

EXHIBIT 1.—ESTIMATE OF COST BURDEN TO RESPONDENTS

| Date collection effort | Number of responses* | Estimated time per respondent in hours | Estimated total burden hours | Average hourly wage rate** (\$) | Estimated annual cost burden to respondents (\$) |
|---|----------------------|--|------------------------------|---------------------------------|--|
| Office Manager baseline survey | 45 | 0.25 | 11.25 | \$34.67 | \$390.04 |
| Physician baseline survey | 45 | 0.25 | 11.25 | 57.90 | 651.38 |
| Physician opinion survey of system | 45 | 0.25 | 11.25 | 57.90 | 651.38 |
| Physician entry of medication error | 216 | 0.134 | 28.94 | 57.90 | 1675.63 |
| Nurse opinion survey of system | 45 | 0.25 | 11.25 | 27.35 | 307.69 |
| Nurse entry of medication error | 18 | 0.134 | 2.4 | 27.35 | 65.64 |
| PA/NP opinion survey of system | 45 | 0.25 | 11.25 | 34.17 | 384.41 |
| PA/NP entry of medication error | 18 | 0.134 | 2.4 | 34.17 | 82.00 |
| Medical assistant survey of system | 45 | 0.25 | 11.25 | 12.58 | 141.53 |
| Medical assistant entry of medication error | 18 | 0.134 | 2.4 | 12.58 | 30.19 |
| Office Manager opinion-survey of system | 45 | 0.25 | 11.25 | 34.67 | 390.04 |
| Total | 585 | | 114.89 | | 4769.93 |

*Based on a six month trial period of MEADER reporting.

**Based upon the mean of the average wages, National Compensation Survey: Occupational wages in the United States 2004, "U.S. Department of Labor, Bureau of Labor Statistics."

This information collection will not impose a cost burden on the respondent beyond that associated with their time to provide the required data. There will be no additional costs for capital equipment, software, computer services, etc.

Estimated Costs to the Federal Government

The total cost to the government for this activity is estimated to be \$1,000,000.00.

Request for Comments

In accordance with the above-cited legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of health care research and information dissemination functions of AHRQ, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of the proposed information collection. All comments will become a matter of public record.

References

¹ Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients: Results of the Harvard Medical Practice Study. *N Engl J Med* 1991; 324:370–376.

² McDonald CJ, Weiner M, Hui SL. Deaths due to medical errors are exaggerated in the Institute of Medicine Report. *JAMA* 2000; 284:93–95.

³ Leape LL. Institute of Medicine medical error figures are not exaggerated. *JAMA*. 2000; 28:95–97.

⁴ Hayward RA, Hofer TP. Estimating hospital deaths due to medical errors: preventability is in the eye of the reviewer. *JAMA*. 2001; 286:415–420

⁵ Institute of Medicine. *To Err is Human: Building a Safer Health System*. Washington, DC: National Academy Press, 2000.

⁶ Institute of Medicine. *Crossing the Quality Chasm: a New System for the 21st Century*. Washington, DC: National Academy Press, 2001.

⁷ Institute of Medicine. *Patient Safety: Achieving a New Standard for Care*. Washington, DC: National Academy Press 2004.

⁸ <http://www.blsmetings.net/PatientSafetyandHIT/> (accessed August 11, 2005).

⁹ Green LA, Fryer GE, Yawn BP, Lanier D, Dovey SM: The ecology of medical care revisited. *N Engl J Med* 2001; 344:2021–2025.

¹⁰ Uribe CL, Schweikhart SB, Pathak DS, Dow M, Marsh GP. Perceived barriers to medical-error reporting: an exploratory investigation. *J Healthcare Management*. 2002; 47(4):263–79.

Dated: January 30, 2007.

Carolyn M. Clancy,

Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 Day–07–05CJ]

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) 371–5960 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

Colorectal Cancer Screening Demonstration Program—New—National Center for Chronic Disease Prevention and Health Promotion (NCDDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) is seeking a 3-year Office of Management and Budget (OMB) approval to collect individual patient-level screening, diagnostic, and treatment data in association with a new colorectal cancer screening demonstration program. CDC funded 5 cooperative agreements in fiscal year

(FY) 2005 to implement these new colorectal cancer (CRC) demonstration programs. These 3-year demonstration programs are designed to increase population-based CRC screening among persons 50 years and older in a geographically defined area, focusing screening efforts on persons age 50 years and older with low incomes and inadequate or no health insurance coverage for CRC screening (priority population).

Colorectal Cancer (CRC) is the second leading cause of cancer-related deaths in the United States, following lung cancer. Based on scientific evidence which indicates that regular screening is effective in reducing CRC incidence and mortality, regular CRC screening is now recommended for average-risk persons with one or a combination of the following tests: fecal occult blood testing (FOBT), flexible sigmoidoscopy, colonoscopy, and/or double-contrast barium enema (DCBE). Fecal immunochemical testing (FIT) is considered an acceptable alternative to FOBT. In the absence of evidence indicating a single most effective test, selected programs chose the screening

test(s) they will use from the above list of recommended tests.

All funded programs are required to submit patient-level data to capture demographic information, CRC screening and diagnostic services provided through this program, and clinical results, and submit these data to Information Management Services (IMS) on a quarterly basis, so that CDC and the programs can evaluate immediate and long term (3 year) program effectiveness and assess the quality and appropriateness of the services delivered, including medical complications. While CDC funds will not be used for treatment, programs will need to monitor treatment and document that patients are receiving appropriate treatment services. Submitted data must contain no patient identifiers. CDC, the funded programs, and IMS worked together to define the key, standardized clinical data elements which are included in a codebook to be used by the programs and CDC known as the Colorectal Cancer Clinical Data Elements (CCDE). Data collection forms have been developed by staff at the programs to collect the standardized

individual patient-level data. IMS will assist CDC by receiving the data from the programs, cleaning the data and producing standardized data reports.

All programs will additionally submit annual cost data to CDC to monitor cost and cost-effectiveness over the 3-year program period.

In developing the definition variable and data definitions to be reported in the CCDEs, CDC has consulted with representatives of the American Cancer Society, The National Cancer Institute, The Agency for Health Care Research and Quality, the Centers for Medicare and Medicaid Services, representatives from professional medical societies involved in colorectal cancer screening, representatives from managed care organizations, representatives from state health departments, and a variety of individuals with expertise and interest in this field.

There are no costs to the respondents other than their time. The total estimated annualized burden hours are 1270.

Estimated Annualized Burden Hours:

| Respondents | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) |
|--|---|-----------------------|------------------------------------|--|
| Colorectal Cancer Demonstration Program Sites. | Colorectal Cancer Data Elements for Colonoscopy Programs. | 2 | 240 | 1 |
| | Colorectal Cancer Data Elements for Fecal Occult Blood Test Programs. | 3 | 1000 | 15/60 |
| | Medical Complications Form | 5 | 6 | 1 |
| | Annual Aggregate Data on Medically Ineligible Clients. | 5 | 1 | 1 |
| | Reimbursement Data Reporting Form | 5 | 1 | 1 |

*Respondents include cooperative agreement recipients.

Dated: February 6, 2007.

Joan F. Karr,
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

Ethics Subcommittee, Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention (CDC); Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention announces the aforementioned Subcommittee meeting.

Times and Dates: 1 p.m.–5 p.m., February 27, 2007. 8:30 a.m.–12 p.m., February 28, 2007.

Place: Centers for Disease Control and Prevention, 1825 Century Center, Conference Room 1 A/B, Atlanta, GA 30345.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 75 people.

Purpose: The Ethics Subcommittee will provide counsel to the ACD, CDC, regarding a broad range of public health ethics questions and issues arising from programs, scientists and practitioners.

Matters To Be Discussed: Agenda items will include public health ethics of genomics; public health ethics of emergency preparedness and response; ethical considerations in pandemic influenza preparedness; ethical considerations for non-research data

collections; demonstration of CDC's public health ethics intranet site; and procedural issues relating to the Ethics Subcommittee. Agenda items are subject to change as priorities dictate.

Due to programmatic matters, this **Federal Register** Notice is being published on less than 15 calendar days notice to the public (41 CFR 102-3.150(b)).

For Further Information Contact: Please contact Drue Barrett, Ph.D., Designated Federal Official, Ethics Subcommittee, CDC, 1600 Clifton Road, NE., M/S D-50, Atlanta, Georgia 30333, telephone 404/639-4690. E-mail: d Barrett@cdc.gov. The deadline for notification of attendance is February 20, 2007. The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other