

that enter the market each year, the costs associated with the Rule's disclosure requirements, beyond the additional labor costs discussed above, are de minimis. Negative option clubs already have access to the ordinary office equipment necessary to achieve compliance with the Rule. Similarly, the Rule imposes few, if any, printing and distribution costs. The required disclosures generally constitute only a small addition to the advertising for negative option plans. Because printing and distribution expenditures are incurred to market the product regardless of the Rule, adding the required disclosures results in marginal incremental expense.

David C. Shonka,
Acting General Counsel.
[FR Doc. E8-23036 Filed 9-30-08; 8:45 am]

[Billing code: 6750-01-S]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Biodefense Science Board; Notification of a Public Teleconference

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

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services is hereby giving notice that the National Biodefense Science Board (NBSB) will be holding a public teleconference. The meeting is open to the public.

DATES: The NBSB will hold a public teleconference on October 14, 2008. The teleconference will be held from 10 a.m. to 11 a.m. EST. Public Conference Call-in Number is available by contacting CAPT Leigh Sawyer (see below). Participants will be asked to provide their name, title, and organization.

ADDRESSES: The conference will be conducted by phone.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing to obtain general information concerning this public teleconference should contact CAPT Leigh A. Sawyer, D.V.M., M.P.H., Executive Director, National Biodefense Science Board, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services, e-mail at: leigh.sawyer@hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to section 319M of the Public Health Service Act (42 U.S.C. 247d-7f) and section 222 of the Public Health Service

Act (42 U.S.C. 217a), the Department of Health and Human Services established the National Biodefense Science Board. The Board shall provide expert advice and guidance to the Secretary on scientific, technical, and other matters of special interest to the Department of Health and Human Services regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate. The Board may also provide advice and guidance to the Secretary on other matters related to public health emergency preparedness and response.

Background: The purpose of the October 14, 2008 teleconference is to discuss recommendations from the Personal Preparedness Working Group and to ensure the public is provided opportunity to be involved in the deliberative process of the Board on personal preparedness issues that will specifically impact the Nation. The recommendations will include suggestions for evaluation of the pre-positioning of Med-Kits for use following an exposure to anthrax. A special meeting of the Board is being convened to assure that the public is given the opportunity to provide comments on the proposed recommendations. There will be time for members of the public to present their comments to the Board on this subject matter.

Availability of Materials: The agenda and other materials will be posted on the NBSB Web site at <http://www.hhs.gov/aspr/omsph/nbsb/index.html> prior to the meeting.

Procedures for Providing Public Input: Interested members of the public may submit relevant written or oral information for the NBSB to consider.

Oral Statements: In general, individuals or groups requesting an oral presentation at a public NBSB teleconference will be limited to three minutes per speaker, with no more than a total of 20 minutes for all speakers. To be placed on the public speaker list, you should notify the operator when you enter the call-in number.

Dated: September 26, 2008.

William C. Vanderwagen,
Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services.

[FR Doc. E8-23144 Filed 9-29-08; 11:15 am]

[BILLING CODE 4150-37-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Member Conflict Review Program Announcement (PA) 07-318

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) announces the aforementioned meeting.

Time and Date: 10 a.m.-12 p.m., November 3, 2008 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of Member Conflict Review, PA 07-318.

Contact Person for More Information: Price Connor, Ph.D., Scientific Review Official, National Institute for Occupational Safety and Health, CDC, 2400 Century Center, Atlanta, GA 30333, Telephone (404) 498-2511.

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 CDC and the Agency for Toxic Substances and Disease Registry.

Dated: September 22, 2008.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E8-23098 Filed 9-30-08; 8:45 am]

[BILLING CODE 4163-18-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

Privacy Act of 1974; CMS Computer Match No. 2008-02 HHS Computer Match No. 0602

AGENCY: Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS).

ACTION: Notice of Computer Matching Program.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, this notice establishes a computer matching agreement between

CMS and the Department of Defense (DoD). We have provided background information about the proposed matching program in the **SUPPLEMENTARY INFORMATION** section below. The Privacy Act requires that CMS provide an opportunity for interested persons to comment on the proposed matching program. We may defer implementation of this matching program if we receive comments that persuade us to defer implementation. See "Effective Dates" section below for comment period.

DATES: *Effective Dates:* CMS filed a report of the Computer Matching Program (CMP) with the Chair of the House Committee on Government Reform and Oversight, the Chair of the Senate Committee on Homeland Security and Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on 09-24-2008. We will not disclose any information under a matching agreement until 40 days after filing a report to OMB and Congress or 30 days after publication, whichever is later.

ADDRESSES: The public should address comments to: Walter Stone, CMS Privacy Officer, Division of Privacy Compliance (DPC), Enterprise Architecture and Strategy Group (EASG), Office of Information Services (OIS), CMS, Mail stop N2-04-27, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9 a.m.—3 p.m., eastern daylight time.

FOR FURTHER INFORMATION CONTACT: Walter Stone, CMS Privacy Officer, Division of Privacy Compliance (DPC), Enterprise Architecture and Strategy Group (EASG), Office of Information Services (OIS), CMS, Mail stop N2-04-27, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

SUPPLEMENTARY INFORMATION:

I. Description of the Matching Program

A. General

The Computer Matching and Privacy Protection Act of 1988 (Pub. L. 100-503), amended the Privacy Act (5 U.S.C. 552a) by describing the manner in which computer matching involving Federal agencies could be performed and adding certain protections for individuals applying for and receiving Federal benefits.

Section 7201 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101-508) further amended the Privacy Act

regarding protections for such individuals. The Privacy Act, as amended, regulates the use of computer matching by Federal agencies when records in a system of records are matched with other Federal, state, or local government records. It requires Federal agencies involved in computer matching programs to:

1. Negotiate written agreements with the other agencies participating in the matching programs;
2. Obtain the Data Integrity Board approval of the match agreements;
3. Furnish detailed reports about matching programs to Congress and OMB;
4. Notify applicants and beneficiaries that the records are subject to matching; and,
5. Verify match findings before reducing, suspending, terminating, or denying an individual's benefits or payments.

B. CMS Computer Matches Subject to the Privacy Act

CMS has taken action to ensure that all CMPs that this Agency participates in comply with the requirements of the Privacy Act of 1974, as amended.

Dated: September 23, 2008.

Charlene Frizzera,

Chief Operating Officer, Centers for Medicare & Medicaid Services.

CMS Computer Match No. 2008-02

HHS Computer Match No. 0602

NAME:

"Disclosure of Enrollment and Eligibility Information for Military Health System Beneficiaries Who are Medicare Eligible."

SECURITY CLASSIFICATION:

Level Three Privacy Act Sensitive.

PARTICIPATING AGENCIES:

The Centers for Medicare & Medicaid Services (CMS); and Department of Defense (DoD), Manpower Data Center (DMDC), Defense Enrollment and Eligibility Reporting System Office (DEERS), and the Office of the Assistant Secretary of Defense (Health Affairs)/TRICARE Management Activity (TMA).

AUTHORITY FOR CONDUCTING MATCHING PROGRAM:

This CMA is executed to comply with the Privacy Act of 1974 (Title 5 United States Code (U.S.C.) § 552a), as amended, (as amended by Public Law (Pub. L.) 100-503, the Computer Matching and Privacy Protection Act of 1988), the Office of Management and Budget (OMB) Circular A-130, titled "Management of Federal Information

Resources" at 61 **Federal Register** (FR) 6435 (February 20, 1996), and OMB guidelines pertaining to computer matching at 54 FR 25818 (June 19, 1989).

Prior to 1991, CHAMPUS entitlement terminated when any individual became eligible for Medicare Part A on a non-premium basis. The National Defense Authorization Act(s) (NDAA) for Fiscal Years (FY) 1992 and 1993 (Pub. L. 102-190) § 704, provide for reinstatement of CHAMPUS as second payer for beneficiaries entitled to Medicare on the basis of disability/End Stage Renal Disease (ESRD) only if they also enroll in Part B.

This agreement implements the information matching provisions of the NDAA, FY 2001 (Pub. L. 106-398) Sections 711 and 712; the NDAA, FY 1993 (Pub. L. 102-484) Section 705; and the NDAA, FY 1992 (Pub. L. 102-190) Sections 704 and 713.

Section 732 of the FY 1996 NDAA (Pub. L. 104-106), directed the administering Secretaries to develop a mechanism for notifying beneficiaries of their ineligibility for CHAMPUS when loss of eligibility is due to disability status.

PURPOSE(S) OF THE MATCHING PROGRAM:

The purpose of this agreement is to establish the conditions, safeguards and procedures under which CMS will disclose Medicare enrollment information to the DoD, DMDC, DEERS, and Health Affairs/TMA. The disclosure by CMS will provide TMA with the information necessary to determine if Military Health System (MHS) beneficiaries (other than dependents of active duty personnel), who are Medicare eligible, are eligible to receive continued military health care benefits. This disclosure will provide TMA with the information necessary to meet the Congressional mandate outlined in legislative provisions in the NDAA listed above.

Current law requires TMA to discontinue military health care benefits to MHS beneficiaries who are Medicare eligible and under the age of 65 when they become eligible for Medicare Part A because of disability/ESRD unless they are enrolled in Medicare Part B. Current law also requires TMA to provide health care and medical benefits to MHS beneficiaries who are Medicare eligible (commonly referred to as the dual eligible population) over the age of 65 who are enrolled in the supplementary medical insurance program under Part B of the Medicare program. This CMA will combine both groups of the MHS beneficiary population described above into one

single database to more effectively carry out this matching program. In order for TMA to meet the requirements of current law, CMS agrees to disclose certain Part A and Part B enrollment data on this dual eligible population, which will be used to determine a beneficiary's eligibility for care under CHAMPUS/TRICARE. DEERS will receive the results of the computer match and provide the information to TMA for use in its matching program.

This computer matching agreement supersedes all existing data exchange agreements between CMS and DMDC applicable to the exchange of personal data for purposes of disclosing enrollment and eligibility information for MHS beneficiaries who are Medicare eligible.

CATEGORIES OF RECORDS AND INDIVIDUALS COVERED BY THE MATCH:

DEERS will furnish CMS with an electronic file on a monthly basis extracted from the DEERS' systems of records containing social security numbers (SSN) for all MHS beneficiaries who may also be eligible for Medicare benefits. CMS will match the DEERS finder file against its "Medicare Beneficiary Database" system of records (System No. 09-70-0536), and will validate the identification of the beneficiary and provide the Health Insurance Claim Number that matches against the SSN and date of birth provided by DEERS, and also provide the Medicare Part A entitlement status and Part B enrollment status of the beneficiary. CMS's data will help TMA to determine a beneficiary's eligibility for continued care under TRICARE. DEERS will receive the results of the computer match and provide the information provided to TMA for use in its program.

DESCRIPTION OF RECORDS TO BE USED IN THE MATCHING PROGRAM:

DoD will use the SOR identified as S322.50, entitled "Defense Eligibility Records," at 69 **Federal Register** (FR) 33376 (June 15, 2004), as amended by 69 FR 67118 (November 16, 2004). SSNs of DoD beneficiaries will be released to CMS pursuant to the routine use set forth in the system notice, which provides that data may be released to HHS "for support of the DEERS enrollment process and to identify individuals not entitled to health care."

Identification and Medicare status of DoD eligible beneficiaries will be provided to TMA to implement the statutory program. Therefore, eligibility information may also be maintained in the SOR identified as DHA 07, entitled "Military Health Information System

(MHIS)," at 70 FR 44574 (August 3, 2005).

The release of the data for CMS is covered under the "Enrollment Database," System No. 09-70-0502 published in the **Federal Register** at 73 FR 10249 (February 26, 2008). Matched data will be released to DEERS pursuant to the routine use number 2 as set forth in the system notice.

INCLUSIVE DATES OF THE MATCH:

The Matching Program shall become effective no sooner than 40 days after the report of the Matching Program is sent to OMB and Congress, or 30 days after publication in the **Federal Register**, which ever is later. The matching program will continue for 18 months from the effective date and may be renewed for an additional 12 month period as long as the statutory language for the match exists and other conditions are met.

[FR Doc. E8-23080 Filed 9-30-08; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0499]

Agency Information Collection Activities; Proposed Collection; Comment Request; Implementation of Sections 222, 223, and 224 of the Food and Drug Administration Amendments Act of 2007

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the requirement established by Title II of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110-85) that device establishments must submit registration and listing information by electronic means, using FDA Form 3673, unless the Secretary of the Department of Health and Human Services (the

Secretary) grants them a waiver from the electronic submission requirement.

DATES: Submit written or electronic comments on the collection of information by December 1, 2008.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Denver Presley, Jr., Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3793.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.