

the Consolidated Health Informatics (CHI) initiative.

FOR FURTHER INFORMATION CONTACT:
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SUPPLEMENTARY INFORMATION:

I. Background

The Consolidated Health Informatics (CHI) initiative began in October 2001 as one of 24 E-Government initiatives included in the President's Management Agenda (PMA). The CHI initiative is a collaborative effort to adopt Federal government-wide health information interoperability standards to be implemented by Federal agencies in order to enable the Federal government to exchange electronic health information.

On May 6, 2004, the Secretary of the Department of Health and Human Services (HHS) announced the adoption by HHS, the Department of Defense, the Department of Veterans Affairs, the Office of Management and Budget, and other participating Federal partners of 15 healthcare messaging and vocabulary standards recommended by the CHI initiative (<http://www.hhs.gov/news/press/2004pres/20040506.html>). The adoption of these standards supplemented the first 5 standards adopted on March 21, 2003 (<http://www.hhs.gov/news/press/2003pres/20030321a.html>), thereby completing the initial CHI portfolio.

The portfolio of 20 adopted standards will be used by all Federal agencies in implementing new, and to the extent possible, in modifying existing health information technology systems, as well as related business processes.

II. CHI Adopted Standards

As a result of work completed in furtherance of CHI, the 20 clinical standards that have been adopted for use by all Federal agencies as they develop and implement new information technology systems are as follows:

1. Laboratory Results Names. Standard: Logical Observation Identifiers Names and Codes (LOINC®).
2. Messaging Standards. Includes: Scheduling, medical record/image management, patient administration, observation reporting, financial management, public health notification, and patient care. Standard: Health Level Seven® (HL7®) Version 2.3 and greater.
3. Messaging Standards. Includes: Retail pharmacy transactions. Standard: National Council for Prescription Drug Programs (NCPDP) SCRIPT®.
4. Messaging Standards. Includes: Device-device connectivity. Standard: Institute of Electrical and Electronics Engineers, Inc.™ 1073.

5. Messaging Standards. Includes: Image information to workstations. Standard: Digital Imaging and Communications in Medicine® (DICOM®).

6. Demographics. Standard: HL7® Version 2.4 and greater.

7. Lab Result Contents. Standard: Systematized Nomenclature of Medicine Clinical Terms® (SNOMED CT®).

8. Units of Measure. Standard: HL7® Version 2.X+.

9. Immunizations. Standard: HL7® Version 2.3.1, specifically the Vaccines Administered (CVX) and Manufacturers of Vaccines (MVX) external code sets maintained by the Centers for Disease Control and Prevention's (CDC) National Immunization Program (NIP).

10. Medications. Standards: Federal Drug Terminologies: (Sub-domain: Standard Adopted):

- *Active Ingredient:* FDA Established Names & Unique Ingredient Identifier (UNII) codes.
- *Manufactured Dosage Form:* FDA/CDER Data Standards Manual.
- *Drug Product:* FDA's National Drug Codes (NDC).
- *Medication Package:* FDA Standards Manual.
- *Label Section Headers:* LOINC® Clinical Structured Product Labeling (SPL).

• *Special Populations:* HL7 Version 2.4 and greater.

• *Drug Classifications:* The Department of Veterans Affairs' National Drug File Reference Terminology (NDF-RT) for mechanism of action and physiologic effect.

• *Clinical Drug:* the National Library of Medicine's RxNorm.

11. Interventions/Procedures (Part A): Lab Test Order Names. Standard: LOINC®.

12. Interventions/Procedures (Part B): Non-laboratory. Standard: SNOMED CT®.

13. Anatomy. Standards: SNOMED CT® and the National Cancer Institute's (NCI) Thesaurus.

14. Diagnosis/Problem Lists. Standard: SNOMED CT®.

15. Nursing. Standard: SNOMED CT®.

16. Financial/Payment. Standard: HIPAA Transactions and Code Sets.

17. Genes. Standard: Human Genome Nomenclature.

18. Clinical Encounters. Standard: HL7® Version 2.4 and greater.

19. Text-Based Reports. Standards: HL7® and Clinical Document Architecture (CDA) Version 1.0-2000 Chemicals.

20. Chemicals. Standard: Environmental Protection Agency's Substance Registry System.

Specific details of these CHI standards can be obtained from the domain-

specific full reports available for download at: <http://www.hhs.gov/healthit/chi.html>.

III. Collection of Information Requirements

This notice does not impose information collection and recordkeeping requirements regulated by the Paperwork Reduction Act of 1995; that is, it does not require obtaining facts or opinions or answers to questions by or for a Federal agency. Consequently, it need not be reviewed by the Office of Management and Budget under 44 U.S.C. 35.

IV. Impact Statement

We have chosen to explain the impact we foresee this notice having on the public as follows: There are indirect impacts for Federal contractors or potential contractors who may be involved in health information technology design, development, or evaluation. The Federal government will require all future health information technology system acquisitions to be based on CHI standards when applicable, whether system development occurs within the Agency or through the use of contractor services.

Authority: The E-Government Act of 2002 (Pub. L. 107-347) (H.R. 2458)

Dated: September 13, 2005.

Mark B. McClellan,
Administrator, Centers for Medicare & Medicaid Services.

Approved: August 25, 2005.

Michael O. Leavitt,
Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10170]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden

estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Retiree Drug Subsidy (RDS) Payment Request and Instructions; *Form Number:* CMS-10170 (OMB#: 0938-0977); *Use:* Under section 1860D-22 of the Social Security Act (Act), added by the Medicare Prescription Drug, Improvement and Modernization Act of 2003, plan sponsors (employers, unions) who offer prescription drug coverage to their qualified covered retirees are eligible to receive a 28 percent tax-free subsidy for allowable drug costs. To receive the subsidy, plan sponsors must submit required prescription cost data. CMS has contracted with an outside vendor (ViPS) to assist in the administration of the retiree drug subsidy (RDS) program; this effort is called the RDS Center. Plan sponsors will request subsidy payments on-line by logging on to the RDS secure Web site. Cost data required for each payment request may be entered into the RDS secure Web site, or uploaded to the RDS Center mainframe. Once the plan sponsor submits the payment request, the RDS Center will process the request to determine if payment is due and the amount of the payment. *Frequency:* Recordkeeping and Reporting—Monthly, Quarterly and Annually; *Affected Public:* Not-for-profit institutions, Business or other for-profit, Federal Government, State, Local, or Tribal Government; *Number of Respondents:* 6,000; *Total Annual Responses:* 6,000; *Total Annual Hours:* 222,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at <http://www.cms.hhs.gov/regulations/prd/>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must

be received at the address below, no later than 5 p.m. on February 21, 2006. CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—C, Attention: Bonnie L Harkless, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: December 13, 2005.

Michelle Shortt,

*Director, Regulations Development Group,
Office of Strategic Operations and Regulatory Affairs.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS R-193 and CMS-2567]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Important Message from Medicare Title XVII Section 1866(a)(1)(M), 42 CFR Sections 466.78, 489.20, and 489.27; *Form Number:* CMS-R-193 (OMB#: 0938-0692); *Use:* Hospitals participating in the Medicare program are required to distribute the "Important Message From Medicare" to all Medicare beneficiaries (including those enrolled in a Medicare

managed care health plan). Hospitals must distribute this notice at or about the same time of a Medicare beneficiary's admission or during the course of his or her hospital stay. Receiving this information will provide all Medicare beneficiaries with some ability to participate and/or initiate discussions concerning actions that may affect their Medicare coverage, payment, and appeal rights in response to a hospital's or Medicare managed care plan's notification that their care will no longer continue; *Frequency:* Recordkeeping and Reporting—Other: Distribution; *Affected Public:* Individuals or Households, Business or other for-profit, Not-for-profit institutions, Federal, State, Local or Tribal Government; *Number of Respondents:* 6,051; *Total Annual Responses:* 12,500,000; *Total Annual Hours:* 208,333.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Statement of Deficiencies and Plan of Correction contained under 42 CFR 488.18, 488.26, and 488.28; *Form Number:* CMS-2567 (OMB#: 0938-0391); *Use:* Section 1864(a) of the Social Security Act requires that the Secretary use State survey agencies to conduct surveys. The surveys are used to determine if health care facilities meet Medicare, Medicaid, and Clinical Laboratory Improvement Amendments (CLIA) participation requirements. The Statement of Deficiencies and Plan of Correction form, is used to record each deficiency discovered during an inspection. Providers, suppliers and CLIA laboratories also utilize this form to outline a corrective action plan for each deficiency. The States and CMS regional offices use this form to document and certify compliance, and to disclose information to the public; *Frequency:* Recordkeeping, Third party disclosure and Reporting—Annually and Biennially; *Affected Public:* Business or other for-profit, Not-for-profit institutions, Federal, State, Local or Tribal Government; *Number of Respondents:* 60,000; *Total Annual Responses:* 60,000; *Total Annual Hours:* 120,000.

To obtain copies of the supporting statement and any related forms for these paperwork collections referenced above, access CMS Web site address at <http://www.cms.hhs.gov/regulations/prd/>, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.