

INFORMATION AND COMMUNICATION SERVICES NIH - TASK ORDER

RFTOP# 22 **TITLE:** Evaluation of Expanding Pharmaceutical Data in the National Health Care Survey. (N.B. This is Phase I of 2 phases. A separate contract will be sought for Phase II.)

PART I - REQUEST FOR TASK ORDER PROPOSALS

A. POINT OF CONTACT NAME: Bruce Cunningham

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SAME

B. PROPOSED PERIOD OF PERFORMANCE: Seven (7) months from award.

C. PRICING METHOD: Firm Fixed Price - Price will be a factor in the determination of the firm that is selected for award.

D. RESPONSE DUE DATE: Monday, August 6, 2001 at 4:00pm Local Time.

E. PROPOSAL INSTRUCTIONS:

A. Business Proposals

Tasks 1- 4 should be priced separately as a unit, and tasks 5, 6 and 7 should each be priced separately.

B. Technical Proposals

Six paper copies of proposals should be provided. Proposals will not be accepted in electronic form.

Proposals should clearly and concisely address the Scope of Work, how the project will be managed and conducted, and address specific issues or problems that may affect the work or the schedule to complete the project.

Proposals must clearly demonstrate an understanding of technical issues regarding survey methodology as well as specific issues regarding the collection of pharmaceutical data.

Demonstrated experience with large scale or nation survey methodology is critical. Demonstrated knowledge and experience of hospital data and data systems, particularly of pharmaceuticals data is highly desirable.

F. TASK DESCRIPTION:

Section II - Statement of Work

The goal of this Task Order (Phase I of a two-phase project) for the National Center for Health Statistics (NCHS) is to conduct tasks preliminary to and in support of a field test (to be conducted in Phase II of the project) to evaluate the collection of pharmaceutical data similar to data collected in the National Hospital Ambulatory Care Survey (NHAMCS) for discharges sampled in the National Hospital Discharge Survey (NHDS). To achieve this goal the contractor shall: 1) evaluate what methods currently employed in the NHAMCS, if any, can be used as part of the larger NHDS; 2) evaluate potential sources and methods to collect pharmaceutical data for inpatients as part of the NHDS if NHAMCS methodology is not transportable; 3) evaluate and describe similarities and differences between drug data collected in hospitals and in the NHAMCS; 4) produce an evaluation report with recommendations for two methods of collecting drug data as part of the NHDS in a pilot test; 5) develop a plan for field testing at most two methods to collect pharmaceutical data as part of the NHDS; 6) develop and/or modify as necessary NHDS forms, procedures and manuals for a field test to collect these pharmaceutical data; and 7) develop training materials for the field test.

In the NHAMCS, pharmaceutical data for hospital outpatient and emergency department visits are abstracted from medical records by either hospital personnel or Bureau of the Census field representatives. Only the names of up to 10 drugs are recorded, as well as the total number of drugs mentioned. It is not possible to distinguish among drugs that are provided by the physician, drugs that are prescribed (but perhaps not obtained by the patient) or actually administered by the physician during the ER or OPD visit. These data are sent to a central processing facility for coding and data entry using a coding system developed by NCHS.

In hospitals, however, drug data obtained from different sources may represent different things. For example, the pharmacy may have a list of drugs that were dispensed to the ward where the patient resides, but the nurse on that ward may for some reason or other not actually dispense a particular medication because the patient changed status, or the medication was determined to be incorrect. The list of drugs recorded at admission may be more similar to data obtained in the NHAMCS, since they are less detailed and may not have actually been taken by the patient, but they are likely to be an underestimate of all drugs the patient was prescribed because the list in

the hospital record may be based on the patient's recall, or his or her family members' recall. Therefore, during the course of this evaluation, the contractor shall document, for each source of pharmacy data examined in the hospital setting, how these data compare to drug "mentions" obtained using the NHAMCS methods, both in terms of whether the patient is likely to have actually received, or taken, the drug, and whether hospital coding systems can be made comparable to NHAMCS coding systems.

The pharmaceutical variables to be considered for evaluation and compared across data sources are:

Prior medications (prescribed prior to admission)
Drug name

For each current medication (prescribed during inpatient status)
Drug name (generic or brand)
Dosage
Route of administration
Frequency
Stat (indication for immediate administration)
Dates (to provide a chronology)

Medications prescribed at discharge.

As a basis for these activities the contractor shall make site visits to nine hospitals in the greater Washington, D.C. area. All data collected about these hospitals and their patient, billing or pharmaceutical data or data systems shall be kept confidential. All materials and reports about hospitals shall be made using a key and not hospital names. Any files containing the names of hospitals used in this study shall be destroyed.

The acronym "TM" throughout this Scope of Work and in the list of Deliverables refers to the Task Order Monitor and/or his designated representatives from NCHS.

All deliverable products will be produced in draft for review by the TM and final products will reflect input from the TM or discussions with the contractor and the TM.

Task 1. Initial Meeting with TM

The contractor shall meet with the TM to discuss the objectives of the project, to develop a general approach to the project and tasks, and to establish completion dates of major project activities and milestones.

Deliverable: Meeting with TM (Week 1)

Task 2. Development of Project Implementation Plan

The contractor shall develop a detailed project implementation plan consisting of all phases necessary for the completion of this project. This will include but not be limited to specifics on: project management and staffing; specifications for the selection of the 9 hospitals; approaches for contacting and eliciting participation

from each of these hospitals; and the development of interview protocols which specify the information to be gathered.

Deliverables: Project Implementation Plan and Protocols for Visits to Nine Hospitals

Task 3. Evaluate Potential Sources and Methodologies for Collecting Pharmaceutical Data in the NHDS.

In concurrence with the TM the contractor shall select, contact and elicit participation from nine hospitals in the greater Washington, D.C. area for the activities described below. Selected hospitals will vary with respect to characteristics such as in size, urbanicity, degree of automation for pharmaceutical data, and whether they are part of a hospital or health care system. Because of the variation between hospitals, a standard data collection instrument cannot be used. A minimum of three hospitals in Maryland will be included in order to evaluate the potential to link computerized discharge data with pharmaceutical data.

The purpose of these visits is to gather information to evaluate individual hospitals as potential sources of pharmaceutical data for inpatients that can be used to develop uniform methods and procedures to collect pharmaceutical data in a large scale national probability sample of hospitals.

The primary focus of potential sources of pharmaceutical data within each hospital shall be medical records and pharmacy departments, but other sources may be identified. We anticipate that this data will be collected from only one individual in each of the appropriate hospital departments. For each of these potential sources basic elements of the evaluation will include the following issues and questions (additional issues for specific sources are listed below):

- consistency and availability of variables;
- level of expertise needed to collect the data;
- time and cost to collect data;
- level of authorization required to collect these data as well as potential obstacles to obtaining it on an ongoing basis;
- the need for payment to collect the data;
- the feasibility of coding pharmaceutical data for inpatients according to the system of coding drug mentions in the NHAMCS.

Medical Records – The potential to abstract pharmaceutical data manually from medical records will be evaluated using the methodology employed in the NHAMCS. Pharmaceutical data for hospital outpatient and emergency department visits in the NHAMCS are abstracted from medical records by either hospital personnel or Bureau of the Census field representatives. These data are sent to a central processing facility for coding and data entry. While the dataset for the NHAMCS is different than that proposed for the NHDS, a primary focus of this project is to evaluate the methodology for inclusion in the NHDS. The following are examples of specific issues and questions for the evaluation of this data source and methodology; additional issues should be addressed as knowledge is gained:

- The location or locations of pharmaceutical data in the medical record.

**Does the entire record need to be examined?
Is there a single “best” location to find pharmaceutical data in inpatient records?**

The difficulty of abstracting these data.

**Are they typed or handwritten?
If handwritten, are they legible?
Are there acronyms or abbreviations used only by this hospital?
Are there other difficulties involved?**

Potential data collection methods.

**Is there a single page or pages of pharmaceutical data (i.e., the physician’s orders) in medical records that can be photocopied with all personal identifiers removed such that hospitals would allow the photocopy to be taken out of the hospital as part of the NHDS?
Would IRB approval be required from the hospital for this method of data collection?**

Hospital Pharmacy -- It is expected that data collection methods from pharmacies will be different than those used in the NHAMCS. For example, data from these sources may be in the form of printouts or computer files. The following are examples of specific issues and questions for the evaluation of this data source and methodology; additional issues should be addressed as knowledge is gained:

Problems, if any, with methods to link pharmacy data to abstracted medical records data sampled for the NHDS.

**How can this linkage be accomplished?
Can a consistent method for linkage be developed across hospitals?
Does it appear that patient names, social security numbers or other personal identifiers will be needed for linkage?**

What administrative procedures, if any, must be added or modified in the NHDS to conduct and coordinate data collection in two hospital departments (pharmacy and medical records)? For example, what difficulties will arise when soliciting hospital personnel to collect data from two departments?

Which order of data collection is best and why: collect data from the medical records and then go to the pharmacy, or collect data in the pharmacy and then go to the medical records? If the latter sequence is best, can hospital pharmacy databases be used as the sample frame for the NHDS?

**Can pharmacies identify all inpatients and exclude non-inpatients?
Are all inpatients included whether or not drugs were ordered or prescribed?**

What is the physical source of data in pharmacies (computer file, computer printout, hand written notes, other)?

For computerized data, what is its format, layout and structure?

How consistent are computerized formats across hospitals?

Are variables coded in a manner that code sheets (legends) are required to interpret the variables? That is, is re-coding required to make a variable(s) consistent across hospitals?

How long are data available (prior to archiving)?

Is a customized printout able to be produced? If so, what would be the total (one-time) cost to elicit and pay to have hospital staff write a program to produce this printout on an ongoing basis? What will be the cost to run this program on a regular basis?

Other Potential Sources – The Contractor shall consider other possible sources of information for pharmacy data that can be linked to individual discharges. These may include billing records, medication administration records (MAR), automated drug dispensing systems, or other sources or systems that come to light during the site visits. For each source the Contractor shall address the basic types of questions posed above to evaluate its potential to be used in the NHDS. .

Linkage with Automated Discharge Data – About 35 percent of hospitals participating in the NHDS provide data from state or commercial sources in electronic form. For any of the potential sources of pharmaceutical data and survey methods that are studied is there a means to link these data with existing electronic discharge databases? As part of addressing this question, 3 of the 9 hospital site visits shall be in Maryland in order to evaluate the potential to link pharmaceutical data from these hospitals with electronic data that these hospitals supply to the State’s Cost Review Commission.

Deliverables: Bi-weekly progress reports.

Task 4. Evaluation and Recommendations

The contractor will prepare a draft report for Task 3. This report will be an organized evaluation that addresses the issues and questions raised above as well as additional issues identified during the site visits. The evaluation will present the strengths and weaknesses of various sources and potential methods to collect pharmaceutical data for inpatients as part of the NHDS. Based on the evaluation the contractor will draft recommendations of potential survey methods for a field test. The contractor shall meet with members of the Division of Health Care Statistics, NCHS, to discuss their findings and proposed options prior to developing a final set of recommendations.

Deliverables:

**Draft Report of Evaluation and Recommendations
Meeting with TM
Final Report of Evaluation and Recommendations**

Task 5. Evaluation Design and Implementation Plan for Field Test

The contractor shall produce an evaluation design and implementation plan to field test at most two methods (as recommended in Task 4) in 4 or 5 States using 40-50 hospitals. The design shall address the following types of issues:

Criteria for selecting States;
Criteria for selecting hospitals;
Assignment of data collection methods across hospitals;
Evaluation procedures for the field test including evaluation questions and design issues;
Potential sources of personnel to conduct the field work (based on level of expertise required);
Data collection period (sample discharges for one or more months);

Deliverable: Report of Evaluation Design and Field Test Plan

Task 6. Modify NHDS Forms, Procedures and Manuals to Collect Pharmaceutical Data

Based on the recommendations generated under Task 4, the contractor shall modify existing NHDS forms, procedures and manuals to allow for the collection of pharmaceutical data in a pretest to be conducted under a separate task order. No more than two methods (procedures) will be tested.

Deliverables: Modified NHDS forms, procedures, and manuals

Task 7. Develop a Training Program and Training Materials for Field Staff

In anticipation of NCHS conducting a field test of methods, the contractor will develop scripted training with accompanying materials including exercises. Training will include hospital induction procedures and data collection for no more than two methods. It is anticipated that training will require a minimum of one day and maximum of two days. (Conducting the training is not part of this Scope of Work.)

Deliverables: Training script, exercises and keys, and related materials.

Section III -- Schedule of Deliverables

Task No.	Task Description	Delivery Date	Quantity and format
Task 1	Initial meeting with Task Monitor	1 week after Effective Date of Contract (EDOC)	
Task 2	Project Implementation Plan and Draft Protocols	2 weeks after EDOC	Diskette* and 6 paper copies
	Final Plan and Protocols	1 week after TM review	Diskette* and 6 paper copies
Task 3	Synopsis of each site visit	1 week after site visit	Email
	Completion of site visits	12 weeks after EDOC	
Task 4	Draft of Evaluation and Recommendations	14 weeks after EDOC	
	Meeting with TM	15 weeks after EDOC	Diskette* and 6 copies
	Final Report of Evaluation and Recommendations	16 weeks after EDOC	Diskette* and 6 copies
Task 5	Draft Report of Evaluation Design and Implementation Plan for a Field Test	20 weeks after EDOC	Diskette* and 6 copies
	Final Report of Evaluation Design and Implementation Plan for a Field Test	1 week after TM review	Diskette* and 6 copies
Task 6	Draft forms, procedures and manuals to collect Pharmaceutical Data in the NHDS	24 weeks after EDOC	Diskette* and 6 copies

	Final forms, procedures and manuals to collect Pharmaceutical Data in the NHDS	1 week after review by TM	Diskette* and 6 copies
Task 7	Draft set of training script and materials	26 weeks after EDOC	Diskette* and 6 copies
	Final set of training script and materials	1 weeks after review by TM	Diskette* and 6 copies

*All diskettes will be run through a virus scan and be free of viruses prior to being sent to the TM.

C. Requirements

Contract employees will view NCHS' Confidentiality Video and sign an NCHS confidentiality pledge.

Reference materials are available upon request.

Appendix 1.

CONFIDENTIALITY AND PRIVACY

Safeguards for Individuals and Establishments Against Invasion of Privacy

In accordance with Subsection (m) of the Privacy Act of 1974 (5 USC 552a) and Section 308(d) of the Public Health Service Act (42 USC 242m), the contractor, and employees of the contractor, are required to comply with the applicable provisions of the Privacy Act and to undertake other safeguards for individuals and establishments against invasions of privacy. To provide these safeguards in performance of the contract, the contractor, and contractor employees shall be bound by the following confidentiality assurance: “In accordance with Section 308(d) of the Public Health Service Act (42 USC 242m), the contractor, you as an employee of the contractor, and NCHS, assure all survey respondents that the confidentiality of their responses will be maintained and that no information will be disclosed in a manner in which an individual or establishment is identifiable, unless the individual or establishment has consented to such disclosure.”

To preclude observation of confidential information by persons not employed on the project, the contractor shall maintain all confidential records that identify individuals or establishments or from which individuals or establishments could be identified under lock and key. Specifically, at each site where these items are processed or maintained, all confidential records that will permit identification of individuals or establishments are to be kept in locked containers when not in use by the contractor’s employees. The keys or means of access to these containers are to be held by a limited number of the contractor’s staff at each site.

If records are maintained in electronic form, the medium on which the files are stored (floppy disks, CD ROMS, removable hard drives) must also be kept in locked fireproof containers or, if maintained on a computer, access secured by all available means (including keyboard locks, passwords, encryption, etc. and office locks). Personal computers containing records should never be maintained in an open, unsecured space.

When confidential records are in use, whether by themselves or viewed on computer monitors, they must be kept out of the sight of persons not authorized to work with the records.

Except as needed for operational purposes, copies of confidential records (paper documents, electronic files, video records, or records of other kinds) are not to be made. Any duplicate copies made of confidential records are to be destroyed as soon as operational requirements permit.

No records containing direct identifiable data may be removed from the contractor's offices to an alternative worksite—including a telecommuting worksite—or electronically accessed from such a site.

After having read the attached non-disclosure agreement (pledge) and viewed the NCHS Confidentiality video, each employee of the contractor participating in this project will sign the non-disclosure statement which indicates he/she has carefully read and understands the assurance which pertains to the confidential nature of all records to be handled in regard to this survey. As an employee of the contractor, he/she understands they are prohibited by law from disclosing any such confidential information which has been obtained under the terms of this contract to anyone other than authorized staff of NCHS. He/she understands that any willful and knowing disclosure in violation of the Privacy Act of 1974 is a misdemeanor and would subject the violator to a fine of up to \$5,000.”

The contractor and his/her professional staff will take steps to insure that the intent of the statement of understanding is enforced at all times through appropriate qualifications standards for all personnel working on this project and through adequate training and periodic follow up procedures.

Confidentiality Statements to be Included on Questionnaire (NOTE: This information must appear on the Questionnaire whether printed by the Government or by a Contractor)

Print on the questionnaire in a clearly visible location and in clearly visible letters the following notice of the confidential treatment to be accorded the information on the questionnaire by any individual who may see:

Confidential Information

Information contained on this form which would permit identification of any individual or establishment has been collected with a guarantee that it will be held in strict confidence by the contractor and NCHS, will be used only for purposes stated in this study, and will not be disclosed or released to anyone other than authorized staff of NCHS without the consent of the individual or establishment in accordance with 308(d) of the Public Health Service Act (42 U.S.C. 242m).

Confidentiality Statements to be Included on the Letter or Form to be Retained by the Individual or Establishment (NOTE: This information must appear on the Letter or Form whether printed by the Government or by a Contractor)

On a letter or other form that can be retained by the individual or the establishment, or on the questionnaire form itself if it is a self-administered questionnaire, inform in clear and simple terms each individual or establishment asked to supply information:

- That the collection of the information by NCHS and its contractor is authorized by Section 306 of the Public Health Service Act (42 U.S.C. 242k);

- Of the purpose or purposes for which the information is intended to be used, clearly stating that the records will be used solely for epidemiological or statistical research and reporting purposes;

- Of the routine uses that may be made of the information, including all disclosures specified in the “Federal Register” for this system of records which may be applicable to this project;

- That participation is voluntary and there are no penalties for declining to participate in whole or in part; and

- That no information collected under the authority of Section 306 of the Public Health Service Act (42 U.S.C. 242k) may be used for any purpose other than the purpose for which it was supplied, and such information may not be published or released in other form if the particular individual or establishment supplying the information or described in it is identifiable to anyone other than authorized staff of NCHS, unless the individual or establishment has consented to such release.

The voluntary disclosure by the respondent of requested information after being informed of the preceding paragraphs is an acknowledgment of the uses and disclosures contained in the aforementioned “Confidential Information” paragraph.

- Release no information which would allow identification of hospitals participating in this study to any persons except authorized staff of NCHS.

- By a specified date, which may be no later than the date of completion of the contract, return all study data to NCHS or destroy all such data, as specified by the contract.

Privacy Act Applicability

The Contractor and its employees are subject to criminal penalties for violation of the Privacy Act to the same extent as employees of the Government. The Contractor shall assure that each of its employees knows the prescribed rules of conduct and that each is

aware that he or she can be subjected to criminal penalty for violation of the Act. A copy of the Privacy Act Regulation is located at the following Internet Site: <http://law2.house.gov/uscode-cgi/fastweb.exe?search>. If preferred, a copy of the Privacy Act Regulation can either be e-mailed or sent through the mail.

The Privacy Act monitor is the Project Officer, who may confer with the NCHS Privacy Official as necessary. The Privacy Act System of Record number is 09-20-0167.

G. EVALUATION FACTORS

1. Understanding of the Scope of Work and Approach (As Demonstrated by the Technical Proposal) Weight - 10%

Does the offeror clearly indicate an understanding of each task and of the problems that may be encountered in its accomplishment?

Are the proposed solutions logical and reasonable? Will they meet the stated objectives of the RFP?

Does the offeror propose a unique or novel solution which could result in a marked advance in the state of the art?

2. Thoroughness and Soundness of Responses to all Work Statement Elements and with Other RFP Requirements Weight - 50%

Does the offeror have a clear understanding of issues related to the development of large scale or national surveys?

Does the offeror clearly indicate an understanding of pharmaceutical data, particularly for the inpatient setting, and how it might be used for research?

Does the offeror have a clear understanding of pharmaceutical data and how they may exist and/or be collected in hospital settings?

Does the proposal thoroughly identify, describe, define, and consider each element of the specifications?

Does the offeror recognize, and place proper emphasis on the more difficult requirements?

Is the proposal presented in a clear and precise manner?

3. Commitment to Meeting the Requirements of the Specification Within a Realistic Program Schedule Weight - 20%

Does the proposed performance schedule indicate realistically the satisfactory accomplishment of the task in accordance with the specified timeframe?

Does the proposal indicate that the offeror is willing to commit its resources to fulfilling the requirements of the work statement?

4. Capability, Responsibility, and Past Performance in Managing and Conduction Similar Programs Weight - 20%

Does the offeror have previous experience in performing similar or related developmental activities?

Does the offeror provide management and personnel to the project with knowledge and experience with pharmaceutical data, inpatient databases and the development of national or very large scale surveys?

RFTOP# 19 TITLE: Age Page Revisions
PART II - CONTRACTOR'S REPLY:
TO # _____ CONTRACT #263-01-D-0_____

Contractor:
Points of Contact:
Phone- _____ Fax- _____
Address: _____

TOTAL ESTIMATED COST: _____ Pricing Method: FFP
TOTAL ESTIMATED NUMBER OF HOURS: _____
PROPOSED COMPLETION DATE: _____

FOR THE CONTRACTOR: _____
Signature Date

SOURCE SELECTION:

WE HAVE REVIEWED ALL SUBMITTED PROPOSALS HAVE DETERMINED THIS FIRM SUBMITTED THE BEST OVERALL PROPOSAL AND THE PRICE/COST IS REASONABLE.

Billing Reference # _____
Appropriations Data: _____
(ATTACH OBLIGATING DOCUMENT IF AN ROC WILL NOT BE USED.)

RECOMMENDED: _____
FAX # _____ Signature - Project Officer Date

APPROVED: _____
FAX # _____ Signature - Contracting Officer Date

NIH APPROVAL -

CONTRACTOR SHALL NOT EXCEED THE TASK ORDER AMOUNT WITHOUT THE WRITTEN APPROVAL OF THE CONTRACTING OFFICER & ICS COORDINATOR

APPROVED: _____
Signature -Anthony M. Revenis, J.D., NIH-ICS Coordinator Date