

and/or public health impact, and in planning and providing such assistance. Disclosing beneficiary-identifiable records for public health-related emergency preparedness and response purposes is a necessary and proper use of the information in the systems of records being modified; the new routine use is compatible with the health care purposes for which the information was collected in the CMS systems of records. Disclosure purposes could include emergency planning for outreach to at-risk populations and individuals during a public health emergency. For example, a public health agency could match the records with publicly available power outage data from another department or agency. In the event of a public health emergency that involves power outages, the public health agency would then be able to use the results of the matched data to identify individuals in the affected community who are dependent on energy for meeting their medical needs, for example individuals living in the community who are dependent on dialysis. The term "public health authority" and the concepts of "public health activity" and "minimum necessary" disclosures are defined in the HIPAA Privacy Rule at 45 CFR §§ 154.502, 164.512(b), 164.502(b) and 164.514(d)(3)(iii)(A).

For the reasons described above, the following routine use is added to the eight systems of records listed below:

To disclose beneficiary-identifiable information to public health authorities, and those entities acting under a delegation of authority from a public health authority, when requesting such information to carry out statutorily-authorized public health activities pertaining to emergency preparedness and response. Disclosures under this routine use will be limited to "public health authorities," "public health activities," and "minimum necessary data" as defined in the HIPAA Privacy Rule (45 CFR §§ 154.502, 164.512(b), 164.502(b) and 164.514(d)(3)(iii)(A)).

1. National Claims History (NCH), System No. 09-70-0588, published at 71 *Federal Register* (Fed. Reg.), 67137 (November 20, 2006).

2. Medicare Integrated Data Repository (IDR), System No. 09-70-0571, published at 71 Fed. Reg., 74915 (December 13, 2006).

3. Common Working Files (CWF), System No. 09-70-0526, published at 71 Fed. Reg., 64955 (November 6, 2006).

4. Enrollment Database (EDB), System No. 09-70-0502, published at 73 Fed. Reg., 10249 (February 26, 2008).

5. Medicare Beneficiary Database (MBD), System No. 09-70-0536, published at 71 Fed. Reg., 70396 (December 4, 2006).

6. Medicare Drug Data Processing System (DDPS), System No. 09-70-0553, published at 73 Fed. Reg., 30943 (May 29, 2008).

7. Long Term Care (LTC)-Minimum Data Set (MDS), System No. 09-70-0528, published at 72 Fed. Reg., 12801 (March 19, 2007).

8. Home Health Agency (HHA) Outcome and Assessment Information Set (OASIS), System No. 09-70-0522, published at 72 Fed. Reg. 63906 (November 13, 2007).

Dated: April 11, 2013.

Michelle Snyder,

Deputy Chief Operating Officer, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0176]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Experimental Study: Examination of Corrective Direct-to-Consumer Television Advertising

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Experimental Study: Examination of Corrective Direct-to-Consumer Television Advertising" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, daniel.gittleson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On January 8, 2013, the Agency submitted a proposed collection of information entitled "Experimental Study: Examination of Corrective Direct-to-Consumer Television Advertising" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0737. The

approval expires on March 31, 2016. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: April 16, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-09482 Filed 4-22-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0477]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Investigational Device Exemptions Reports and Records

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Investigational Device Exemptions Reports and Records" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, daniel.gittleson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On January 3, 2013, the Agency submitted a proposed collection of information entitled "Investigational Device Exemptions Reports and Records" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0078. The approval expires on March 31, 2016. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: April 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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