



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention
INTER/INTRA-AGENCY AGREEMENT (IAA)
Payable Agreements (CDC is Procuring Agency)



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| 1. CDC IAA #: (10 to 13 digits) 10FED1004110 | 2. PARTICIPATING AGENCY IAA #: CPSC-IAG-01-1163, Mod 43 | 3. TYPE OF AGREEMENT <input checked="" type="checkbox"/> New <input type="checkbox"/> Modification <input type="checkbox"/> Administrative Modification Number: |
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4. TITLE OF PROJECT:
Adverse Effects Due to Therapeutic Drugs

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| 5. DESCRIPTION OF WORK: <i>(Please attach)</i> See Attached | 6. AMOUNT: <i>(Not to exceed without written modification)</i> \$ 109,000.00 |
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| 7. NAME AND ADDRESS OF PARTICIPATING FEDERAL AGENCY: Consumer Product Safety Commission 4330 East West Highway, Room 604D Bethesda, MD 20814-4408 DUNS #069287522 | LIAISON NAME: Tom Schroeder EMAIL ADDRESS: tschroeder@cpsc.gov | PHONE #: (301) 504-7431 FAX #: |
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| 8. NAME AND ADDRESS OF CDC, CENTER, INSTITUTE OR OFFICE: Centers for Disease Control and Prevention 1600 Clifton Road, NE, Mailstop A-24 Atlanta, GA 30333 DUNS #927645465 | LIAISON NAME: Dan Budnitz, MD, MPH EMAIL ADDRESS: dbudnitz@cdc.gov | PHONE #: (404) 639-4096 FAX #: (404) 639-4045 |
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| 9. PROJECT PERIOD: from: 04/19/2010 through: 09/30/2010 | FUNDING PERIOD: from: 04/19/2010 through: 09/30/2010 |
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10. CDC AUTHORITY:
 Economy Act approved June 30, 1932, as amended by 31 U.S.C. 1535 and 1536 (See also item #14)
 Other *(Please specify)*

11. PARTICIPATING AGENCY AUTHORITY:
 Section 601 of the Economy Act, as amended (31 U.S.C. 1535) and the Consumer Product Safety Act

12. CDC FUNDING INFORMATION: FOR CDC USE ONLY *(CDC internal form 6012 - modified Document History Record)* APPROPRIATION NUMBER: 75100943

| T.C. (For Accounting Use Only) | FY (2 digits) (Required) | DOC. REF. (For Accounting Use Only) | DOC. NO. (Original 10 digits) (Required) | CAN (7 digits) (Required) | O.C. (5 digits) (Required) | BACS (10 digits) (For Budget Use Only) | \$ AMOUNT |
|-----------------------------------|--------------------------------|--|--|---------------------------------|----------------------------------|--|--------------|
| 050 | 10 | 214 | 10FED1004110 | 921HQ46 | 25330 | 5603841101 | \$109,000.00 |

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| 6012 ADMINISTRATIVE APPROVAL NAME and EMAIL ADDRESS: <i>(Please print)</i> Robyn Hughes Palmes, Principal Management Official CCID/NCPDCID/DHQP- email: RHughes@cdc.gov (Should not be the same as Block #18) | FMO BUDGET ANALYST SIGNATURE: ADMINISTRATIVE APPROVAL SIGNATURE: |
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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CDC IAA #: 10FED1004110

13. ADMINISTRATIVE BILLING REQUIREMENTS: CDC's ALC is **75090421**. Other Agency ALC: *(required)* 610000001

Billing is to be made through the use of the Online Payment and Collection (OPAC) system. **Please include CDC's Official IAA # from Block #1 on all OPAC billings and correspondence.** When CDC provides funds to the performing agency, in advance of receiving the goods or services, the performing agency agrees to provide, within 15 days of the end of each quarter, statements of obligations and expenditures made during the quarter. The statements shall be provided to the following address: **DHHS, CDC, FMO, AP, Attn: ADVANCES/OPAC Desk, MS D-06, 1600 Clifton Road, Atlanta, GA 30333.** (If required by other agency, CDC's Tax Identification # is 586051157.)

14. ADDITIONAL BILLING REQUIREMENTS: *(This block must be completed if procuring services under the Economy Act.)*

- All funds provided by CDC under this agreement must be obligated by the performing agency by the end of the FY in which the funds expire. Any unobligated but expired funds may not be used to fund services in subsequent periods. The CDC Financial Management Office (FMO) must be notified of any unobligated funds pertaining to this agreement at least 15 days before the end of the FY so that the agreement may be modified to reduce the funding amount when appropriate. This notification shall be provided to the following address:
DHHS, CDC, FMO, AP, Attn: OPAC Desk, MS D-06, 1600 Clifton Road, Atlanta, GA 30333.

15. PARTICIPATING AGENCY FUNDING and/or INFORMATION:

(Please include name, telephone number, and email address of contact person.)

| | | |
|--------------|----------------|------------------|
| Name: | Telephone #: | Email: |
| Debbie Hodge | (301) 504-0018 | dhodge@cpssc.gov |

16. The participating agency as a signatory to the Common Rule states that in accepting these Interagency Agreement funds, it will abide by the human subjects research requirements stated in the Common Rule, and certify that all necessary assurances and institutional review board (IRB) approvals are obtained.
- The participating agency is NOT a signatory to the Common Rule. Upon issuance of these Interagency Agreement funds, it is the responsibility of the CDC Center, Institute, or Office (CIO) to certify that all necessary assurances and institutional review board (IRB) approvals are obtained. The CIO Associate Director for Science (ADS) must determine the Applicability of Human Subjects Regulations.

17. OTHER REQUIREMENTS:

A. Travel under this agreement is subject to allowances authorized in accordance with Federal Travel Regulations, Joint Federal Travel Regulations, and/or Foreign Service Regulations.

B. CDC will retain the title to any equipment procured under this agreement, unless otherwise justified in the statement of work.

18. CDC ACCEPTANCE: *(please print)*

Name: Thomas L. Hearn, PhD

Title: Acting Director, NCEZID (Proposed)

Email address: THearn@cdc.govSignature: *J. Todd Mercer*Date: *4/16/10*19. PARTICIPATING AGENCY ACCEPTANCE: *(please print)*

Name: Donna Hutton

Title: Contracting Officer

Email address: dhutton@cpssc.govSignature: *Donna Hutton*Date: *5/5/10*

This agreement may be terminated by either agency upon a 30-day advance written notice. This agreement may be modified by mutual written consent of all parties.

Funding for Interagency Agreement 10FED1004110
Title: Adverse Effects Due to Therapeutic Drugs
Period of Performance: April 19, 2010 to September 30, 2010

I. Purpose

This agreement is to provide funding for the continued collection of adverse drug event-related injury and illness data in Fiscal Year 2010. Under this agreement between the Centers for Disease Control and Prevention (CDC) and the U.S. Consumer Product Safety Commission (CPSC), CDC will contribute to the cost of the National Electronic Injury Surveillance System (NEISS) and CPSC will continue to maintain or enhance the current scope of NEISS to accommodate the special interests and needs of CDC for adverse drug event-related injury and illness data for victims of all ages from October 1, 2009 through September 30, 2010. It is recognized that through a collaborative, long term commitment to the NEISS that both agencies benefit from program improvements, training, and cost sharing that assist in the timely assessment of injury/illness incidents and that foster future projects of common interest.

II. Background

CPSC contracts with hospital emergency rooms to collect injury/illness data for the data system known as NEISS. This system is used by CPSC to identify and measure the magnitude of the injury problems associated with consumer products that are treated in hospital emergency departments in the U.S. and its territories.

NEISS is a tri-level data collection system, with the capacity for collecting data at emergency departments, from telephone follow-up interviews with hospital staff and/or victims, and from in-depth interviews with injured/ill parties and/or witnesses at the sites where the injuries/illnesses occurred. One, two, or all three of these levels are used by CPSC as primary data collection tools.

Since 1978, other Federal Agencies have found it useful to share NEISS, including having CPSC expand the scope of the injuries collected or add to the list of variables to be collected. Agencies which have shared NEISS data through interagency agreements in the past include: Environmental Protection Agency (EPA), Centers for Disease Control and Prevention (CDC), National Highway Traffic Safety Administration (NHTSA), Food and Drug Administration (FDA), and the Bureau of Justice Statistics (BJS). Through interagency agreements with CDC in FY 2003 through FY 2008, CPSC expanded NEISS to include all adverse drug event-related incidents.

CDC has a continuing need to measure the number and rate of adverse drug-related injuries. NEISS has provided this information on an ongoing basis and in a timely and cost-effective manner. Under this agreement, CDC will contribute funds towards the cost of NEISS contracts in return for continued sharing of data from this system.

III. Scope of Work

- A. Under the terms of this agreement, CPSC agrees to continue in effect modifications to NEISS to meet the needs of CDC in collecting adverse drug event-related injury and illness data. These modifications were put in place in past agreements dating most recently back to FY96. These modifications expanded the scope of data collected through the NEISS system to include adverse drug event-related injuries and illnesses regardless of product involvement, added CDC special study variables to the NEISS surveillance system for adverse drug event-related cases, and established a system whereby CDC is routinely provided with adverse drug event-related data collected through the NEISS system. This agreement covers adverse drug event-related injuries and illnesses to victims of all ages who are treated in the CDC hospital sub-sample (nominally 63 hospitals) of the entire NEISS hospital emergency department sample (nominally 100 hospitals) from October 1, 2009 through September 30, 2010.

Under the terms of this agreement CPSC shall:

1. Deliver to hospital coders instructional materials for identifying and coding adverse drug event-related injuries and illnesses as provided by CDC and approved by CPSC, including printed instructions, background materials, posters, etc.
2. From time to time (e.g., during visits by CPSC staff to hospitals), provide to current hospital coders within the CDC hospital sub-sample informal training and review on identifying adverse drug event-related injury and illness cases and recording adverse drug event-related information.
3. At the time of hiring, provide training to new hospital coders within the CDC hospital sub-sample on identifying adverse drug event-related injury and illness cases and recording adverse drug event-related information.
4. Provide CDC with all in-scope adverse drug event-related injury and illness data from the CDC hospital sub-sample, including standard NEISS data variables and CDC special study variables for adverse drug event-related cases.
5. CPSC will monitor the data collection process and perform routine quality assurance and quality control procedures on CDC adverse drug event-related case variables in addition to the standard NEISS variables.
6. CPSC will routinely provide these data to CDC monthly in a file format (e.g., SAS) and on electronic media that are mutually agreeable. For special studies or to meet other unusual data needs, CPSC will provide CDC the data electronically at more frequent intervals up to weekly.
7. Finalized data will be provided to CDC yearly, and CPSC will provide a statistical weighting factor for each case based on the CDC sub-sample and statistical support, as necessary, to enable the calculation of national estimates and error terms associated with the estimates.
8. Quarterly, CPSC will provide CDC with a list of changes, if any, in hospitals participating in the CDC sub-sample (including hospital number, name, address, and CPSC regional coordinator), dates of participation/case submissions if not the full

quarter, hospital strata, and the number of standard NEISS and adverse drug event-related cases entered during the quarter. CPSC will maintain an up-to-date CDC sample design document detailing sample design changes, monthly hospital participation, and assigned statistical weights and annually provide a revised copy to CDC.

9. CPSC will notify CDC in advance of major changes to the sample design, variables collected, variable coding schemes, and other factors that materially influence the collection or analysis of the NEISS data.

- B. CDC will be responsible for analysis of any of the data resulting from this agreement. CPSC will provide consultation on matters concerning the data collection, quality control, sample design, injury/illness estimates, sampling errors and questionnaire design.

- D. CDC will be responsible for public release of NEISS data that are identified as adverse drug event-related cases including printed and/or electronic dissemination of data. Public release of data shall exclude hospital and case identifiers, and other NEISS data variables that identify an individual calendar day, and consumer product or manufacturer identifiers as described in Section XVI. Information Safeguards.

IV. Duration of Agreement

This agreement is approved from the date of signature for both agencies through September 30, 2010.

V. Estimated Costs

Estimated costs are \$109,000. This cost estimate is broken down into the following sub-categories:

\$75,000 for adverse drug event-related case reporting and quality assurance
\$34,000 for administrative costs of programming support, delivering data, improving quality assurance, and evaluation activities

TOTAL: \$109,000

The distribution of funds within the categories may be modified as needed by CPSC to complete the collection of the CDC adverse drug event-related injury and illness data through NEISS.

VI. Funding

All funds provided by CDC in this agreement must be obligated by the performing agency by the end of the fiscal year in which the funds expire. Any unobligated but expired funds may not be used to fund services in subsequent periods. The CDC Financial Management Office (FMO) must be notified of any unobligated funds pertaining to this agreement at least 60 days before the end of the fiscal year so that the agreement can be amended to reduce the obligated amount when appropriate. The notification must be provided to the address cited below (in paragraph VIII).

VII. Conditions of Payment (including under a Continuing Resolution)

Under terms of this agreement, CDC will effect the transfer of \$109,000 to CPSC in Fiscal Year 2010 immediately upon receipt of this signed Interagency Agreement and billing statements.

VIII. Accounting and Billing Information

Funds for this project for FY2010 in the amount not to exceed \$109,000.00 will be transferred to CPSC via IPAC using the following account data:

| | <u>From</u> | <u>To</u> |
|---------------|--------------|---------------------------------------|
| Agency | CDC | CPSC |
| Appropriation | 75100943 | 0100A10DPS 2010 1117900000 EXFM004310 |
| EIN | 586051157 | US Treas Code: 61-0100 252E0 |
| ALC | 75090421 | 61-00-0001 |
| | | |
| DUNS# | 927645465 | 069287522 |
| TIN | | 520978750 |
| CAN | 921HQ46 | |
| Object Class | 25330 | 252E |
| Amount | \$109,000.00 | \$109,000.00 |

When billing CDC through the IPAC system, CPSC will reference agreement number CDC 10FED1004110; CPSC-IAG-01-1163 Mod#45

When funds are provided to the performing agency in advance of services being performed or goods being delivered, the performing agency is required to provide, within 15 days of the end of each quarter, statements of obligations and expenditures made during the quarter. These statements are also provided to the address below:

CDC, FMO
 Attn: IPAC Desk
 1600 Clifton Road, MS D-06
 Atlanta, GA 30333

IX. Equipment

If equipment is procured by CPSC to accomplish the program's goals and objectives using funds provided by this interagency agreement, CDC will retain title to the equipment, with the exception of equipment procured in support of the overall NEISS project for which CPSC shall retain title of equipment.

X. Travel

Travel under this agreement is subject to allowances authorized in accordance with the Federal Travel Regulations, Joint Federal Travel Regulations, and/or Foreign Service Regulations.

XI. Conflict with Existing Agreements

There is no duplication or conflict with existing agreements, policy, or statute.

XII. Program Contacts

CDC: Daniel Budnitz
DHQP/NCDPCID/CCID/CDC
1600 Clifton Rd, NE, MS-A-24
Atlanta, GA 30333
(404) 639-4096
DBudnitz@cdc.gov

CPSC: Tom Schroeder
CPSC
4330 East West Highway, Rm 604D
Bethesda, MD 20814-4408
(301) 504-7431
TSchroeder@cpsc.gov

XIII. Budget Contacts

CDC: Geneva Nathani
Budget Analyst
1600 Clifton Rd, NE, MS-A-07
Atlanta, GA 30333
(404) 639-3418
gnathani@cdc.gov

CPSC: Debbie Hodge, Director of Division of Finance
4330 East West Highway, Rm 522A
Bethesda, MD 20814-4408
(301) 504-0018 ext 1132
DHodge@cpsc.gov

XIV. Modification and Cancellation

This agreement may be modified by mutual consent of both parties or canceled upon 60 days advance written notice by either party.

XV. Authority

This agreement is entered into under Section 601 of the Economy Act, as amended (31 U.S.C. 1535) and the Consumer Product Safety Act.

XVI. Information Safeguards

CDC shall comply with the Privacy Act in using and storing information related to this agreement. CDC shall provide CPSC with written assurances satisfactory to CPSC that the identity of any injured/ill person, and of any person who treated an injured/ill person, shall not be included in any report or information made available by CDC to any member of the public. CDC also agrees that it shall not disclose information compiled under this agreement to the public if the information describes a consumer product in such a manner that will permit the public to ascertain readily the identity of the manufacturer or private labeler of a consumer product under the authority of the Commission unless the Commission is notified, and the Commission complies with Section 6(b) of the CPSA (15 U.S.C. 2055).

CDC shall maintain all publicly accessible NEISS data records through internet file downloads, web-based query systems, or other electronic mechanisms such that individuals or NEISS hospitals are not directly or indirectly identifiable. CDC shall refer all public requests for hospital identities to CPSC. CDC shall provide CPSC, at their discretion, the opportunity to review for up to 30 days all bulk NEISS adverse drug event-related data prior to intended release via internet file downloads, web-based query systems, or other electronic mechanisms.

CDC shall be considered the originating agency for all adverse drug event-related injury and illness cases, including basic NEISS case data and any supplemental data collected. CDC shall serve as the CDC center responsible for employing adequate and effective security controls to protect the confidentiality, availability, and integrity of adverse drug event-related NEISS data, including all data shared with other organizations. CDC shall ensure, prior to the sharing of any data, that the recipient organization affords the appropriate equivalent level of security controls as maintained by CDC, the originating agency. Since data security remains the responsibility of CDC, procedures shall be agreed to in advance that provide for the security controls of the recipient organization.

Because individual NEISS case information for adverse drug event-related injuries and illnesses are considered extremely sensitive and public release of the NEISS data may harm the affected patient, CDC, as the originating agency shall establish agreements with recipient agencies that consider and apply all appropriate management, operational, and technical security controls including physical security needs, such as whether personal information is so sensitive that it should be kept in an approved security container, or whether access to where the information is located should be limited; personnel security needs, such as additional controls over individuals who have access to data; network security, including encryption for data in transit and protection for data at rest; and procedures for the retention and timely destruction of identifiable records. CDC shall provide CPSC a period of up to 30 days to review and provide comment on the privacy and security implications of new data sharing agreements. Once appropriate interagency data sharing agreements have been established between CDC and recipient agencies, CDC may, at its discretion, authorize CPSC to provide NEISS adverse drug event-related case data directly to the recipient agency.

From time to time, CPSC may be contracted by other agencies to collect supplemental information on specific cases that include adverse drug event-related injuries and illnesses. Because the activities of the contracting agency and subsequent release of the adverse drug event-related data collected has the potential to harm individual patients and compromise CDC's ability to continue to collect adverse drug event-related injury and illness data through NEISS, CPSC shall provide CDC a period of up to 30 days to review and provide comment on the privacy and security implications of the new data collection. CPSC shall ensure that agreements with contract agencies include provisions requiring the contracting agencies to apply all appropriate management, operational, and technical security controls including physical security needs, personnel security needs, network security, and procedures for the retention and timely destruction of directly or indirectly identifiable records. Additionally, CPSC shall make a reasonable effort to ensure that CDC have, at their discretion, a period of up to 30 days for review of products arising from such agreements that include adverse drug event-related case information and that are intended for public release. The CDC review shall not prohibit data release nor shall it be implied to indemnify CPSC or other agencies in the event of public release of personal identifiers through their data release mechanisms.

CDC, as the originating agency, shall be notified in a timely fashion of all adverse drug event-related data requests under the Freedom of Information Act (FOIA) or other applicable court order. Routine FOIA requests specific to only adverse drug event-related case information shall be referred to CDC for disposition. Requests for mixed data including more than just adverse drug event-related case information shall be responded to by CPSC with the opportunity for CDC to provide comment on the releasability of the adverse drug event-related case data.

The provisions in this section, Information Safeguards, shall not in any way prohibit or limit the use of the NEISS adverse drug event-related injury and illness data by CPSC staff in fulfillment of their agency mission and responsibilities. CPSC shall make a reasonable effort to ensure that CDC have, at their discretion, a period of up to 30 days for review of products that include significant adverse drug event-related case information and that are intended for public release. The CDC review shall not prohibit data release nor shall it be implied to indemnify CPSC.

Approved and Accepted for Consumer Product Safety Commission:

Signature: *Donna Hutton* Date: 5/5/10

Name: Donna Hutton
Title: Contracting Officer
Address: Division of Procurement Services
U.S. Consumer Product Safety Commission
4330 East West Highway, Room 517
Bethesda, Maryland 20814
Phone: 301-504-7009

Approved and Accepted for CDC:

Signature: *J. Todd Mearns* Date: 4/16/10

Name: *J. Todd Mearns* Thomas L. Hearn, PhD
Title: Acting Director, NCEZID (Proposed)
Address: 1600 Clifton Road, NE, MS-C-12
Atlanta, Georgia 30333
Phone: 404-718-1048

Determination and Findings (D&F)
Regarding Interagency Agreement Request 10FED1004110
Between the Centers for Disease Control and Prevention
National Center for Preparedness, Detection, and Control of Infectious Diseases,
Division of Healthcare Quality Promotion and the
U.S. Consumer Product Safety Commission
Office of Hazard Analysis and Reduction, Directorate for Epidemiology

1. Nature and/or description of the action being approved. The purpose of the project titled: "Adverse Events due to Therapeutic Drugs (ADEs)" is public health monitoring of serious adverse effects from medications. The U.S. Consumer Product Safety Commission (CPSC) will provide timely ADE data from the National Electronic Injury Surveillance System (NEISS) to CDC. This system is unique in the capacity to provide timely, detailed, and nationally representative data on adverse drug events treated in emergency departments. Findings that detail the particular circumstances, facts, or reasoning essential to support the determination are detailed in the attached interagency agreement. In summary, this activity supports CDC's goals of integrating and enhances existing surveillance systems to detect, monitor, report, and evaluate public health threats and to prevent adverse events in patients.

It is agreed that NCPDCID will reimburse CPSC for the joint support of this project, which is being carried out under the direction of Joel Friedman, Project Officer.

It is agreed that DHQP will participate in the scientific and technical oversight of the project in conjunction with CPSC. CPSC will be responsible for the fiscal management of the project. This project does not involve human subjects research.

2. This D&F is based on the provisions of the Economy Act, 31 U.S.C. 1535
3. The use of an interagency acquisition is in the best interests of the Government, and the supplies or services cannot be obtained as conveniently or economically by contracting directly with a private source. Specifically, no other mechanism can provide ongoing, timely data on drug-related emergency department visits, including adverse events associated with antivirals and vaccines, from a large probability sample of hospitals throughout the US as conveniently or economically.
4. The acquisition will appropriately be made under an existing contract of the servicing agency, entered into before placement of the order, to meet the requirements of the servicing agency for the same or similar supplies or services.

Robyn H. Palmes
Robyn Hughes Palmes
Principal Management Official
Division of Healthcare Quality Promotion
National Center for Preparedness, Detection
and Control of Infectious Diseases

Date: 4/13/10

Edward Schultz
Ed Schultz
Contracting Officer, PGO

Date: 4/16/2010