DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institute for Occupational Safety and Health

Final Effect of Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) gives notice concerning the final effect of the HHS decision to designate a class of employees at Nuclear Materials and Equipment Corporation (NUMEC) in Apollo, Pennsylvania, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On November 29, 2007, as provided for under 42 U.S.C. 7384q(b), the Secretary of HHS designated the following class of employees as an addition to the SEC:

Atomic Weapons Employer (AWE) employees who were monitored or should have been monitored for exposure to ionizing radiation while working at the Nuclear Materials and Equipment Corporation (NUMEC) in Apollo, Pennsylvania from January 1, 1957, through December 31, 1983, for a number of work days aggregating at least 250 work days or in combination with work days within the parameters established for one or more other classes of employees in the Special Exposure Cohort.

This designation became effective on December 29, 2007, as provided for under 42 U.S.C. 7384*l*(14)(C). Hence, beginning on December 29, 2007, members of this class of employees, defined as reported in this notice, became members of the Special Exposure Cohort.

FOR FURTHER INFORMATION CONTACT: Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 513–533–6800 (this is not a toll-free number). Information requests can also be submitted by e-mail to *OCAS@CDC.GOV*.

Dated: January 15, 2008.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. E8–1018 Filed 1–22–08; 8:45 am]

BILLING CODE 4160–17–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Scientific Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) and the Assistant Secretary for Health have taken final action in the following case:

Scott E. Monte, Huntington Memorial Hospital: Based on the findings of an investigation conducted by Huntington Memorial Hospital (HMH) and information obtained by the Office of Research Integrity (ORI) during its oversight review, the U.S. Public Health Service (PHS) found that Scott E. Monte, L.V.N., former Clinical Research Associate, HMH, engaged in scientific misconduct by knowingly and intentionally falsifying and fabricating clinical research records in HMH cancer prevention and treatment protocols supported by National Cancer Institute (NCI), National Institutes of Health (NIH), awards U10 CA69651, U10 CA12027, U10 CA32012, and U10 CA86004.

Specifically, Mr. Monte knowingly and intentionally:

(1) Entered falsified and fabricated laboratory data or physical examination results on five (5) research protocol case report forms (CRFs);

(2) Falsified a gynecological examination report in a physician's progress note and entered the falsified document in the patient's research chart; and

(3) Fabricated progress notes for four patients and a case report form for one of these patients.

ORI has implemented the following administrative actions for a period of three (3) years, beginning on January 7, 2008:

(1) Dr. Monte is debarred from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government pursuant to HHS' implementation of the OMB Guidelines to Agencies on Governmentwide Debarment and Suspension at 2 CFR Part 376; and

(2) Dr. Monte is prohibited from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8800.

Chris B. Pascal,

Director, Office of Research Integrity.

[FR Doc. E8–1024 Filed 1–22–08; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology (ONC), DHHS

Notice of Availability: Secretarial Recognition of Certain Healthcare Information Technology Standards Panel (HITSP) Interoperability Specifications as Interoperability Standards for Health Information Technology

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), DHHS.

Authority: Executive Order 13335 (''Incentives for the Use of Health Information Technology and Establishing the Position of the National Health Information Technology Coordinator''), Executive Order 13410 (''Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs''), Public Law 110–161, (''Consolidated Appropriations Act, 2008''), 42 U.S.C.1395nn(b)(4), 42 U.S.C. 1302(a), and 42 CFR 411.357(w).

SUMMARY: By publication of this document, we are informing the public of the Secretary's recognition of certain Healthcare Information Technology Standards Panel (HITSP) ''Interoperability Specifications'' as interoperability standards for health information technology. The Secretary accepted these HITSP ''Interoperability Specifications'', Version 1.2, in December of 2006, and hereby recognizes them as interoperability standards in updated versions in January of 2008. The list of recognized interoperability standards is provided below and is available at *http://www.hitsp.org*; click on ''HITSP Interoperability Specifications HERE'' box.

SUPPLEMENTARY INFORMATION: The Healthcare Information Technology Standards Panel (HITSP) was created in 2005 to serve as a cooperative partnership between the public and private sectors for the purpose of achieving a widely accepted and useful set of standards specifically to enable and support widespread interoperability

among healthcare software systems, as they will interact in a local, regional, and the Nationwide Health Information Network in the United States.

Under a contract with the Department of Health and Human Services, the American National Standards Institute (ANSI) established HITSP, following a neutral and inclusive governance model. The process was built by vendors, standards development organizations (SDOs), consumers, payers, providers, etc. HITSP is a multi-stakeholder organization involving more than 600 different healthcare industry organizations and technical experts whose activities to date on these Interoperability Specifications represent more than 20,000 volunteer hours of effort.

In March of 2006, HITSP was given three initial priority areas (use cases): Consumer Empowerment, Biosurveillance, and Laboratory Electronic Health Record Interoperability. HITSP converted those use cases into detailed requirements documents and examined more than 700 standards that would meet those requirements and assessed their readiness and appropriateness. From those 700 standards, HITSP identified 30 named standards, and produced detailed implementation guidance, ''constructs,'' that describe the specific transactions and use of these named standards. The Secretary therefore is recognizing the ''constructs'' associated with the as interoperability standards to clarify the intended use and application of the ''named standards''.

On October 31, 2006, HITSP presented to the American Health Information Community (AHIC) three sets of Interoperability Specifications. The AHIC is a Federal Advisory Committee Act (FACA) advisory body, chartered in 2005 to make recommendations to the Secretary on methods for accelerating the development and adoption of health information technology. At the October 31, 2006, AHIC meeting, the members discussed the HITSP Interoperability Specifications and made the consensus recommendation that the Interoperability Specifications be recognized by the Secretary. Secretary Leavitt accepted these Interoperability Specifications in December 2006 with the intent to recognize them one year later, presuming that any changes would be minimal, reflecting public comment and/or of a minor and technical nature. On March 1, 2007, the Department published a Notice in the **Federal Register** (72 FR 9339) announcing the Secretary's acceptance and planned recognition of certain interoperability specifications.

The HITSP Panel approved the subsequent version of the interoperability specifications on May 11, 2007. No additional constructs or standards were added as a result of implementation testing feedback. All changes were minor or of a technical nature to the implementation guidance. On June 12, 2007, HIC presented to Secretary Leavitt these completed Interoperability Specifications, including 28 of 30 completely balloted named standards and implementation guidance in the form of constructs. As detailed below, in December 2007, one of the two outstanding named standards passed ballot by its SDO; after the designated 6-month waiting period, this named standard and two associated constructs will achieve full recognition status by the Secretary in June 2008 by the Secretary. The final standard is still under ballot.

The three high level groupings of these interoperability standards are as follows.

I. Electronic Health Record (EHR) Laboratory Results Reporting

The purpose of the EHR interoperability specification is to allow ordering clinicians to electronically access laboratory results, and to allow non-ordering authorized clinicians to electronically access historical and other laboratory results for clinical care. The recognized version of the standard addresses the lack of harmonization among data interoperability standards including vocabulary and laboratory and other messaging standards; it also accommodates both laboratory message transaction and document-sharing paradigms. In addition, a laboratory message implementation guide has been completed to meet AHIC use case requirements. The EHR specification is complete and includes all of the implementation guidance necessary to implement and the final balloted work products of all the standards development organizations involved, with one caveat. The messaging standard for laboratories, HL–7 2.5.1, passed ballot in December 2007, with final implementation guidance to be incorporated into the HITSP specifications. This standard, along with an associated construct, the Lab Result Message Component (C36) will achieve full recognition status by the Secretary in June 2008.

The interoperability standards—Interoperability Specification including Constructs (Components, Transactions, and Transaction Packages) and Named Standards associated with EHR are listed below.

Interoperability Specification Constructs (Components (C), Transactions (T), and Transaction Packages (TP)) for EHR

- EHR Lab Reporting Interoperability Specification (HITSP V2.1 2007 IS01).
- Lab Result Terminology Component (HITSP V2.0 2007 C35).
- Lab Report Document Component (HITSP V2.0 2007 C37).
- Secure Web Connection Component (HITSP V2.0 2007 C44).
- View Lab Result From Web App Transaction (HITSP V2.0 2007 T18).
- Patient Demographics Query Transaction (HITSP V2.0 2007 T23).
- Notification of Document Availability Transaction (HITSP V2.0 2007 T29).
- Manage Sharing of Documents Transaction Package (HITSP V2.2 2007 TP13).
- Send Lab Result Message Transaction Package (HITSP V2.1 2007 TP14).
- Patient ID Cross-Referencing Transaction Package (HITSP V2.0 2007 TP22).

Named Standards for EHR

- Portions of the Clinical Laboratory Improvement Amendments (CLIA) of 1988 (42 CFR part 493).
- Portions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA)—Administrative Simplification.
- Health Level Seven (HL7) Version 2.5.
- Health Level Seven (HL7) Version 2.5/2.5.1.
- Health Level Seven (HL7) Version 3.0 Clinical Document Architecture (CDA/CDA R2).
- Hypertext Transfer Protocol Secure (HTTPS) 443/tcp.
- Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI–TF) Revision 3.0.
- Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI–TF) Revision 4.0.
- Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI–TF) Revision 4.0—Registry Stored Query Transaction for XDS Profile Supplement.
- Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI–TF) Revision 4.0 XCA Supplement.
- Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF)

Supplement—ITI–25 Notification of Document Availability (NAV) June 28, 2005.

• Integrating the Healthcare Enterprise (IHE) Laboratory Technical Framework Supplement 2006–2007 Revision 1.0.

• International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®).

• International Organization for Standardization (ISO) Electronic business eXtensible Markup Language (ebXML), Technical Specification # 15000—Part 4: Registry services specification (ebRS), May, 2004.

• Logical Observation Identifiers Names and Codes (LOINC®).

• Unified Code for Units of Measure (UCUM).

II. Biosurveillance (BIO)

The purpose of the BIO interoperability specification is to transmit essential ambulatory care and emergency department visit, utilization, and laboratory result data from electronically enabled healthcare delivery and public health systems in standardized and anonymized format to authorized Public Health Agencies with less than one day lag time. The BIO specification is complete and includes all of the implementation guidance necessary to implement and the final balloted work products of all the standards development organizations involved, with two exceptions. The messaging standard for laboratories, HL–7 2.5.1, passed ballot in December 2007, with final implementation guidance to be incorporated into the HITSP specifications. This standard, along with two associated constructs, the Lab Result Message Component (C36) and the Resource Utilization Component (C47), will achieve full recognition status by the Secretary in June 2008. The Hospital Availability Exchange Standard (HAVE) is still under the SDO ballot process.

The interoperability standards—Interoperability Specification including Constructs (Components, Transactions, and Transaction Packages) and Named Standards associated with BIO are listed below.

Interoperability Specification Constructs (Components (C), Transactions (T), and Transaction Packages (TP)) for BIO

• Biosurveillance Interoperability Specification (HITSP V2.1 2007 IS02).

• Anonymize Component (HITSP V2.1 2007 C25).

• Lab Result Terminology Component (HITSP V2.0 2007 C35).

• Lab Report Document Component (HITSP V2.0 2007 C37).

• Encounter Message Component (HITSP V2.0 2007 C39).

• Radiology Result Message Component (HITSP V2.0 2007 C41).

• Encounter Document Component (HITSP V2.1 2007 C48).

• Pseudonymize Transaction (HITSP V2.1 2007 T24).

• Notification of Document Availability Transaction (HITSP V2.0 2007 T29).

• Manage Sharing of Documents Transaction Package (HITSP V2.2 2007 TP13).

• Patient ID Cross-Referencing Transaction Package (HITSP V2.0 2007 TP22).

• Sharing Radiology Results Transaction Package (HITSP V2.0 2007 TP49).

• Retrieve Form for Data Capture Transaction Package (HITSP V2.1 2007 TP50).

Named Standards for BIO:

• American Medical Association (AMA) Current Procedural Terminology (CPT®) Fourth Edition (CPT–4).

• Clinical Care Classification (CCC) Version 2.0 [formerly known as the Home Healthcare Classification (HHCC) System].

• Portions of the Clinical Laboratory Improvement Amendments (CLIA) of 1988 (42 CFR part 493).

• Digital Imaging and Communications in Medicine (DICOM) Attribute Level Confidentiality Supplement: # 55.

• Federal Information Processing Standards (FIPS) Codes for the Identification of the States, the District of Columbia and the Outlying Areas of the United States, and Associated Areas Publication # 5–2, May, 1987.

• Portions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA)—Administrative Simplification.

• Health Level Seven (HL7) Version 2.5.

• Health Level Seven (HL7) Version 2.5/2.5.1.

• Health Level Seven (HL7) Version 3.0.

• Health Level Seven (HL7) Version 3.0 Clinical Document Architecture (CDA/CDA R2).

• Healthcare Common Procedure Coding System (HCPCS) Level II Code Set.

• Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI–TF) Revision 3.0.

• Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI–TF) Revision 4.0.

• Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI–TF) Revision 4.0—Registry Stored Query Transaction for XDS Profile Supplement.

• Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI–TF) Revision 4.0 XCA Supplement.

• Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) Supplement—ITI–25 Notification of Document Availability (NAV) June 28, 2005.

• Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) Supplement—Retrieve Form for Data Capture (RFD) Sept 25, 2006.

• Integrating the Healthcare Enterprise (IHE) Laboratory Technical Framework Supplement 2006–2007 Revision 1.0.

• Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Framework Revision 3.0.

• Integrating the Healthcare Enterprise (IHE) Radiology Technical Framework Revision 7.0.

• International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–CS).

• International Classification of Diseases, 10th Revision, Related Health Problems (ICD–10–CM).

• International Classification of Diseases, 9th Revision, Clinical Modifications (ICD–9–CM).

• International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®).

• International Organization for Standardization (ISO) Health informatics—Pseudonymization, Unpublished Technical Specification # 25237.

• International Organization for Standardization (ISO) Electronic business eXtensible Markup Language (ebXML), Technical Specification # 15000—Part 4: Registry services specification (ebRS), May, 2004.

• Logical Observation Identifiers Names and Codes (LOINC®).

• National Library of Medicine (NLM) Unified Medical Language System (UMLS) RxNorm.

• National Uniform Billing Committee (NUBC) Uniform Bill Version 1992 (UB–92) Current UB Data Specification Manual Field 22, Patient Discharge Status, Codes.

• Organization for the Advancement of Structured Information Standards

(OASIS) Emergency Data Exchange Language (EDXL) Distribution Element (DE).

• Unified Code for Units of Measure (UCUM).

III. Consumer Empowerment (CE)

The purpose of the CE interoperability specification is to allow consumers to establish and manage permissions access, rights, and informed consent for authorized and secure exchange, viewing, and querying of their linked patient registration summaries and medication histories between designated caregivers and other health professionals. The CE specification is complete and includes all of the implementation guidance necessary to implement and the final balloted work products of all the standards development organizations involved.

The interoperability standards—Interoperability Specification including Constructs (Components, Transactions, and Transaction Packages) and Named Standards associated with CE are listed below.

Interoperability Specification Constructs (Components (C), Transactions (T), and Transaction Packages (TP)) for CE

• Consumer Empowerment Interoperability Specification (HITSP V2.1 2007 IS03).

• Summary Documents Using CCD Component (HITSP V2.1 2007 C32).

• Patient Demographics Query Transaction (HITSP V2.0 2007 T23).

• Manage Sharing of Documents Transaction Package (HITSP V2.2 2007 TP13).

• Patient ID Cross-Referencing Transaction Package (HITSP V2.0 2007 TP22).

Named Standards for CE

• Accredited Standards Committee (ASC) X12 Insurance Subcommittee (X12N) Implementation Guides Version 004010 plus Addenda 004010A1.

• Accredited Standards Committee (ASC) X12 Standards Release 004010.

• American Society for Testing and Materials (ASTM) Standard Specification for Coded Values Used in the Electronic Health Record: # E1633–02.

• American Society for Testing and Materials (ASTM) Standard Specification for Continuity of Care Record (CCR): # E2369–05.

• CDC Race and Ethnicity Code Sets.

• Council for Affordable Quality Health Care (CAQH) Committee on Operating Rules for Information Exchange (CORE) Phase I Operating Rules.

• Federal Medication Terminologies.

• Health Care Provider Taxonomy.

• Health Level Seven (HL7) EHR System Functional Model Draft Standard for Trial Use (DSTU).

• Health Level Seven (HL7) Version 2.5.

• Health Level Seven (HL7) Version 2.5/2.5.1.

• Health Level Seven (HL7) Version 3.0.

• Health Level Seven (HL7) Version 3.0 Clinical Document Architecture (CDA/CDA R2).

• HL7 Implementation Guide: CDA Release 2—Continuity of Care Document (CCD), Release 1.0, April 1, 2007.

• Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI–TF) Revision 3.0.

• Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI–TF) Revision 4.0.

• Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI–TF) Revision 4.0—Registry Stored Query Transaction for XDS Profile Supplement.

• Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI–TF) Revision 4.0 XCA Supplement.

• Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Framework Revision 3.0.

• International Organization for Standardization (ISO) Electronic business eXtensible Markup Language (ebXML), Technical Specification # 15000—Part 4: Registry services specification (ebRS), May, 2004.

• Logical Observation Identifiers Names and Codes (LOINC®).

• National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard Version 8.1.

• Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity.

We recognize that certain legal obligations may flow from the recognition of these interoperability standards. First, pursuant to Executive Order 13410 (EO 13410) dated August 22, 2006, recognition of interoperability standards would require each Federal health agency, as it implements, acquires, or upgrades health information technology systems used for the direct exchange of health information between agencies and with non-Federal entities, to ''utilize, where available, health information technology systems and products that meet interoperability standards recognized by the Secretary.'' Therefore, Federal agencies would be required to appropriately consider health information technology systems and products that comply with these Interoperability Specifications when purchasing, implementing, or upgrading such items.

Similarly, the EO 13410 directs Federal agencies to contractually require, to the extent permitted by law, certain entities with whom they do business, to use, where available, health information technology systems and products that meet recognized interoperability standards.

In addition, the regulations promulgated on August 8, 2006 (see 71 FR 45140 and 71 FR 45110) established exceptions and safe harbors to the physician self-referral law and the anti-kickback statute, respectively, for certain arrangements involving the donation of electronic prescribing and electronic health records (EHR) technology and services. The EHR exception and safe harbor require that the software be ''interoperable'' as defined in the regulations. The rules also provide that certain software will be deemed to be ''interoperable'' if that software has been certified by a certifying body recognized by the Secretary within 12 months prior to the donation. Under the interim guidance for the recognition of certifying bodies published by the ONC (''Office of the National Coordinator for Health Information Technology (ONC) Interim Guidance Regarding the Recognition of Certification Bodies''), for an organization to be recognized as a recognized certifying body (RCB), the organization must:

Have in place a demonstrated process for and experience in certifying products to be in compliance with criteria recognized by the Secretary;

Have a method by which they can incorporate all applicable standards and certification criteria recognized by the Secretary into their certification processes; and

Have the ability to adapt their processes to emerging certification criteria recognized by the Secretary.

The RCBs would therefore have to certify such products in conformity with, among other provisions, these interoperability specifications for the certified products to meet the interoperability deeming provisions of the physician self-referral exception and anti-kickback safe harbor, respectively.

The Secretary is mindful that the ability of software to be interoperable evolves as technology develops. Consequently, if an enforcement action is initiated for an allegedly improper donation of EHR non-certified software,

the Secretary would review whether the software was interoperable, as defined in the regulations. The Secretary would consider the prevailing state of technology at the time the items or services were provided to the recipient. As explained in the regulations, the Secretary understands that parties should have a reasonable basis for determining whether the EHR software is interoperable. We therefore indicated that ''it would be appropriate—and, indeed, advisable—for parties to consult any standards and criteria related to interoperability recognized by the Department.''

Compliance with these standards and criteria, as we explained in the regulations, ''will provide greater certainty to donors and recipients that products meet the interoperability requirement, and may be relevant in an enforcement action.''

Based on the changing nature of technological development noted above, the Secretary has accepted and recognized these Interoperability Specifications. He has also delegated authority to ONC to coordinate and oversee the incorporation of these Interoperability Specifications in relevant activities among Federal agencies and other partner organizations, as appropriate.

FOR FURTHER INFORMATION CONTACT: Judith Sparrow at (202) 690–7151.

Dated: January 17, 2008.

Robert M. Kolodner,

National Coordinator for Health Information Technology, Office of the National Coordinator for Health Information Technology.

[FR Doc. 08–234 Filed 1–17–08; 1:18pm]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–08–05CZ]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov*. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

Assessing the Diabetes Detection Initiative for Policy Decisions—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Type II diabetes is a chronic disease that affects more than 18 million Americans, approximately 5 million of whom do not know that they have the disease. As the disease progresses, it often causes severe complications, including heart disease, blindness, lower extremity arterial disease, and kidney failure. American Indians, African Americans, Latino Americans, and some Asian Americans and Pacific Islanders are disproportionately affected by diabetes. Identifying persons who have undiagnosed diabetes and treating them could prevent or delay diabetes complications.

In November 2003 the Diabetes Detection Initiative (DDI) was launched in 10 regional locations around the U.S. to identify a portion of the estimated 5 million people with undiagnosed Type II diabetes. The DDI was designed to refer persons at increased risk of Type II diabetes to diagnostic testing, and if appropriate, to follow-up treatment. Whether or not the DDI should be expanded to other communities depends on the health benefit and costs of the program. The CDC plans to conduct a one-year study to provide this critical information.

The planned information collection will assess the resources used, the cost per case detected, and the perceived benefit of the DDI to patients. Information for the assessment will be obtained by conducting the following surveys: (1) A health clinic leadership survey will be completed by the clinic director or representative of each of the 43 clinics that participated in the DDI. The survey will obtain information on all activities and resources used at the clinic level related to diabetes screening, detection, and outreach services. Approximately 30 of the 43 eligible clinics are expected to participate in the survey. (2) A patient survey will be administered to a sample of 600 patients from the participating clinics. The survey will collect information about each patient's background and out-of-pocket medical and non-medical direct health care costs (e.g., co-payments, transportation costs, and the value of the patient's time associated with clinic visits). The DDI Patient Survey will include a computer-assisted personal interview (CAPI) module to collect information about each patient's stated preferences with respect to diabetes screening options.

The results of the study will also provide information needed for evaluating the long-term cost-effectiveness of screening for undiagnosed diabetes in the United States.

There are no costs to the respondents other than their time. The total estimated annualized burden hours are 263.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden (in hours)
DDI Clinic Representatives	DDI Health Clinic Leadership Survey	30	1	1
Patients at DDI Clinics	Screening Questions for the DDI Patient Survey	1,000	1	2/60
	DDI Patient Survey	600	1	20/60