

Company/Jayhawk Works near Pittsburg, Kansas, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On August 15, 2008, the Secretary of HHS designated the following class of employees as an addition to the SEC:

All Atomic Weapons Employer (AWE) employees who worked at Spencer Chemical Company/Jayhawk Works near Pittsburg, Kansas, from January 1, 1956 through December 31, 1961 for a number of work days aggregating at least 250 work days occurring either solely under this employment 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 will become effective on September 14, 2008, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the **Federal Register** reporting the addition of this class to the SEC or the result of any provision by Congress regarding the decision by HHS to add the class to the SEC.

**FOR FURTHER INFORMATION CONTACT:**

Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 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](mailto:OCAS@CDC.GOV).

Dated: August 22, 2008.

**Christine M. Branche,**

*Acting Director, National Institute for Occupational Safety and Health.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[30Day-08-08AL]

**Proposed Data Collections Submitted for Public Comment and Recommendations**

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](mailto: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**

The Natural History of Spina Bifida in Children Pilot Project-New-National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

Spina Bifida (SB) is one of the most common birth defects, affecting approximately 2 per 10,000 live births in the United States annually. To date, there are no U.S. population-based cohort studies or programs on the natural history of SB. This is of importance because persons with SB often experience condition-specific difficulties and secondary conditions that detrimentally affect several aspects of their lives. The long-term purpose of this project is to increase the knowledge about the natural history of Spina Bifida by prospectively studying children who

were born with this potentially disabling condition. We estimate to enroll approximately 40 parents with a child with Spina Bifida ages 3-, 4-, or 5-years of age, and 20 of the children of these forty parents. The data to be collected will relate to medical concerns prevalent among individuals with Spina Bifida in the areas of neurology/neurosurgery, urology, and orthopedics; development and learning; nutrition and physical growth; mobility and functioning; general health; and family demographics. Families interested in participating can choose between participating in a phone survey (no more than 45 minutes) or an in-person assessment (no more than 3 hrs). For families who participate in the in-person assessment (estimated to be twenty of the forty families), the child will also be invited to participate in a child-appropriate assessment.

Data will also be collected on the actual recruitment process. Results from the project will be evaluated and disseminated to provide guidance for states that are interested in following children with Spina Bifida prospectively. The proposed project is the initial step to document the development, the health status, and the onset of complications among children with SB in order that effective interventions may be identified that will ameliorate the course of this complex, multi-system condition. Long-term results will help determine if it would be beneficial to systematically screen children with Spina Bifida for certain health-related educational and developmental problems that these children are at an increased risk of experiencing and at what age such a screening should be performed.

There will be no cost to the respondents other than their time. The total estimated annualized burden hours are 97.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Parents (phone survey) .....	20	1	45/60
Parents (in-person assessment) .....	20	1	2.5
Child (in-person assessment) .....	20	1	1.5
SB Clinic Coordinator (recruitment effort) .....	1	1	2

Dated: August 22, 2008.

**Maryam I. Daneshvar,**

*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Consolidated Vaccine Information Materials for Multiple Infant Vaccines; Revised Instructions for Use of Vaccine Information Statements

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** Under the National Childhood Vaccine Injury Act (NCVIA) (42 U.S.C. § 300aa-26), the CDC must develop vaccine information materials that all health care providers are required to give to patients/parents prior to administration of specific vaccines. CDC seeks written comment on a proposed new vaccine information statement that consolidates the six vaccine information statements for the following childhood vaccines: DTaP, *Haemophilus influenzae* type b, inactivated polio vaccine, pneumococcal conjugate vaccine, hepatitis B, and rotavirus. This consolidated Vaccine Information Statement would be available to be used by vaccination providers as an alternative to providing the six individual Vaccine Information Statements for the same vaccines. On October 4, 2007, CDC published a notice in the **Federal Register** (72 FR 56765) seeking public comments on the proposed consolidated vaccine information materials. The 60 day comment period ended on December 3, 2007. Following review of the comments submitted and consultation as required under the law, CDC has finalized these vaccine information materials. The final materials, and revised instructions for their use and for use of materials for other covered vaccines, are contained in this notice.

**DATES:** Beginning August 28, 2008, each health care provider who administers vaccine that contains diphtheria, tetanus, pertussis, hepatitis B, pneumococcal conjugate, inactivated polio, *Haemophilus influenzae* type b, or rotavirus vaccines may, prior to administration of each dose of these vaccines, provide a copy of the vaccine

information materials contained in this notice, dated January 30, 2008, to the parent or legal representative of any child to whom such provider intends to administer the vaccines, in lieu of providing vaccine information materials for each individual vaccine.

**FOR FURTHER INFORMATION CONTACT:**

Anne Schuchat, M.D., Director, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Mailstop E-05, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone (404) 639-8200.

**SUPPLEMENTARY INFORMATION:** The National Childhood Vaccine Injury Act of 1986 (Pub. L. 99-660), as amended by section 708 of Public Law 103-183, added section 2126 to the Public Health Service Act. Section 2126, codified at 42 U.S.C. 300aa-26, requires the Secretary of Health and Human Services to develop and disseminate vaccine information materials for distribution by all health care providers in the United States to any patient (or to the parent or legal representative in the case of a child) receiving vaccines covered under the National Vaccine Injury Compensation Program.

Development and revision of the vaccine information materials, also known as Vaccine Information Statements (VIS), have been delegated by the Secretary to the Centers for Disease Control and Prevention (CDC). Section 2126 requires that the materials be developed, or revised, after notice to the public, with a 60-day comment period, and in consultation with the Advisory Committee on Childhood Vaccines, appropriate health care provider and parent organizations, and the Food and Drug Administration. The law also requires that the information contained in the materials be based on available data and information, be presented in understandable terms, and include:

- (1) A concise description of the benefits of the vaccine,
- (2) a concise description of the risks associated with the vaccine,
- (3) a statement of the availability of the National Vaccine Injury Compensation Program, and
- (4) such other relevant information as may be determined by the Secretary.

The vaccines initially covered under the National Vaccine Injury Compensation Program were diphtheria, tetanus, pertussis, measles, mumps, rubella and poliomyelitis vaccines. Since April 15, 1992, any health care provider in the United States who intends to administer one of these covered vaccines is required to provide

copies of the relevant vaccine information materials prior to administration of any of these vaccines. Hepatitis B, *Haemophilus influenzae* type b (Hib), varicella (chickenpox), pneumococcal conjugate, hepatitis A, meningococcal conjugate and polysaccharide, rotavirus, human papillomavirus (HPV), and trivalent influenza vaccines have subsequently been added to the National Vaccine Injury Compensation Program. Use of the Vaccine Information Statements applicable to all of these vaccines, [except meningococcal, rotavirus and HPV,] is also required. [(Interim versions of Vaccine Information Statements for meningococcal, rotavirus and HPV vaccines are available for discretionary use pending completion of the statutory process for finalizing VISs applicable to those vaccines.)] Instructions for use of the vaccine information materials and copies of the materials can be found on the CDC Web site at: <http://www.cdc.gov/vaccines/pubs/vis>. In addition, single camera-ready copies are available from State health departments. A list of State health department contacts for obtaining copies of these materials is included in a December 17, 1999 **Federal Register** notice (64 FR 70914).

#### Consolidated Vaccine Information Materials

With six vaccines recommended for infants from birth through 6 months of age—all covered by the National Vaccine Injury Compensation Program—CDC, as required under 42 U.S.C. 300aa-26, developed Vaccine Information Statements for each of those vaccines. CDC proposed an alternative consolidated Vaccine Information Statement covering those six vaccines in one document, which providers could choose to use instead of the existing individual Vaccine Information Statements for the same vaccines.

Following consultation as required under the law and review of comments submitted, these vaccine information materials have been finalized and are contained in this notice. They are entitled *Your Baby's First Vaccines: What You Need to Know*, and are dated January 30, 2008. CDC has also revised the Instructions for the Use of Vaccine Information Statements. The revised instructions, dated May 12, 2008, are included in this notice. These instructions and copies of the materials for all covered vaccines can also be found on the CDC Web site at: <http://www.cdc.gov/vaccines/pubs/VIS>.

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