

Dated: August 26, 2004.

Alvin Hall,

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

[FR Doc. 04-20011 Filed 9-1-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Healthcare Infection Control Practices Advisory Committee (HICPAC): Conference Call Meeting

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 following meeting.

Name: Healthcare Infection Control Practices Advisory Committee.

Time and Date: 1 p.m.–3 p.m., September 10, 2004.

Place: The conference call will originate at the Division of Healthcare Quality Promotion (DHQP), in Atlanta, Georgia. Please see **SUPPLEMENTARY INFORMATION** for details on accessing the conference call.

Status: Open to the public, limited only by the availability of telephone ports.

Purpose: The committee is charged with providing advice and guidance to the Secretary, the Assistant Secretary for Health, the Director, CDC, and the Director, National Center for Infectious Diseases (NCID), regarding: (1) The practice of hospital infection control; (2) strategies for surveillance, prevention, and control of infections (e.g., nosocomial infections), antimicrobial resistance, and related events in settings where healthcare is provided; and (3) periodic updating of guidelines and other policy statements regarding prevention of healthcare-associated infections and healthcare-related conditions.

Matters To Be Discussed: The HICPAC will convene by conference call to discuss the draft Guidance Document on Public Reporting of Healthcare-associated Infection Rates.

Supplementary Information: This conference call is scheduled to begin at 1 p.m., Eastern Time. To participate in the conference call, please dial 1-877-675-5901 and enter Pass Code 254137. You will then be automatically connected to the call.

For Further Information Contact: Harriette Lynch, Committee Management Specialist, HICPAC, Division of Healthcare Quality Promotion, NCID, CDC, 1600 Clifton Road, NE, M/S A-07, Atlanta, Georgia 30333, telephone 404/498-1182, fax 404/498-1188.

Due to programmatic issues that had to be resolved, the **Federal Register** notice is being published less than fifteen days before the date of the meeting.

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: August 26, 2004.

Alvin Hall,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; Computer Matching Program (Match No. 2001-03)

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 announces a new computer matching agreement that CMS plans to conduct with the Internal Revenue Service (IRS), Social Security Administration (SSA), and Centers for Medicare & Medicaid Services (CMS). We have provided background information about the proposed matching program in the **SUPPLEMENTARY INFORMATION** section below. The Privacy Act provides an opportunity for interested persons to comment on the proposed matching program, CMS invites comments on all portions of this notice. See **EFFECTIVE DATES** section below for comment period.

EFFECTIVE DATES: CMS filed a report of the Computer Matching Program with the Chair of the House Committee on Government Reform and Oversight, the Chair of the Senate Committee on Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on August 19, 2004. 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. We may defer implementation of this matching program if we receive comments that persuade us to defer implementation.

ADDRESSES: The public should address comments to: Director, Division of Privacy Compliance Data Development (DPCDD), Enterprise Databases Group, Office of Information Services, HCFA,

Mailstop 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 time zone.

FOR FURTHER INFORMATION CONTACT: John Albert, CMS, Center for Medicare Management Services, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. The telephone number is (410) 786-7457, or facsimile (410) 786-9963.

SUPPLEMENTARY INFORMATION:

I. Description of the Matching Program

A. General

The Computer Matching and Privacy Protection Act (CMPPA) of 1988 (Public Law (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. 100-508) 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 Boards (DIB) 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 of the computer matching programs that this agency participates in complies with the requirements of the Privacy Act of 1974, as amended.

Dated: August 19, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

CENTER FOR MEDICARE & MEDICAID SERVICES

Computer Match No. 2001-03

NAME:

Medicare Secondary Payer Program.

SECURITY CLASSIFICATION:

Level Three Privacy Act Sensitive.

PARTICIPATING AGENCIES:

Internal Revenue Service (IRS), Social Security Administration (SSA) and Centers for Medicare & Medicaid Services (CMS).

AUTHORITY FOR CONDUCTING MATCHING PROGRAM:

This agreement implements the provisions of section 1862(b)(5) of the Social Security Act, (42 U.S.C. 1395y(b)(5)), section 6103(l)(12) of the Internal Revenue Code, (26 U.S.C. 6103(1)(12)), and the Privacy Act, (5 U.S.C. 552a) as amended.

PURPOSE(S) OF THE MATCHING PROGRAM:

1. The purpose of this agreement is to establish the conditions under which:

a. The Internal Revenue Service (IRS) agrees to disclose return information relating to taxpayer identity to the Social Security Administration (SSA); and

b. The SSA agrees to disclose return information relating to employer identity, commingled with taxpayer identity information disclosed by the IRS, to the Centers for Medicare & Medicaid Services (CMS).

2. These disclosures will provide CMS with information for use in determining the extent to which any Medicare beneficiary is covered under any Group Health Plan (GHP). This Matching Agreement between the Department of the Treasury Internal Revenue Service (IRS), and the Social Security Administration (SSA) and the Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) is executed pursuant to the Privacy Act of 1974 (5 U.S.C. 552a), as amended and the Office of Management and the Budget (OMB) Final Guidance interpreting that Act. This agreement implements the information matching provisions of 26 U.S.C. 6103(1)(12) and 42 U.S.C. 1395y(b)(5).

CATEGORIES OF RECORDS AND INDIVIDUALS COVERED BY THE MATCH:

IRS—IRS will disclose taxpayer identity information from the Individual

Master File (IMF), Treas/IRS 24.030, published at 63 FR 69854 (12/17/98). The IRS component responsible for the disclosure of the return information is the Office of Government Liaison and Disclosure. **SSA**—SSA will extract identifying information of Medicare beneficiaries from the Master Beneficiary Record (MBR), SSA/OSR 09-60-0090, published at 65 FR 46997 (08/01/00). SSA will validate the taxpayer SSN by matching information from the IMF against the Master Files of Social Security Number Holders, (NUMIDENT), SSA/OSR 09-60-0058, published at 63 FR 14165 (03/24/98). SSA will extract employer identity information from the Earnings Recording and Self-Employment Income System, SSA/OSR 09-60-0059, referred to as the Master Earnings File (MEF), published at 62 FR 11939 (03/13/97). The SSA component responsible for the disclosure of the return information is the Office of Systems Requirements (OSR). **CMS**—CMS will utilize a database, System Number 09-70-4001, published at 57 FR 60818 (12/22/92), of the GHP information received from employers containing verified instances of employment and GHP coverage for Medicare beneficiaries and Medicare eligible spouses identified from the IMF and MEF extracts. CMS will match the GHP information against the Carrier Medicare Claims Records, System Number 09-70-0501, published at 59 FR 37243-02 (7/21/94), maintained at the CMS Common Working File (CWF), System Number 09-70-0526, published at 53 FR 52792 (12/29/88). CMS will match GHP information against the Carrier Medicare Claims Records, System Number 09-70-0501, published at 59 FR 37243-02 (7/21/94), maintained at the CMS Common Working File (CWF), System Number 09-70-0526, published at 53 FR 52792 (12/29/88), which is the repository database for current MSP information. This file contains information or records needed to properly process and pay medical insurance benefits to, or on behalf of, entitled beneficiaries who have submitted claims for Supplementary Medical Insurance Benefits (Medicare Part B). The file is accessed when a claim is submitted for payment. CMS will match GHP information against the Intermediary Claims Records, System Number 09-70-0503, published at 59 FR 37243-02 (7/21/94), maintained at the CWF.

This file contains information or records needed to properly process and pay Medicare benefits to, or on behalf of, eligible individuals. The file is accessed when a claim is submitted for

payment. CMS will match GHP information against the National Claims History (NCH), which is contained in the National Claims History File, Privacy Act System, HHS, CMS, BDMS 09-70-0005 published at 59 FR 19181 (4/22/94), maintained at CMS Data Center (HDC), located in Baltimore, Maryland. NCH contains records needed to facilitate obtaining Medicare utilization review data that can be used to study the operation and effectiveness of the Medicare program. The CMS component responsible for receipt and verification of the return information is the Office of Information Services (CMS/OIS).

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 extended for an additional 12 months thereafter, if certain conditions are met.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D-0320]

Guidance for Industry and Clinical Investigators on the Use of Clinical Holds Following Clinical Investigator Misconduct; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry and clinical investigators entitled "The Use of Clinical Holds Following Clinical Investigator Misconduct." This guidance provides information on FDA's use of its authority to impose a clinical hold on a study if FDA finds that a clinical investigator conducting the study has committed serious violations of our regulations pertaining to clinical trials involving human drug or biological products or has submitted false information to FDA or to the study's sponsor in any report. The guidance is intended to inform interested persons of the circumstances in which we may impose a clinical hold following the discovery of a clinical investigator's misconduct and the steps