Revised Document

1. The Categories of Individuals Covered by the System section in the System of Records Notice (SORN) is revised to include other HHS personnel who may treat individuals. The section is revised as follows:

The individuals covered by the system are all persons and owners of animals treated by NDMS and other HHS medical personnel when the NDMS Disaster Medical Assistance Teams (DMATs), National Veterinary Response Teams (NVRTs), or other HHS medical personnel are activated to respond to emergency situations, or as a response to any other situation for which they are activated.

2. The Purpose(s) section in the SORN is revised to include other HHS personnel who may treat individuals. The first sentence of that section is revised to read:

Medical and demographic information is collected on all patients seen and/or treated by NDMS or other HHS personnel.

3. Routine Use No. 1 in the SORN is revised to clarify that it refers to sharing information between NDMS partner agencies, and to include a discussion, at the end of the routine use, of the relationship between all of the NDMS partners regarding the use of medical records as follows:

NDMS is a coordinated effort between HHS, the Department of Homeland Security (DHS), the Department of Defense (DoD), and the Department of Veterans Affairs (VA). As such, the medical treatment and movement of patients is a shared responsibility between these partnership agencies. The medical and demographic information collected during the treatment of a patient is shared with the partners to ensure that patients treated through NDMS receive the appropriate level of health care. The health information disclosed among the partners is limited to what is needed for continuity of health care operations.

4. Routine Use No. 4 in the SORN is revised to include volunteers as follows:

Disclosure to agency contractors, consultants, grantees, or volunteers who have been engaged by the agency to assist in the performance of a service related to this collection and who have a need to have access to the records in order to perform the activity.

5. Routine Use No. 6 in the SORN is revised to include a discussion, at the end of the routine use, of the circumstances when the agency will not disclose the patient's location or status to family members as follows:

Disclosure of a patient's location or status is not permitted when there is a reasonable belief that disclosing such information could endanger the life, safety, health, or well-being of the patient.

6. In the SORN, in the Policies and Practices for Storing, Retrieving, Accessing, Retaining, and Disposing of Records in the System, in the Disposition authority subsection, the first two sentences are revised as follows:

Patient Care Forms or other Medical Records created by the Federal Medical Station(s) (FMS) or by any component of HHS/ASPR inclusive of NDMS during a response to an event while caring for victims of that event are cutoff at the end of the response activity by the Federal Medical Station(s) or HHS/ASPR component for a particular event. Cutoff refers to breaking, or ending files at regular intervals, usually at the close of a fiscal or calendar year, to permit their disposal or transfer in complete blocks and, in this case, cutoff is at the end of the response activity. The cutoff date marks the beginning of the records retention period.

Dated: March 3, 2008.

Kevin Yeskey,

Deputy Assistant Secretary, Director, Office of Preparedness and Emergency Operations.

[FR Doc. E8–6238 Filed 3–26–08; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (0MB) approve the proposed information collection project: ''Health Care Systems for Tracking Colorectal Cancer Screening Tests.'' In accordance with the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A), AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by May 27, 2008.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by e-mail at: *doris.lefkowitz@ahrq.hhs.gov.*

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by e-mail at: *doris.lefkowitz@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Health Care Systems for Tracking Colorectal Cancer Screening Tests

AHRQ proposes to implement and assess a system redesign intervention to improve colorectal cancer (CRC) screening and follow-up among patients 50–79 years-old. Other goals of the intervention include: (1) Achieving a high level of satisfaction with the intervention among patients, providers, and practice staff, (2) promoting patient-centered care through the intervention, (3) being a cost-effective intervention, and (4) demonstrating the benefits to businesses for implementing the intervention. The research is sponsored by AHRQ under its ACTION (Accelerating Change and Transformation in Organizations and Networks) program, and will be conducted for AHRQ by The CNA Corporation (CNA) and its partners Thomas Jefferson University (TJU) and Lehigh Valley Physician Hospital Organization (LVPHO).

Colorectal cancer screening is recommended as routine preventive care and this intervention, which is consistent with current CRC screening guidelines, carries no greater risk than that which occurs in usual delivery of healthcare (i.e., screening and follow up done without benefit of this intervention).

Nevertheless, as part of standard research practice, the intervention and assessment protocol will be submitted to the Institutional Review Boards (IRB) at both LVPHO and TJU so that they can review the protocols to ensure that they are consistent with the requirements of human subjects protection as outlined in federal statute, regulations, and guidelines. These approvals will be obtained before the study begins. Additionally, CNA and LVPHO have a business associate agreement, and all parties involved with the study (CNA, LVPHO, and TJU) will comply with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, 45 CFR Parts 160 and 164. To further protect patient privacy, neither CNA nor TJU will have access to any personally-identifiable data. Only PHO personnel will have access to

identifiable data, which they will de-identify before sending to CNA and TJU for analysis. Consistent with this protocol, only LVPHO staff will have access to patient names and addresses and will conduct all mailings of letters and related material to patients.

The intervention will be implemented in both Family Medicine and General Internal Medicine practices affiliated with the LVPHO, and will involve 20 intervention practices and 5 control practices (25 practices total). The intervention will consist of inviting and assisting eligible patients of intervention practices to be screened for CRC, providing academic detailing to intervention practice providers regarding CRC screening and appropriate follow-up for positive screens, and assisting providers to identify and follow up with their patients who have positive screens.

Patient eligibility criteria for the intervention include: being between the ages of 50–79, having no recent CRC screening test, not having a previous diagnosis of CRC, and not having a family history of CRC before age 60. Eligible patients will be identified through a two step process: (1) An electronic records review to identify potentially eligible patients; and (2) a mailed Screening Eligibility Assessment (SEA) form from their primary care practice to allow potentially eligible patients to confirm or refute their eligibility, and provide selected additional demographic and perceived health status information. Patients will also have the opportunity to opt out of the study on the SEA form.

Patients who are deemed eligible and have not opted out of the study through the SEA form will then receive a mailing from their practice inviting them to be screened for colorectal cancer. The invitation will include a letter on practice letterhead signed by the practice's primary care providers, a brochure that describes the benefits of CRC screening and the alternative screening modalities that are consistent with American Cancer Society guidelines, a Stool Blood Test (SBT) kit with an envelope to return it for processing for those patients who want to use that screening modality, and a list of colonoscopists that the practice refers patients to for those patients who prefer colonoscopy to a SBT. In addition to the list of colonoscopists, the accompanying letter from the practice will also include wording to make sure patients are aware they can select other colonoscopists who may not be on the list. As this invitation mailing is part of normal recommended clinical practice and requires no response on the part of the patient other than participating in the clinically recommended screening, it is not considered to be a data collection.

Patient electronic records will be tracked by LVPHO personnel for evidence of screening. Patients whose records do not indicate they have been screened within a certain amount of time will be sent a reminder letter. As with the invitation mailing, this reminder mailing is part of normal recommended clinical practice and requires no response on the part of the patient other than participating in the clinically recommended screening, and is not considered to be a data collection.

There will be no additional cost to patients for CRC screening beyond that which occurs in the usual delivery of health care. Patients insured through a LVPHO insurance product will be covered for diagnosis and treatment. Patients covered through non-LVPHO plans (public as well as private) will also likely be covered, and such coverage will be documented to determine its impact on the effectiveness of the intervention. Patients who are underinsured or uninsured are eligible to use systems for charity and discounted care available in the Lehigh Valley Hospital and Healthcare Network, including access to hospital clinics and access to financial advisors.

Clinicians and staff of intervention practices will participate in a brief academic detailing session to review the current evidence-based guidelines for CRC screening from the American Cancer Society, to receive information regarding appropriate follow-up to positive screens, and to receive the operational details of the implementation that will affect the practice (including being provided information about the intervention that may be necessary for answering questions from patients). Academic detailing will not be provided to control practices. As educational information is only being provided, this component of the intervention is not a data collection.

Method of Collection

Data will be collected through six modes: (1) A SEA form; (2) focus groups of providers and staff at each intervention and control practice; (3) brief informal interviews with selected providers and staff at each practice; (4) a survey of all clinicians and staff at each practice; (5) patient chart audits; and (6) patient focus groups. The data will be collected to obtain the following types of information needed for determining patient eligibility for the intervention and for conducting an assessment of the intervention: patient's screening history and eligibility information; patient demographics; patient, provider, and practice satisfaction with the intervention; practice attitudes; practice procedures and systems for screening and tracking results; and patient-perceived barriers and facilitators for following screening and follow-up recommendations.

SEA Form

Potentially eligible patients identified by electronic records review will receive a SEA form and accompanying letter. This form will ask patients to confirm or refute their eligibility based on all eligibility criteria. The form will also ask patients for additional socio-demographic and perceived health status data, and allow patients to opt out of participation in the intervention if they so choose.

Practice Focus Groups

The practice focus groups will be conducted both prior to the intervention and following the intervention at each intervention practice. The pre-intervention focus groups are designed to collect information to establish a baseline. The post-intervention focus groups will be conducted to assess satisfaction with the intervention and to identify changes in attitudes and behaviors regarding screening and follow-up and changes in management of normal and abnormal screening tests resulting from the intervention. In addition, focus groups at control practices will be conducted late in the intervention period to gather comparison information similar to the baseline information gathered from intervention practices.

Brief Informal Interviews

Brief informal interviews with selected intervention practice providers and staff will be conducted as a follow-up to the focus groups to ascertain additional baseline information about procedures and systems for screening results (pre-intervention), and additional information about each practice's experience with the intervention and facilitators and barriers to the intervention's implementation (post-intervention). In addition, similar baseline information will be collected from control practices late in the intervention period.

Practice Survey

A pre-intervention practice survey of providers and staff will be administered in the intervention practices to provide a baseline of the current CRC screening environment at each practice. The survey will be administered again post-

intervention to ascertain changes in behavior or attitudes resulting from the intervention. In addition, the survey will also be administered in the control practices late in the intervention period to gather comparison information similar to the baseline information gathered from intervention practices.

Patient Chart Audits

Study personnel will track patient screening rates and outcomes as well as follow-up rates at intervention and control practices by conducting chart audits on patients whose electronic data are inconclusive, or on patients who are part of practices without electronic medical records (EMR) systems. Chart audits will be performed by study personnel; however, practice staff will be required to identify, locate, and make charts available to study personnel.

Patient Focus Groups

Focus groups of patients will be conducted to better understand the intervention from the patient's perspective. Focus groups with the intervention practices will be held at two sites geographically situated across the region. At each site, three focus groups will be conducted for each of the following types of intervention patients: (1) Those who did not get the recommended screening after receiving the invitation packet, (2) those who did get the recommended screening and whose test was negative, and (3) those who did get screened and whose test was positive. For purposes of comparison, two focus groups of patients from control group practices will also be conducted. Participants will be asked about their attitudes and beliefs regarding colorectal cancer screening and what they believe would help them get the screening they need.

Estimated Annual Respondent Burden

Exhibit I shows the estimated annualized burden hours for the respondents to participate in this project. The SEA form will be sent to a maximum of 7,500 patients across the 20 intervention practices and will require an average of 10 minutes to complete each. Practice focus groups will be conducted with 10 individuals per practice, and will last approximately 30 minutes each. The pre-intervention and post-intervention practice focus groups will be held with intervention practices only (20 practices). Focus groups will also be held at each of the control practices for comparison purposes (5 practices). Informal interviews will be conducted with three individuals per practice, and will last about 10 minutes each. The pre and post-intervention informal interviews will be conducted among the intervention practices (20 practices). Informal interviews will also be conducted in the control practices for comparison purposes (5 practices). A survey of providers and staff will be conducted with 10 individuals at each practice, and the survey will take approximately 15 minutes to complete. The survey will be administered to the intervention practices during the pre and post-intervention practice focus group (20 practices). The survey will also be administered to the control practices for comparison purposes (5 practices). Patient chart audits will be performed post-intervention at both intervention and control practices as a supplement to the information available through electronic records. Among the 25 practices, about 50 patients from each practice will have their charts audited, which should take about 10 minutes per chart. Patient focus groups will be held post-intervention and will include six groups of 10 patients from the intervention group practice sites, and two groups of 10 patients from the control group practice sites (80 patients total). These focus groups are expected to last about 2 hours. The total burden for all phases of the project is estimated to be 1,978.33 hours.

Exhibit 2 shows the estimated annualized cost burden for the respondents' time to participate in the project. The total cost is estimated to be $29,844.73.

EXHIBIT 1.—ESTIMATED ANNUALIZED BURDEN HOURS

Data collection mode	Number of respondents	Number of responses per respondent	Est. time per respondent in hours	Total burden hours
Screening Eligibility Assessment (SEA) Form	7,500	1	10/60	1250
Pre-interventlon practice focus groups	20	10	30/60	100
Post-intervention practice focus groups	20	10	30/60	100
Control practice focus groups	5	10	30/60	25
Pre-intervention informal interviews with selected providers and staff	20	3	10/60	10
Post-intervention informal interviews with selected providers and staff	20	3	10/60	10
Control informal interviews with selected providers and staff	5	3	10/60	2.5
Pre-intervention survey of clinicians and staff	20	10	15/60	50
Post-intervention survey of clinicians and staff	20	10	15/60	50
Control survey of clinicians and staff	5	10	15/60	12.5
Chart audits	25	50	10/60	208.33
Patient Focus Groups (post-intervention)	80	1	2	160
Total	7,740	.....	.....	1,978.33

EXHIBIT 2.—ESTIMATED ANNUALIZED COST BURDEN

Data collection mode	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Screening Eligibility Assessment (SEA) Form(1)	7,500	1,250	$12.54	$15,675
Pre-intervention practice focus groups(2)	20	100	28	2,800
Post-intervention practice focus groups(2)	20	100	28	2,800
Control practice focus groups(2)	5	25	28	700
Pre-intervention informal interviews with selected providers and staff(2)	20	10	28	280
Post-intervention informal interviews with selected providers and staff(2)	20	10	28	280
Control informal interviews with selected providers and staff(2)	5	2.5	28	70
Pre-intervention survey of clinicians and staff(2)	20	50	28	1,400

EXHIBIT 2.—ESTIMATED ANNUALIZED COST BURDEN—Continued

Data collection mode	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Post-intervention survey of clinicians and staff(2)	20	50	28	1,400
Control survey of clinicians and staff(2)	5	12.5	28	350
Chart audits(3)	25	208.33	10	2,083.33
Patient Focus Groups (post-intervention)(1)	80	160	12.54	2,006.40
Total	7,740	1,978.33	.....	29,844.73

(1) Patient average hourly wage based on the average per capita income of $26,088 (computed into an hourly wage rate of $12.54) in Lehigh Valley, Pennsylvania: ''Demographic Information for the Lehigh Valley'' from the Lehigh Valley Economic Development Corporation 2006.

(2) Provider and practice hourly wage based on an average of the following estimates from LVPHO: physician = $70/hour; manager = $19/hour; clinical staff = $13/hour; and clerical staff = $10/hour.

(3) Practice clerical staff will retrieve the charts to be audited by study personnel; therefore only the time of the practice staff is included in Exhibit 1 and in the Exhibit 2 cost estimate. Practice clerical staff hourly wage is estimated by LVPHO to be $10/hour.

Estimated Annual Costs to the Federal Government

The estimated total cost to the Federal government is $271,764.68. The average annualized cost over the two years of the project is $135,882.34 per year. Exhibit 3 shows a breakdown of the costs.

EXHIBIT 3.—ESTIMATED ANNUAL COSTS TO THE FEDERAL GOVERNMENT

Component	Year 1	Year 2	Total
The cost of developing the data collection instruments	$24,765.38	$0	$24,765.38
The cost of implementing the data collections	99,061.52	24,601.75	123,663.27
The cost of analyzing the data and publishing the results	49,530.76	73,805.26	123,336.02
Total	173,357.66	98,407.02	271,764.68

Request for Comments

In accordance with the above-cited Paperwork Reduction Act 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 AHRQ health care research and health care information dissemination functions, 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 Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: March 20, 2008.

Carolyn M. Clancy,

Director.

[FR Doc. E8–6073 Filed 3–26–08; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0180]

Draft Guidance for Industry on Coronary Drug Eluting Stents–Nonclinical and Clinical Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Coronary Drug Eluting Stents—Nonclinical and Clinical Studies.'' This draft guidance is intended to provide recommendations to sponsors or applicants planning to develop, or to submit to FDA, a marketing application for a coronary drug eluting stent (DES). The draft guidance discusses the clinical studies that should be performed and the data that should be submitted to support such an application. The draft guidance is being issued in two parts. The companion document provides additional and more detailed guidance on some of the recommendations included in this document. The companion document is intended to be used together with this draft guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by July 25, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to