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		DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service Centers for Disease Control and Prevention <b>INTER/INTRA-AGENCY AGREEMENT (IAA)</b> Payable Agreements (CDC is Procuring Agency)					
1. CDC IAA #: (10 to 15 digits) 00FED05404- <del>07</del> 13		2. PARTICIPATING AGENCY IAA #: CPSC-IAG-00-1157		3. TYPE OF AGREEMENT <input type="checkbox"/> New <input checked="" type="checkbox"/> Modification <input type="checkbox"/> Administrative Modification Number: 7/13			
4. TITLE OF PROJECT: Adverse Effects Due to Therapeutic Drugs							
5. DESCRIPTION OF WORK: (Please attach) See Attached Statement of Work			6. AMOUNT: (Not to exceed without written modification) \$ 153,000.00				
7. NAME AND ADDRESS OF PARTICIPATING FEDERAL AGENCY: Consumer Product Safety Commission 4330 East West Highway, Rm 517 Bethesda, MD 20814-4408			LIAISON NAME: Art McDonald EMAIL ADDRESS: amcdonal@cpsc.gov		PHONE #: (301) 504-0539 FAX #: (301) 504-0038		
8. NAME AND ADDRESS OF CDC, CENTER, INSTITUTE OR OFFICE: National Center for Injury Prevention and Control Division of Injury and Disability Outcomes and Programs 4770 Buford Highway, NE, Mailstop F-41 Atlanta, GA 30341			LIAISON NAME: Dan Budnitz, M.D. EMAIL ADDRESS: DBudnitz@cdc.gov		PHONE #: (770) 488-1486 FAX #: (770) 488-4338		
9. PROJECT PERIOD: from: 10/1/2002 through: 09/30/2003			FUNDING PERIOD: from: 10/01/2002 through: 09/30/2003				
10. CDC AUTHORITY: <input checked="" type="checkbox"/> Economy Act approved June 30, 1932, as amended by 31 U.S.C. 1535 and 1536 (See also item #14) <input type="checkbox"/> Other (Please specify) <u>CDC DUNS 927645465 CPSC DUNS 1787717013</u>							
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: 7530943		
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. (4 digits) (Required)	ALLOWANCE (5 digits) (For Budget Use Only)	\$ AMOUNT
050	03	214	00FED05404	39211995	253R	3-11817-00	\$52,083.00
050	03	214	00FED05404	392101UK	253R	3-11817-00	\$100,917.00
		214					
		214					
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		214					
6012 ADMINISTRATIVE APPROVAL NAME and EMAIL ADDRESS: (Please print) Diana Miles Administrative Officer, DIDOP, NCIPC dzm6@cdc.gov				FMO BUDGET ANALYST SIGNATURE: <i>Rob Yearman</i> 7/7/03 ADMINISTRATIVE APPROVAL SIGNATURE: <i>Diana Miles</i> 7/2/03			



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)



CDC IAA #: OOPED05404-0713

13. ADMINISTRATIVE BILLING REQUIREMENTS: CDC's ALC is **75090421**. Other Agency's ALC: *(required)* 4610000010

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:
Deborah Hodge	(301) 504-7130	dhodge@cpsc.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: Sue Binder, M.D.

Title: Director, NCIPC, CDC

Email address: SBinder@cdc.gov

Signature: *S. Belloni for* Date: 7/7/03

19. PARTICIPATING AGENCY ACCEPTANCE: *(please print)*

Name: Donna Hutton

Title: Contracting Officer

Email address: dhutton@cpsc.gov

Signature: *Donna Hutton* Date: 7/1/03

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.

**STATEMENT OF WORK  
INTERAGENCY AGREEMENT BETWEEN  
THE CONSUMER PRODUCT SAFETY COMMISSION (CPSC)  
AND  
THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)  
(00FED05404-01)**

13

This document sets forth the terms of agreement for services, supplies, and/or material between the U.S. Consumer Product Safety Commission (CPSC) and the Department of Health and Human Services (DHHS), Centers for Disease Control and Prevention (CDC).

This document serves as an addendum to the Interagency Agreement (number 00FED05404) between the Centers for Disease Control and Prevention and the U.S. Consumer Product Safety Commission covering the expansion of the National Electronic Injury Surveillance System (NEISS) to collect data on all injuries.

This addendum covers a special study entitled: "Adverse Events due to Therapeutic Drugs (ADEs)" which is outlined below. Description of the data collection instrument is attached as Appendix A.

**I. DESCRIPTION OF SERVICES**

**A. Background**

Adverse events due to therapeutic drugs (ADEs) may be responsible for over 100,000 deaths a year, which would make ADEs the 5<sup>th</sup> leading cause of death in the United States (JAMA 1998;279:1200-5, 1216-7). Several large studies have focused on ADEs in the hospital setting. In the outpatient setting, however, we know relatively little about adverse drug events.

The National Electronic Injury Surveillance System – All Injury Program (NEISS) can play an important role in collecting information about outpatient ADEs. In FY02, a pilot study in which 10 NEISS hospital coders were trained to collect data on ADEs for 10 weeks demonstrated the feasibility of training NEISS hospital coders to collect data on ADEs. Based on the results of the pilot study, the Food and Drug Administration (FDA) and CDC collaborated to improve the data collection instrument and coder training that was used in the pilot study. CPSC has incorporated the improved data collection instrument ("second screen") into the computerized data collection system used in NEISS.

**B. Purpose**

All NEISS-AIP hospital coders will now be trained to identify and report information on patients with ADEs. Hospital coders will be trained during a July training conference. Those hospital coders who cannot attend the training conference will be trained by a distance education module.

Data collection using the computerized data instrument will begin August 1 and end of the current fiscal year. However, the parties in good faith intend to continue the funding and data collection outlined in this agreement in FY04. Preliminary data from ADE cases will be provided to FDA and CDC on a monthly basis in the form of SAS datasets. Final data will be provided to FDA and CDC at six month intervals.

### C. Overview of Methods

1. Training Conference: CPSC will invite hospital coders from all NEISS-AIP hospitals to attend a training conference on July 30-31, 2003. CPSC will arrange the logistics and reimbursement of attendees from the NEISS-AIP hospitals. CDC and FDA will create the training materials to include lecture presentation, handbook, examples, and practice exercises.
2. Distance Education: NEISS-AIP hospital coders who cannot attend the training conference will be trained by a distance education module based on the conference training. CDC and FDA will create the CD-ROM based training. CPSC will assist in the distribution of the distance education module by July 15, 2003 and will ensure that the coders complete the module by July 31, 2003.
3. Data Collection: The computerized data collection instrument specifications are included in appendix A. The data collection instrument will be available for use by NEISS-AIP coders by August 1, 2003. CPSC will manage the collection of data in this instrument as it manages other data reported in NEISS-AIP.
4. Quality Assurance: Data entered in the ADE instrument will be quality reviewed in the manner of other data entered in NEISS-AIP. In addition, CDC and FDA will be provided with a preliminary dataset of ADE cases at approximately 2 and 6 weeks after the training conference so that timely feedback and follow-up training can be given to hospital coders. Using this data, CDC researcher, FDA researcher, or CPSC hospital liaison will contact the NEISS hospital coders to address questions, problems, and to provide feedback on improving ADE case ascertainment and reporting.
5. Data Delivery: Preliminary data from ADE cases will be provided to FDA and CDC on a monthly basis in the form of SAS datasets. Finalized data will be provided to FDA and CDC at six month intervals. CPSC will also provide data and statistical support so that population-based estimates, time trends, and comparative estimates may be calculated.

## II. DURATION OF AGREEMENT

This agreement is approved from the date of signature for both agencies through September 30, 2003. Funding for additional years, if required, will be provided separately by an amendment to this Intra-agency Agreement, subject to the availability of funds.

**III. ESTIMATED COSTS**

The estimated cost of expansion phase of the NEISS Special Study of Adverse Drug Events is **\$153,000**.  
The breakdown in cost is as follows:

**CPSC Charges**

- |                                                                                                                                                              |           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| 1. Convening a 2 day NEISS-AIP coding conference in July 2003<br>60 coders from 40 hospitals x \$1,833 each coder                                            | \$110,000 |
| 2. Training the remaining NEISS-AIP coders by mailed self-instruction and<br>self-assessment, and feedback<br>35 coders from 25 hospitals x \$285 each coder | \$10,000  |
| 3. ADE Case reporting for 2 months<br>1,000 cases per month x 2 months x \$4 each case                                                                       | \$8,000   |
| 4. Administrative costs for quality review of cases and programming support<br>for reporting cases to CDC and FDA                                            | \$25,000  |

**TOTAL** **\$153,000**

**IV. ACCOUNTING AND BILLING INFORMATION**

FOR CPSC:

03 PS EXOB 4310 11179 253e

APPENDIX A

**CDC Adverse Drug Event Special Study**

**Criteria:** Treatment dates – Summer 2003 through Summer 2004  
**Participants:** All all-trauma hospitals (65 hospitals).  
**Suspended Edits:** None  
**Priority:** After poisoning (09) and before firearms (04).  
**Assignments:** If the record is out-of-scope, it cannot be assigned.  
**Edits:** See attached table.

- Other:**
- 1) Marking scope on these records is the same as for normal records (spty=0).
  - 2) New daily report for ADE study cases.
  - 3) Add capability to edit/display study record in EPHQ.
  - 4) Priority for changing database applications: EPID, scope, HIDMIG, EPHQ.
  - 5) The list boxes are accompanied by text boxes. These textboxes can be invisible until the coder chooses "other" from the list box. Once the coder has chosen "other" we would like the form to prompt the coder to "Please specify" by entering text in the text box.
  - 6) The options for each list box should come out of a table so if we need to add or update an option it will only require updating the table.
  - 7) We did not specify the number of varchar for all fields.
  - 8) The number of varchar for a given field is an estimate. Modify based on the number of varchar you think is needed.
  - 9) Please use QC prompts similar to those used during the ADE pilot study and based on the same criteria as in the pilot study to apprise the coder that a particular NEISS case may be an ADE case and they need to fill out the second screen.
  - 10) Create a new QC prompt that opens a popup dialog box on the event of the coder clicking on the "special study" screen after they have entered an intent of 1 (assault) or 2 (suicide) that states, "If this is an intentional or suicidal incident, do not fill out the ADE second screen."
  - 11) The coding schema for the list boxes is suggested and was created with the intention of making it easy to add a new option in the future. However, if the programmers cannot work with this coding schema and need to create a new coding schema that is acceptable.
  - 12) For column names/field names, please use the name listed under the "Column" column, not the name listed under the "Old name" column.
  - 13) Populate the special study fields: hospital ID, case number, , treatment date and patient's age with the similar fields from the core NEISS record.
  - 14) We may want to change the text box for the question: "What was the primary reason the patient came to the ED?" to a list box in the future when we know which options we would want to list.

**Tables:** Variables for Programming the Adverse Drug Event Special Study Second Screen for:

- Table 1: Variables captured by the core NEISS record
- Table 2: Variables captured by the Adverse Drug Event Second Screen
- Table 3: Variables for the list boxes incorporated in the ADE Second Screen
- Table 4: ADE pilot study second screen: Prototype for ADE Second Screen

**Table 1: Variables captured by the core NEISS record**

Column	"Old" name	Type	Description	Edits
	cno			
	nek			
	age			
	bdpt			
	diag		NEISS diagnosis	
	disp		Disposition	
	fmv			
	loc			
	sex			
	type			
	prod1			
	prod2			
	prod3			
	wt			
	race			
	raceoth			
	intent			If intent =2 or intent=1 then "error" msg
	diagoth			
	pr_dob			
	cmt1			
	cmt2			
	dtbirth			
	dtcol			
	dt_col			
	dtchg			
	dt_chg			
	dtrun			
	seq			
	sev			
	spty			
	ecode			
	ecodever			
	ecodesrc			
	zip			
	scope			
	wordflag			
	perpage			
	randnum			
	spcodes			
	dt_birth			
	Case_ID			
	Hosp_ID			
	Coder_Initials			
	Case_Trmt Date			
	Case_Pt Age			

Table 2: Variables captured by the Adverse Drug Event Second Screen

Column	"Old" Name	Type	Description	Edits	Required
reason		Varchar(100)	What was the primary reason the patient came to the ED?	transform to all lowercase	X
drug1	Case_Q2a	Varchar(40)	What was the name of Drug 1?	transform to all lowercase	X
drug2	Case_Q2b	Varchar(40)	What was the name of Drug 2?	transform to all lowercase	
mgs1	Case_Q2c	Number	How much was taken at a time? How many mgs of Drug 1?		mgs1 or pills1 or odose1
mgs2	Case_Q2d	Number	How much was taken at a time? How many mgs of Drug 2?		
pills1	Case_Q2e	Number	How much was taken at a time? How many pills of Drug 1?		mgs1 or pills1 or odose1
pills2	Case_Q2f	Number	How much was taken at a time? How many pills of Drug 2?		
odose1	Case_Q2x	Varchar(300)	How much was taken at a time? Other dose description of Drug 1?	transform to all lowercase	mgs1 or pills1 or odose1
odose2	Case_Q2y	Varchar(300)	How much was taken at a time? Other dose description of Drug 2?	transform to all lowercase	
freq1	Case_Q2g	Combo(frequency)	How many times a day did the patient take Drug 1?	if text, transform to lower case	X
freq2	Case_Q2h	Combo(frequency)	How many times a day did the patient take Drug 2?	transform to all lowercase	
route1	Case_Q2i	Combo(route)	How did the patient take Drug 1?	if text, transform to lower case	X
route2	Case_Q2j	Combo(route)	How did the patient take Drug 2?	transform to all lowercase	
length1	Case_Q2k	Number	How long has the patient taken Drug 1 (number)?		X
inter1	Case_Q2k	Combo(interval)	How long has the patient taken Drug 1 (interval)?	if text, transform to lower case	X
length2	Case_Q2l	Number	How long has the patient taken Drug 2 (number)?		
inter2	Case_Q2l	Combo(interval)	How long has the patient taken Drug 2 (interval)?	if text, transform to lower case	
dx		Varchar(100)	What was the final diagnosis (Dx) or clinical impression?	transform to all lowercase	X
treat	Case_Q5	Varchar(100)	What treatment was given in the ED?	transform to all lowercase	
allergy		Yes/No/Unknown	Did the patient appear to have an allergic reaction to the drug(s)? If yes, check any of the following that apply:		X
anaphix		Yes/No	Anaphylaxis / Anaphylactic Reaction		
angio		Yes/No	Angioedema (Swelling of face, lips, eyes, or throat)		
breath		Yes/No	Shortness of Breath		
rash		Yes/No	Urticaria (Hives)		
hives		Yes/No	Stevens Johnson Syndrome (Skin necrosis)		
sjs		Yes/No	Photosensitivity / Photoallergy (Rash to sunlight)		
photo		Yes/No	Other Rash		
oallergy		Varchar(100)	Other Allergic Reaction	transform to all lowercase	
test	Case_Q4	Varchar(40)	If any special lab tests were ordered, which ones and what were the results?	transform to all lowercase	
oinfo	Case_Q6	Varchar(300)	Other information describing the event?	transform to all lowercase	
odruga	Case_Q3a	Varchar(40)	What other drugs was the patient taking (drugA)?	transform to all lowercase	
odrugb	Case_Q3b	Varchar(40)	What other drugs was the patient taking (drugB)?	transform to all lowercase	
odrugc	Case_Q3c	Varchar(40)	What other drugs was the patient taking (drugC)?	transform to all lowercase	
odrugd		Varchar(40)	What other drugs was the patient taking (drugD)?	transform to all lowercase	
odruge		Varchar(40)	What other drugs was the patient taking (drugE)?	transform to all lowercase	

odrugf	Varchar(40)	What other drugs was the patient taking (drugF)?	transform to all lowercase
odrugg	Varchar(40)	What other drugs was the patient taking (drugG)?	transform to all lowercase
odruhh	Varchar(40)	What other drugs was the patient taking (drugH)?	transform to all lowercase
odrugj	Varchar(40)	What other drugs was the patient taking (drugJ)?	transform to all lowercase
odrugk	Varchar(40)	What other drugs was the patient taking (drugJ)?	transform to all lowercase

**Table 3: Variables for the list boxes incorporated in ADE Second Screen**

<b>Frequency</b>			
Code	Coders Select1	Coders Select2	
1	One time		
2	Daily		
3	2x a day		
4	3x a day		
5	4x a day		
6	5x or more a day		
88	Other	Varchar(300)	
99	Unknown		
<b>Route</b>			
Code	Coders Select1	Coders Select2	Coders Select3
1	Orally		
1.1		Swallowed	
1.2		Chewed	
1.3		Under tongue	
1.88		Other oral	Varchar(300)
2	Injected		
2.1		Under skin (SQ)	
2.2		In the muscle (IM)	
2.3		In the vein (IV)	
2.4		In the spinal fluid (Intrathecal)	
2.88		Other injected	Varchar(300)
3	Inhaled		
3.1		Through the mouth	
3.2		Through the nose	
3.88		Other inhaled	Varchar(300)
4	Skin Contact		
5	In Ear (OT)		
6	In Eyes (IO)		
7	In Rectum (PR)		
8	In Vagina		
88	Other	Varchar(300)	
99	Unknown		
<b>Interval</b>			
Code	Coders Select1	Coders Select2	
1	Hours		
2	Days		
3	Weeks		
4	Months		
5	Years		
6	As Necessary		
88	Other	Varchar(300)	
99	Unknown		

Table 4: ADE pilot study second screen: Prototype for ADE Second Screen

Adverse Drug Events Study - [Adverse Drug Event Special Study]			
File Edit Insert Records Window Help			
ADVERSE DRUG EVENT SPECIAL STUDY			
Hospital	<input type="text"/>	Treatment Date	<input type="text"/>
Case ID#	<input type="text"/>	Patient's Age	<input type="text"/>
What was the primary reason the patient came to the ED?			
<input type="text"/>			
Record the following information about the drug linked to the adverse event (up to 2 drugs can be listed).			
* If there is no information type or select "UNKNOWN"	Drug #1	Drug #2	
What was the name of the drug?	<input type="text"/>	<input type="text"/>	
How much was taken at a time? If a pill, list milligrams and number of pills. If other dosing information is reported, record this in the box below	<input type="text"/> mg <input type="text"/> pills	<input type="text"/> mg <input type="text"/> pills	
How many times a day did the patient take the drug?	<input type="text"/>	<input type="text"/>	
How did the patient take the drug?	<input type="text"/>	<input type="text"/>	
How long has the patient been taking the drug? Enter a number then choose the time period.	<input type="text"/> Enter a #	<input type="text"/> Enter a #	<input type="text"/>
What was the final diagnosis (Dx) or clinical impression?	<input type="text"/>		
What treatments were given in the ED?	<input type="text"/>		
Was the patient treated for an anaphylactic reaction?	<input type="text"/>		
If any special lab tests were ordered for the adverse drug event, which ones and what were the results?	<input type="text"/>		
Please record any other information describing the event? (This is the comments section for this case)			
<input type="text"/>			
If the patient was taking other drugs, what were the names of these drugs? (May list up to 10)			
<input type="text"/>			