before December 17, 2010.

ADDRESSES: Written comments may be submitted through *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–AN83—Presumptive Service Connection for Diseases Associated With Persian Gulf War Service: Functional Gastrointestinal Disorders (FGIDs)."

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 at *http://www.Regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Gerald Johnson, Regulations Staff (211D), Compensation and Pension Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461- 9727 (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: The Secretary of Veterans Affairs has determined that the available scientific and medical evidence presented in the National Academy of Sciences (NAS) April 2010 report, titled *Gulf War and Health, Volume 8: Update on the Health Effects of Serving in the Gulf War* is sufficient to warrant a presumption of service connection for FGIDs in individuals deployed to the Southwest Asia theater of operations during the Persian Gulf War. Pursuant to that determination, this document proposes to clarify that the Department of Veterans Affairs (VA) adjudication regulations (38 CFR Part 3), specifically 38 CFR 3.317, would include FGIDs as medically unexplained chronic multisymptom illnesses subject to presumptive service connection. FGIDs include, but are not limited to, such conditions as irritable bowel syndrome (IBS) and functional dyspepsia.

National Academy of Sciences (NAS) Reports

FGIDs, Including, But Not Limited to, Irritable Bowel Syndrome (IBS) and Functional Dyspepsia

The NAS issued its report titled *Gulf War and Health, Volume 8: Update on Health Effects of Serving in the Gulf War,* on April 9, 2010. The NAS was asked to review, evaluate, and summarize the literature to determine if any of the health outcomes noted in its 2006 report, titled *Gulf War and Health, Volume 4: Health Effects of Serving in the Gulf War,* appear at higher incidence or prevalence levels in Gulf War-deployed veterans. The NAS sought to characterize and weigh the strengths and limitations of the available evidence. The NAS Update committee reviewed over 1000 relevant studies and focused on over 400 relevant references, including the studies reviewed in the Volume 4 report. The NAS determined that there is sufficient evidence of an association between deployment to the Gulf War and FGIDs, including, but not limited to, IBS and functional dyspepsia. The committee also noted that there is inadequate evidence of an association between deployment to the Gulf War and structural gastrointestinal (GI) disease.

FGIDs, such as IBS or functional dyspepsia, are syndromes characterized by recurrent or prolonged GI symptoms that occur together. They are distinguished from structural or "organic" GI disorders in that they generally are not associated with detectable anatomical abnormalities. The severity of FGIDs ranges from occasional mild episodes to more persistent and disabling symptoms. According to the NAS report, there have been numerous reports of GI disturbances in Gulf War veterans and the symptoms have continued to be persistent in the years since that war. All studies examined by NAS favored a greater prevalence of various GI symptoms and primary functional GI disorders, including IBS and dyspepsia. In NAS's opinion, there also was compelling emerging evidence of exposure during deployment to enteric pathogens leading to the development of post-infectious IBS.

The overall pattern of symptoms found in the primary and secondary studies NAS reviewed confirms an association between deployment to the Gulf War and functional GI symptoms, including abdominal pain, diarrhea, nausea, and vomiting. The NAS recommended that further studies be conducted to determine the role of prior acute gastroenteritis among deployed servicemembers in the development of FGIDs.

Detailed information on the committee's findings may be found at: *http://www.iom.edu/Reports/2010/Gulf-War-and-Health-Volume-8–Health-Effects-of-Serving-in-the-Gulf-War.aspx.* The report findings are organized by category and can be found under the heading, "Table of Contents."

Statutory Provisions

Pursuant to 38 U.S.C. 1118, VA must establish a presumption of service connection for each illness shown by sound scientific and medical evidence to have a positive association with exposure to a biological, chemical, or other toxic agent, environmental or wartime hazard, or preventive medicine or vaccine known or presumed to be associated with service in the Armed Forces in the Southwest Asia theater of operations during the Persian Gulf War. Because the recent NAS report was primarily a review of the prevalence of illnesses among Gulf War veterans, it generally did not state conclusions as to whether the illnesses are associated with the types of exposures referenced in § 1118. The NAS noted that there was significant emerging evidence that FGIDs may be associated with exposure to enteric pathogens during Gulf War deployments and recommended further study of that issue. However, NAS did not state a conclusion concerning the strength of the evidence of an association between FGIDs and exposure to enteric pathogens. VA has determined that resolution of that question is not necessary for purposes of this rule, because FGIDs are within the scope of the existing presumption of service connection for medically unexplained chronic multisymptom illnesses.

Section 1117 of title 38, United States Code, provides a presumption of service connection for "qualifying chronic disability" in veterans who served in the Southwest Asia theater of operations during the Persian Gulf War. The statute defines the term "qualifying chronic disability" to include "[a] medically unexplained chronic multisymptom illness (such as chronic fatigue syndrome, fibromyalgia, and irritable bowel syndrome) that is defined by a cluster of signs or symptoms." 38 U.S.C. 1117(a)(2)(B). The plain language of the statute makes clear that it applies to all medically unexplained chronic multisymptom illnesses including, but not limited to, the three conditions parenthetically listed as examples. VA recently amended its regulation at 38 CFR 3.317 to clarify that the

presumption is not limited to the three listed examples. *See* 75 FR 61995.

FGIDs are medically unexplained chronic multisymptom illnesses within the meaning of the statute and regulation. These disorders are defined by clusters of signs and symptoms affecting GI functions. Further, FGIDs are "medically unexplained" because they are, by definition, disorders that cannot be attributed to observable structural or organic changes and the causes of the disorders are generally not known. Irritable Bowel Syndrome, which is a form of FGID, is expressly identified in the current statute and regulation as a medically unexplained chronic multisymptom illness. Because other FGIDs, such as functional dyspepsia and functional vomiting, also are medically unexplained chronic multisymptom illnesses, the current statute and regulation, as recently amended, provide a presumption of service connection for FGIDs in veterans who served in the Southwest Asia theater of operations during the Persian Gulf War. In view of the findings in the recent NAS report identifying FGIDs as prevalent and persistent illnesses among Gulf War Veterans, VA has determined that its regulations should be revised to expressly identify FGIDs as a type of medically unexplained chronic multisymptom illness within the scope of the existing presumption.

Regulatory Amendments

We propose to amend 38 CFR 3.317 to incorporate the more specific language regarding FGIDs. We propose to: Revise § 3.317(a)(2)(i)(B)(3) by removing "Irritable Bowel Syndrome" and replacing it with "Functional gastrointestinal disorders, including, but not limited to, irritable bowel syndrome and functional dyspepsia (excluding structural gastrointestinal diseases)"; and add a Note with the definition of functional gastrointestinal disorders. The intended effect of this change is to clarify that FGIDs are medically unexplained chronic multisymptom illnesses and are thus within the scope of the presumption of service connection for such illnesses.

Other Illnesses

This proposed rule does not reflect determinations concerning any illnesses other than those discussed in this proposal. The Secretary's determinations concerning other illnesses discussed in the NAS report will be addressed in other documents published in the **Federal Register**.

Paperwork Reduction Act

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

Regulatory Flexibility Act

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

Executive Order 12866

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Executive Order classifies a "significant regulatory action," requiring review by the Office of Management and Budget (OMB), 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 not to be a significant regulatory action under the Executive Order because it would not result in a rule that may materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof.

Unfunded Mandates

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

Catalog of Federal Domestic Assistance Numbers and Titles

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

Comment Period

Although under the rulemaking guidelines in Executive Order 12866 VA ordinarily provides a 60-day comment period, the Secretary has determined that there is good cause to limit the public comment period on this proposed rule to 30 days. The current proposed rule does not create a new presumption of service connection. Consistent with 38 U.S.C. 1117, it clarifies that functional gastrointestinal disorders fall within the scope of the existing presumption of service connection for medically unexplained chronic multisymptom illnesses. Because this rule merely clarifies VA's interpretation of the existing statute and regulation, a public comment period is not required under the Administrative Procedures Act. However, because this clarifying rule relates to VA's response to a report referred to in 38 U.S.C. 1118, VA has determined that it is appropriate to provide for public comment as provided in that statute. A 30-day notice and comment period will enable the rapid issuance of final regulations providing the public and VA adjudicators with clear guidance regarding the interpretation of the existing statute and regulation as they pertain to FGIDs. This will ensure that Veterans suffering from FGID will receive a fair determination of benefit eligibility, and will promote rapid action on affected benefits claims.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. John R. Gingrich, Chief of Staff, Department

of Veterans Affairs, approved this document on October 18, 2010, for publication.

List of Subjects in 38 CFR Part 3

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

Dated: November 9, 2010.

Robert C. McFetridge,

Director, Regulations Policy and Management, Department of Veterans Affairs.

■ For the reasons set out in the preamble, VA proposes to amend 38 CFR part 3 as follows:

PART 3—ADJUDICATION

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

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

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

2. Amend § 3.317 by revising paragraph (a)(2)(i)(B)(*3*) to read as follows:

§ 3.317 Compensation for certain disabilities due to undiagnosed illnesses.

(a) * * *

(2) * * *

(i) * * *

(B) * * *

(3) Functional gastrointestinal disorders, including, but not limited to, irritable bowel syndrome and functional dyspepsia (excluding structural gastrointestinal diseases); or **Note to paragraph (a)(2)(i)(B)(3):** Functional gastrointestinal disorders are a group of conditions characterized by chronic or recurrent symptoms that were present for at least 6 months prior to diagnosis and have been currently active for 3 months, that are unexplained by any structural, endoscopic, laboratory, or other objective signs of disease or injury and that may be related to any part of the gastrointestinal tract. Common symptoms include abdominal pain, substernal burning or pain, nausea, vomiting, altered bowel habits (including diarrhea, constipation), indigestion, bloating, postprandial fullness, and painful or difficult swallowing. Specific functional gastrointestinal disorders include, but are not limited to, irritable bowel syndrome, functional dyspepsia, functional vomiting, functional constipation, functional bloating, functional abdominal pain syndrome, and functional dysphagia.

[FR Doc. 2010–28707 Filed 11–16–10; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Chapter IV

[CMS–1345–NC]

Medicare Program; Request for Information Regarding Accountable Care Organizations and the Medicare Shared Saving Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Request for information.

SUMMARY: This document is a request for comments regarding certain aspects of the policies and standards that will apply to accountable care organizations (ACOs) participating in the Medicare program under section 3021 or 3022 of the Affordable Care Act.

DATES: *Comment Date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 3, 2010.

ADDRESSES: In commenting, please refer to file code CMS–1345–NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

- *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow "Submit a comment" instructions.
- *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1345–NC, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

- *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1345–NC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.
- *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to one of the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT: Thomas Carey, (410) 786–4560 or *Thomas.Carey@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

The Affordable Care Act seeks to improve the quality of health care services and to lower health care costs by encouraging providers to create integrated health care delivery systems. These integrated systems will test new reimbursement methods intended to