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Kathleen Sebelius,
Secretary.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-13-0852]

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 (404) 639-7570 or send an email to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Prevalence Survey of Healthcare-Associated Infections (HAIs) and Antimicrobial Use in U.S. Acute Care Hospitals—Reinstatement—(0920-0852 exp 5/31/13)—National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Preventing healthcare-associated infections (HAIs) is a CDC priority. An essential step in reducing the occurrence of HAIs is to estimate accurately the burden of these infections in U.S. hospitals, and to describe the types of HAIs and causative organisms.

The scope and magnitude of HAIs in the United States were last directly estimated in the 1970s in which comprehensive data were collected from a sample of 338 hospitals; 5% of hospitalized patients acquired an infection not present at the time of admission. Because of the substantial resources necessary to conduct hospital-wide surveillance in an ongoing manner, most of the more than 4,500 hospitals now reporting to the CDC's current HAI surveillance system, the National Healthcare Safety Network (NHSN 0920-0666 expiration 1/31/15), focus instead on device-associated and procedure-associated infections in selected patient locations, and do not report data on all types of HAIs occurring hospital-wide. Periodic assessments of the magnitude and types of HAIs occurring in all patient populations within acute care hospitals are needed to inform decisions by local and national policy makers and by hospital infection control personnel regarding appropriate targets and strategies for HAI prevention.

During 2008-2009 in the previous project period, CDC developed a pilot protocol for HAI point prevalence survey, conducted over a 1-day period at each of nine acute care hospitals in one U.S. city. This pilot phase was followed in 2010 by a phase 2, limited roll-out HAI and antimicrobial use prevalence survey, conducted during July and August in 22 hospitals across 10 Emerging Infections Program (EIP) sites (in California, Colorado, Connecticut, Georgia, Maryland, Minnesota, New Mexico, New York, Oregon, and Tennessee). Experience gained in the phase 1 and phase 2 surveys was used to conduct a full-scale, phase 3 survey in 2011, involving 183 hospitals in the 10 EIP sites. Over 11,000 patients were surveyed, and

analysis of HAI and antimicrobial use data is ongoing at this time.

This reinstatement is sought, to allow a repeat HAI and antimicrobial use prevalence survey to be performed in 2014. A repeat survey will allow further refinement of survey methodology and assessment of changes over time in prevalence, HAI distribution, and pathogen distribution. It will also allow for a re-assessment of the burden of antimicrobial use, at a time when antimicrobial stewardship is an area of active engagement in many acute care hospitals. The 2014 survey will be performed in a sample of up to 500 acute care hospitals, drawn from the acute care hospital populations in each of the 10 EIP sites (and including participation from many hospitals that participated in prior phases of the survey). Infection prevention personnel in participating hospitals and EIP site personnel will collect demographic and clinical data from the medical records of a sample of eligible patients in their hospitals on a single day in 2014, to identify CDC-defined HAIs. The surveys will provide data for CDC to make estimates of the prevalence of HAIs across this sample of U.S. hospitals as well as the distribution of infection types and causative organisms. These data can be used to work toward reducing and eliminating healthcare-associated infections—a Department of Health and Human Services (DHHS) Healthy People 2020 objective (<http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=17>). This survey project also supports the CDC Winnable Battle goal of improving national surveillance for healthcare-associated infections (<http://www.cdc.gov/winnablebattles/Goals.html>).

There are no costs to respondents other than their time. The estimated annualized burden is 6,325 hours.

Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Infection Preventionist	Healthcare Facility Assessment (HCA)	500	1	45/60
Infection Preventionist	Patient Information Form (PIF)	500	42	17/60

Kimberly S. Lane,

*Deputy Director, Office of Scientific Integrity,
Office of the Associate Director for Science,
Office of the Director, Centers for Disease
Control and Prevention.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-6023-N3]

Medicare Program; Approval of Accrediting Organization for Suppliers of Advanced Diagnostic Imaging Supplier Accreditation Program

AGENCY: Centers for Medicare &
Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces our approval of RadSite™, a national accreditation organization to accredit suppliers seeking to furnish the technical component (TC) of advanced diagnostic imaging services under the Medicare program.

FOR FURTHER INFORMATION CONTACT:
Sandra Bastinelli (410) 786-3630.

SUPPLEMENTARY INFORMATION:

I. Background

Section 135(a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) added section 1834(e) to the Social Security Act (the Act) requiring the Secretary to designate organizations that accredit suppliers furnishing the technical component (TC) of advanced diagnostic imaging (ADI) service and establish procedures to ensure that the criteria used by an accreditation organization are specific to each imaging modality. Section 1834(e)(1)(B) of the Act defines advanced diagnostic imaging services as—

(i) [D]iagnostic magnetic resonance imaging, computed tomography, and nuclear medicine (including positron emission tomography); and

(ii) [S]uch other diagnostic imaging services, including services described in section 1848(b)(4)(B) (excluding X-ray, ultrasound, and fluoroscopy), as specified by the Secretary in consultation with physician specialty organizations and other stakeholders.

Section 1848(b)(4)(B) of the Act defines imaging services as “imaging and computer-assisted imaging services,” including x-ray, ultrasound (including echocardiography), nuclear medicine (including positron emission

tomography), magnetic resonance imaging, computed tomography, and fluoroscopy, but excluding diagnostic and screening mammography. Suppliers, which include physicians, non-physician practitioners and physician and non-physician organizations, of the TC of advanced diagnostic imaging services for which payment is made under the fee schedule established under section 1848(b) of the Act, were required to be accredited by an accreditation organization designated by the Secretary beginning January 1, 2012.

The application requirements for accrediting organizations were finalized in the Calendar Year 2010 Physician Fee Schedule final rule published on November 25, 2009 (74 FR 61738), as corrected in the November 30, 2009 correcting document (74 FR 62579) and set forth as application criteria in a November 25, 2009 **Federal Register** notice (74 FR 62189), as corrected in the November 30, 2009 correction notice (74 FR 62579).

In the January 26, 2010, **Federal Register** (75 FR 4088), we announced the approval of the American College of Radiology (ACR), the Intersocietal Accreditation Commission (IAC), and The Joint Commission (TJC) as designated accreditation organizations to accredit suppliers furnishing the technical component of the following advanced diagnostic imaging modalities: Computerized tomography, nuclear medicine, positron emission tomography, and magnetic resonance imaging.

II. Application Requirements, Review, and Approval

We received the completed application from RadSite™ to be considered as a designated accreditation organization for advanced diagnostic imaging services on January 18, 2011. An internal professional panel reviewed and compared the standards contained in the application with our requirements in 42 CFR 414.68. Accordingly, to be considered for approval as a designated accreditation organization, the accreditation organization had to furnish the following information specified in 42 CFR 414.68(c):

- A list of the categories of advanced diagnostic imaging services for which the organization is requesting approval.
- A description of the accrediting organization’s duration of accreditation (annual, biannual, and triennial), to include a summary of activities that occur at each cycle.
- A detailed description of how the organization’s accreditation criteria

satisfy the statutory standards at section 1834(e)(3) of the Act, including the following:

++ Qualifications of medical personnel who are not physicians and who furnish the TC of advanced diagnostic imaging services.

++ Qualifications and responsibilities of medical directors and supervising physicians, such as training in advanced diagnostic imaging services in a residency program, expertise obtained through experience or continuing medical education courses.

++ Procedures to ensure the safety of persons who furnish the TC of advanced diagnostic imaging services and individuals to whom such services are furnished.

++ Procedures to ensure the reliability, clarity, and accuracy of the technical quality of diagnostic images produced by the supplier.

++ Procedures to assist the beneficiary in obtaining the beneficiary’s imaging records on request.

++ Procedures to notify CMS of any changes to the modalities subsequent to the organization’s accreditation decision.

- An agreement to conform accreditation requirements to any changes in Medicare statutory requirements authorized by 1834(e) of the Act.

- An agreement to maintain or adopt standards that are equal to, or more stringent than, those of Medicare.

- Information that demonstrates the accreditation organization’s knowledge and experience in the advanced diagnostic imaging arena.

- A plan for reducing the burden and cost of accreditation to small and rural suppliers that include—

++ The organization’s proposed fees for accreditation for each modality in which the organization intends to offer accreditation; and

++ Any specific documentation requirements and attestations requested by CMS as a condition of designation.

- A detailed description of the organization’s survey process, to include the following:

++ Type and frequency of the surveys performed.

++ The ability of the organization to conduct timely reviews of accreditation applications.

++ Description of the organization’s audit procedures, including random site visits; site audits or other strategies for ensuring suppliers accredited by the organization maintain compliance throughout the period of accreditation.

++ Procedures for performing unannounced site surveys.