

research coordinator at the Stratton VA Medical Center. This action is taken pursuant to the HHS government-wide nonprocurement debarment and suspension regulation at 45 CFR part 76. As such, Mr. Kornak is excluded for life from participating in any and all Federal agency transactions, both procurement and nonprocurement, as set forth in part 76.

Of the 48 criminal charges contained in his Indictment, Paul Kornak pled guilty to the three criminal charges listed above. See *United States of America v. Paul H. Kornak*, Criminal Action No. 03-CR-436 (FJS), U.S. District Court (N.D.N.Y.) (January 18, 2005). In addition to the 71-month term of imprisonment imposed, Mr. Kornak was directed to pay restitution to two pharmaceutical companies and the VA in the amount of approximately \$639,000.

As part of his guilty plea, Mr. Kornak admitted to the following facts:

- In August 2000, Mr. Kornak applied for employment to the VA, submitting a false "Declaration for Federal Employment" form. Mr. Kornak denied that he had been convicted or on probation in the preceding 10 years, whereas in fact, he had been convicted of mail fraud in 1992 and placed on probation for 3 years.

- By October of 2000, Mr. Kornak was responsible for organizing, coordinating, implementing, and directing all research elements in the Stratton VA Medical Center oncology research program. Specifically, Mr. Kornak was the site coordinator at the Stratton VA Medical Center for the "Iron (Fe) and Atherosclerosis Study" (FeAST), cancer studies known as Tax 325 and Tax 327, and a bladder cancer study. The FeAST study was a clinical trial that tested a novel procedure for controlling atherosclerosis, also known as hardening of the arteries, by reducing the iron in the body through blood drawing. The Tax 325 cancer treatment study involved the administration of pharmaceutical products to patients with metastatic or locally recurrent gastric cancer previously untreated with chemotherapy for advanced disease. The Tax 327 study involved the administration of pharmaceutical products to patients with metastatic hormone refractory prostate cancer. The purpose of the bladder cancer study, which was co-sponsored by the National Cancer Institute, National Institutes of Health, was to compare the use of difluoromethylornithine (DFMO) to the use of a placebo in patients with low grade superficial bladder cancer according to time to first recurrence of the tumor and toxicities.

- From May 14, 1999, to July 10, 2002, in connection with the above protocols, Mr. Kornak participated in a scheme to defraud the sponsors of the clinical studies in that "he would and repeatedly did submit false documentation regarding patients and study subjects and enroll and cause to be enrolled persons as study subjects who did not qualify under the particular study protocol."

- Mr. Kornak caused the death of a study subject when he "failed to perceive a substantial and unjustifiable risk that death would occur when he knowingly and willfully made and used * * * documents falsely stating and representing the results of [the study subject's] blood chemistry analysis * * *, which false documents purported that [the study subject] met the inclusion and exclusion criteria for participation in Tax 325 when the actual results did not meet the inclusion and exclusion criteria and showed impaired kidney and liver function, and [the study subject] thus was administered the chemotherapeutic drugs docetaxel, cisplatin, and 5-FU in connection with Tax 325 on or about May 31, 2001, and died as a result thereof on or about June 11, 2001."

Based on the criminal conviction and the facts admitted to above, HHS and VA believe that a debarment period longer than the standard length of debarment is warranted in this case. Mr. Kornak admitted to a dishonest handling of the research records and demonstrated a complete disregard for the well-being of vulnerable human subjects under his care. In pleading guilty to criminally negligent homicide, Mr. Kornak admitted that a reasonable person would have perceived a substantial and unjustifiable risk of death if an ineligible subject were enrolled in the cancer study in question and that his failure to perceive such a risk in enrolling the ineligible subject constituted a gross deviation from the standard of care.

Moreover, a longer debarment period is warranted in this case because of an established pattern of misconduct and criminal behavior on the part of Mr. Kornak. As stated above, Mr. Kornak has a prior conviction of mail fraud. In addition, the Office of Personnel Management excluded Mr. Kornak from all Federal nonprocurement transactions for an indefinite period, effective July 22, 1993. Nonetheless, beginning in 1999, Mr. Kornak actively participated in federally sponsored research protocols in violation of the imposed exclusion.

A lifetime debarment of Mr. Kornak is necessary to protect the public interest

overall. Given the scope of his criminal conviction, his longstanding pattern of criminal behavior, and his total disregard for the safety and well-being of human subjects, Mr. Kornak's responsibility to engage in transactions with the Federal Government cannot be assured at any time in the future.

FOR FURTHER INFORMATION CONTACT:

Director, Division of Investigative

Oversight,

Office of Research Integrity,
1101 Wootton Parkway, Suite 750,
Rockville, MD 20852.

(240) 453-8800,

or

Peter Poon,

Health Science Specialist,
Office of Research Oversight,
Veteran's Health Administration, VA,

811 Vermont Ave., NW. (10R), Suite
574,

Washington, DC 20420.

(202) 565-8107.

Chris B. Pascal,

Director, Office of Research Integrity.

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BILLING CODE 4160-17-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 (OMB) allow the proposed information collection project: "Use of IT and Health IT Among Health Centers funded under Section 330 of the Public Health Service Act". In accordance with the Paperwork Reduction Act of 1995, Public Law 104-13 (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 April 25, 2006.

ADDRESSES: Written comments should be submitted to: Cynthia D. McMichael, Reports Clearance Officer, AHRQ, 540 Gaither Road, Suite 5022, Rockville, MD 20850. Copies of the proposed collection plan, data collection instrument, and specific details on the estimated burden can be obtained from AHRQ's Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT:

Cynthia D. McMichael, AHRQ, Reports Clearance Officer, (301) 427-1651.

SUPPLEMENTARY INFORMATION:

Proposed Project

“Use of IT and Health IT Among Health Centers funded under Section 330 of the Public Health Service Act.”

This project is being conducted under contact 290-04-0016 between the Agency for Healthcare Quality and Research and the National Opinion Research Center (NORC) at the University of Chicago, the prime contractor for AHRQ’s National Resource Center for Health Information Technology. AHRQ, in close collaboration with the Health Resources and Services Administration’s (HRSA) Bureau of Primary Health care (BPHC), is requesting that NORC conduct an assessment of the use of information technology (IT) at ambulatory health centers funded under Section 330 of the Public Health Services Act. Specifically, the project will assess IT applications which assist in improving the quality, safety, efficiency, and effectiveness of health care (health IT) at HRSA-funded ambulatory health centers.

For the purposes of this project, AHRQ and HRSA have drafted an Intra-Agency Agreement (AHRQ IAA #05-404R-05) which establishes roles and responsibilities for both agencies. HRSA, AHRQ and NORC will work collaboratively to develop the analytic questions, survey tool, sampling strategy and analysis plan. AHRQ and HRSA will review data runs as well as descriptive and comparative analysis. NORC will field the survey, conduct descriptive and comparative analysis, and report findings to both AHRQ and HRSA.

The HRSA-funded health centers from a key part of the nation’s health care “safety net,” delivering primary care medical services to vulnerable populations. Special administrative requirements, including tracking and reporting on their patient populations, maintaining patient-specific data and supporting disease registries for vulnerable populations, make health centers a prime target for implementing health IT applications. As such, health centers represent an early laboratory for health IT adoption, use, and impact among ambulatory health care providers.

The study will inquire about the gains and challenges experienced at selected health centers in the implementation of IT programs. Information will be collected with regard to the following topics and issues: current state of Health Information Technology (HIT) use, goals and approach to HIT, readiness for HIT adoption and expansion, management of HIT issues and adherence to requirements, and overall experience with HIT implementation of sustainability, including successes experienced and barriers encountered.

Findings from the proposed collection will assist policy makers at AHRQ, HRSA and elsewhere as they seek to build on this early IT adoption among health centers and promote policy efforts to encourage the implementation of IT in ambulatory health care settings to achieve efficiency and quality of care objectives.

Date Confidentiality

To obtain the necessary information, surveys will be conducted with staff at selected HRSA-funded health centers. The study will primarily involve the use of web-based interviews, although some telephone interviews will be conducted when selected health centers do not

respond online. All appropriate measures will be taken to protect the confidentiality of individual respondents and their institution. Web surveys are administered using an encrypted SSL connection using secured web data collection servers. Access to response data will be limited on a strictly “need to access” basis and any person accessing the data will have signed a corporate confidentiality pledge which clearly enumerates their responsibilities in this regard including AHRQ’s statutory confidentiality requirements and specific consequences of improper disclosures or allowing breaches in confidentiality.

Methods of Collection

The data will be collected from a systematic random sample of 450 of the approximately 920 total HRSA Section 330-funded Health Centers. Centers will be chosen stratified by urbanicity (urban, rural and suburban) and geographical area. The expected response rate of 75 percent will result in data from approximately 338 centers.

One survey will be completed by each organization. Multiple individuals from each Health Center may be respondents, including senior management and administrative personnel, information technology staff, and clinicians.

Based on experience with surveys of similar length, the estimate is that the questionnaire will take one hour to complete. The primary method of data collection will be web-based self-administered questionnaire. All sample centers will receive an advance e-mail followed a week later by an e-mail containing instructions for accessing the Web survey. We will use a multiple mode approach to follow-up with centers that do not complete the survey within 4 weeks of the initial e-mailing.

ESTIMATED ANNUAL RESPONDENT BURDEN

Data collection effort	Number of respondents	Estimated time per respondent (minutes)	Estimated total burden to respondents (hours)	Average hourly wage rate	Estimated annual cost to health center respondent
Online and Telephone Surveys *	338	60	338	\$42.38	\$14,324.44

* Using the mean of the average wages for managers in medicine, physicians and computer systems analyst/scientist as reported in the National Compensation Survey: Occupational Wages in the United States, 2004, (U.S. Department of Labor, Bureau of Labor Statistics, September 2004), we estimate the total hourly cost to respondents to be \$42.38 or \$14,324.44 across all 338 health center respondents.

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 functions of AHRQ,

including whether the information will have practical utility; (b) the accuracy of AHRQ’s estimate of burden (including hours and cost) of the proposed collection 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.

Dated: February 16, 2006.

Carolyn M. Clancy,
Director.

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BILLING CODE 4160-90-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Meetings on Patient Safety and Quality Improvement

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice of public meetings, including telephone call-in.

SUMMARY: We are considering how to implement the Patient Safety and Quality Improvement Act of 2005 (Act), including such questions as how the Act might be applied to various organizational configurations and how best to ensure that the statute's fundamental confidentiality objectives are achieved. To help us better understand the thinking and plans of providers that are interested in seeking out patient safety organization (PSO) services, and of entities that anticipate establishing such an organization, this notice invites the public to provide information that may assist the Agency, either in person or by telephone call-in, at three related public meetings.

DATES: The three public meetings will be held on Wednesday, March 8, 2006; Monday, March 13, 2006; and Thursday, March 16, 2006. Each meeting will be held from 12:30 p.m. EST until finished (no later than 3:30 p.m. EST).

ADDRESSES: The meetings on March 8 and 13 will be held at AHRQ, John M. Eisenberg Building, 540 Gaither Road, Rockville, MD 20850. The meeting on March 16 will be held at Hilton Washington Embassy Row, 2015 Massachusetts Ave. NW., Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Eileen Hogan, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850; Telephone: 301-427-1307; E-mail: Eileen.Hogan@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION: The Act is intended to help health care providers improve patient safety, reduce the incidence of events that adversely affect patient safety, and otherwise improve the quality of health care delivery. More specifically, the Act, by establishing a

Federal privilege and mandating confidentiality protection, encourages health care providers to contract with PSOs to collect and analyze data on patient safety events (including "near misses," "close calls," and "no-harm" events as well as other types of patient safety events), to develop and disseminate information to improve patient safety, and to provide feedback and assistance to reduce patient risk. The decision to contract with a PSO is voluntary.

Registration and Other Information About the Meetings

We request that interested persons register with the Cygnus Corporation on the Internet at <http://www.cygnusc.com/> to participate in one or more meetings either in person or by telephone. The contact at Cygnus Corporation is Megan Griggs who can be reached by telephone at (301) 231-7537, ext. 260 and by e-mail at griggsm@cygnus.com. Interested persons should register at least the day before a meeting in which they wish to participate. Non-registered individuals will be able to attend a meeting in person if space is available. However, we will not be able to provide a telephone hook-up for those that do not register at least the day before the meeting.

If sign language interpretation or other reasonable accommodation for a disability is needed, please contact Mr. Donald L. Inniss, Director, Office of Equal Employment Opportunity Program Support Center, on (301) 443-1144.

Each public meeting is scheduled for a three-hour period, but will end sooner if participants have finished providing input before the time period expires. We are asking for input concerning specific topics as follows:

March 8, 2006: Provider-PSO relationships, contracts, and disclosures. March 13, 2006: Operation of a component PSO (a PSO that is part of another organization). March 16, 2006: Security and Confidentiality issues.

We request that input regarding the specified topics be provided at the meeting scheduled for that topic. After those who wish to provide input on the specific topics have finished, participants will be welcome to provide input on other issues regarding the implementation of the Act. The format for the meetings is intended to allow participants not only to provide input, but also to respond to the input provided by others. We especially request input from entities interested in becoming or creating PSOs and from

providers interested in contracting with PSOs.

To help interested individuals prepare for the meetings, we invite review of the Act. The full text is set forth on the Internet at: <http://www.gpoaccess.gov/plaws/> (search for "Public Law 109-41.")

Also, we will establish an e-mail notification list to provide interested parties with automatic notification of relevant information posted on the AHRQ Web site (<http://www.ahrq.gov>) concerning the PSO program. To be added to the e-mail notification list, send your e-mail address to Eileen.Hogan@ahrq.hhs.gov and use the words "Add me to the list" in the subject line.

These meetings will be primarily listening sessions for the Agency and potentially an opportunity for dialogue among participants. We believe that the input received at the public meetings will be most helpful in providing the Agency with background information, fostering fact finding, and broadening awareness of issues raised by the legislation. We generally will not respond to the presentations during the meetings and will not regard them as formal comments that must be addressed in later rulemaking documents.

Dated: February 17, 2006.

Carolyn M. Clancy,
Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-06-0576]

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) 639-5960 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.