public docket. 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.

Use of the www.regulations.gov Web site to submit comments to EPA electronically is EPA’s preferred method for receiving comments. The electronic public docket system is an “anonymous access” system, which means EPA will not know your identity, email address, or other contact information unless you provide it in the body of your comment. In contrast to EPA’s electronic public docket, EPA’s electronic mail (email) system is not an “anonymous access” system. If you send an email comment directly to the Docket without going through www.regulations.gov, your email address is automatically captured and included as part of the comment that is placed in the official public docket, and made available in EPA’s electronic public docket.

Dated: July 31, 2013.

Lorie J. Schmidt,
Associate General Counsel.

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984.

Interested parties may submit comments on the agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within ten days of the date this notice appears in the Federal Register.

Copies of the agreements are available through the Commission’s Web site (www.fmc.gov) or by contacting the Office of Agreements at (202) 523–5793 or tradeanalysis@fmc.gov.

Agreement No.: 002206–006.
Title: California Association of Port Authorities—Northwest Marine Terminal Association Terminal Discussion Agreement.


Filing Party: Patti A. Fulghum, Executive Officer; Northwest Marine Terminal Association; P.O. Box 5684; Bellevue, WA 98006.

Synopsis: The amendment reflects the addition of the Port of St. Helens, Oregon as a member to the agreement.

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice of a Department of Health and Human Services Public Meeting and Request for Comments on Matters Related to the Protection of Human Subjects and Research Studying Standard of Care Interventions; Amended Notice of Meeting

SUMMARY: On June 26, 2013, the Department of Health and Human Services (HHS) published in the Federal Register an announcement of a public meeting to be held on August 28, 2013, to discuss how certain provisions of the HHS protection of human subjects regulations should be applied to research studying one or more interventions which are used as standard of care treatment in the non-research context (78 FR 38343).

In the June 26, 2013 meeting announcement, HHS stated that presenters will be scheduled to speak at the public meeting in the order in which they register. Notice is hereby provided that HHS may group presenters according to the topic of their presentation.

FOR FURTHER INFORMATION CONTACT: Dr. Jerry Menikoff, Director, Office for Human Research Protections, Department of Health and Human Services, 1101 Wootton Parkway, Suite 200; Rockville, MD 20852, 240–453–6900; email Jerry.Menikoff@hhs.gov.

DATED: August 1, 2013.

Howard K. Koh,
Assistant Secretary for Health.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Health Statistics

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS) announces the following meeting of the aforementioned committee:

TIMES AND DATES: 11:00 a.m.—5:30 p.m., September 19, 2013; 8:30 a.m.—1:00 p.m., September 20, 2013.

PLACE: NCHS Headquarters, 3311 Toledo Road, Hyattsville, Maryland 20782

STATUS: This meeting is open to the public; however, visitors must be processed in accordance with established federal policies and procedures. For foreign nationals or non-US citizens, pre-approval is required [please contact Gwen Mustaf, 301–458–4500, glm4@cdc.gov or Virginia Cain, vcain@cdc.gov at least 10 days in advance for requirements]. All visitors are required to present a valid form of picture identification issued by a state, federal or international...
government. As required by the Federal Property Management Regulations, Title 41, Code of Federal Regulation, Subpart 101–20.301, all persons entering in or on Federal controlled property and their packages, briefcases, and other containers in their immediate possession are subject to being x-rayed and inspected. Federal law prohibits the knowing possession or the causing to be present of firearms, explosives and other dangerous weapons and illegal substances. The meeting room accommodates approximately 100 people.

PURPOSE: This committee is charged with providing advice and making recommendations to the Secretary, Department of Health and Human Services; the Director, CDC; and the Director, NCHS, regarding the scientific and technical program goals and objectives, strategies, and priorities of NCHS.

MATTERS TO BE DISCUSSED: The agenda will include welcome remarks by the Acting Director, NCHS; Demo of the NHIS Online Analytic Real-time System (OARS); initiation of Office of Analysis and Epidemiology review.

Requests to make oral presentations should be submitted in writing to the contact person listed below. All requests must contain the name, address, telephone number, and organizational affiliation of the presenter.

Written comments should not exceed five single-spaced typed pages in length and must be received by September 4, 2013.

The agenda items are subject to change as priorities dictate.

CONTACT PERSON FOR MORE INFORMATION: Virginia S. Cain, Ph.D., Director of Extramural Research, NCHS/CDC, 3311 Toledo Road, Room 7208, Hyattsville, Maryland 20782, telephone (301) 458–4500, fax (301) 458–4020.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities for both Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,
Management Analysis and Services Office, Centers for Disease Control and Prevention.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
[CMS–3284–N]
Medicare Program; Revised Process for Making National Coverage Determinations
AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.
ACTION: Notice.

SUMMARY: This notice updates the process we use for opening, deciding or reconsidering national coverage determinations (NCDs) under the Social Security Act (the Act). It addresses external requests and internal reviews for new NCDs or for reconsideration of existing NCDs. The notice further outlines an expedited administrative process to remove certain NCDs, thereby enabling local Medicare contractors to determine coverage under the Act. This notice does not alter or amend our regulations that establish rules related to the administrative review of NCDs.

DATES: This notice is effective on August 7, 2013.

FOR FURTHER INFORMATION CONTACT: Katherine Tillman, (410) 786–9252.

SUPPLEMENTARY INFORMATION:
I. Background
In a September 26, 2003, Federal Register notice (68 FR 55634), we announced our procedures for considering national coverage determination (NCD) requests and our procedure for issuing NCDs, including the role of external public requests to open an NCD and our procedures for internally-generated NCD reviews. As we strive to continually improve our processes and in recognition of the changes made by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted on December 8, 2003), we are superseding the 2003 Federal Register notice with this updated notice.

II. Provisions of the Notice
This notice establishes the procedures for requesting an NCD or reconsideration of an existing NCD. We also describe how the public may participate in the NCD process during the indicated comment period(s). The topics addressed in the notice include the following:
• What constitutes a complete, formal request for an NCD or formal request for reconsideration of an existing NCD.
• External requests for NCDs, including the following:
  ++ Request by an external party for a new NCD.
  ++ Request by an external party for reconsideration of an existing NCD.
  ++ Request by an aggrieved party (as defined below) to issue an NCD when no NCD exists.
• CMS internally-generated review of NCDs, including the following:
  ++ CMS internal review for a new NCD.
  ++ CMS internal review for reconsideration of an existing NCD.
• An expedited process to remove NCDs under certain circumstances.

Based on our experience since 2003 with the current NCD process, we are establishing a new procedure to be used in circumstances in which we have previously issued an NCD, but have now determined that the NCD is no longer needed. Since we would not be establishing a new NCD, we would use an expedited process to remove these NCDs. After the effective date of the removal of the NCD, local Medicare contractors would determine coverage under section 1862(a)(1) of the Act for those specific items or services previously addressed through the NCD. We describe this process and the opportunity for public participation in this process in section IV.C of this notice.

We are also restating our process for developing an NCD to provide clarity and transparency for the public pertaining to modifications made to the coverage process since the MMA. As in the 2003 Federal Register notice, we will inform the public by addressing the following in this notice:
• The internal and external processes for requesting an NCD or an NCD reconsideration.
• A tracking system that provides public notice of our acceptance of a complete, formal request and subsequent actions in a web-based format.
• The process we use to afford notice and opportunity for public comment before issuing a decision memorandum.
• How we use public comments to inform the NCD final decision.

We continue to pursue our efforts to work with various sectors of the scientific and medical community to develop and publish on our Web site documents that describe our approach when analyzing scientific and clinical evidence to develop an NCD. The CMS coverage Web site can be accessed at...