

Operations, Office of the Chief Financial Officer, General Services Administration, 1800 F Street, NW., Washington DC, 20405.

NOTIFICATION PROCEDURE:

Employees may obtain information about whether they are a part of this system of records from the system manager at the above address.

RECORD ACCESS PROCEDURES:

Requests from individuals for access to their records should be addressed to the system manager.

CONTESTING RECORD PROCEDURES:

GSA rules for access to systems of records, contesting the contents of systems of records, and appealing initial determinations are published at 41 CFR Part 105—64.

RECORD SOURCE CATEGORIES:

The sources are individuals, other employees, supervisors, other agencies, management officials, and non-Federal sources such as private firms.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; Health Information Technology Extension Program

ACTION: Notice and request for comments.

SUMMARY: This notice announces the draft description of the program for establishing regional centers to assist providers seeking to adopt and become meaningful users of health information technology, as required under Section 3012(c) of the Public Health Service Act, as added by the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5) (ARRA).

DATES: All comments on the draft Plan should be received no later than 5 p.m. on June 11, 2009.

ADDRESSES: Electronic responses are preferred and should be addressed to HealthIT-comments@hhs.gov. Written comments may also be submitted and should be addressed to the Office of the National Coordinator for Health Information Technology, 200 Independence Ave, SW., Suite 729D, Washington, DC 20201, Attention: Health IT Extension Program Comments.

FOR FURTHER INFORMATION CONTACT: The Office of the National Coordinator for

Health, Information Technology, 200 Independence Ave, SW., Suite 729D, Washington, DC 20201, Phone 202–690–7151, E-mail: onc.request@hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5) (ARRA) includes provisions to promote the adoption of interoperable health information technology to promote meaningful use of health information technology to improve the quality and value of American health care. These provisions are set forth in Title XIII of Division A and Title IV of Division B, which may together be cited as the “Health Information Technology for Economic and Clinical Health Act” or the “HITECH Act”.

The ARRA appropriates a total of \$2 billion in discretionary funding, in addition to incentive payments under the Medicare and Medicaid programs for providers’ adoption and meaningful use of certified electronic health record technology.

Providers that seek to adopt and effectively use health information technology (health IT) face a complex variety of tasks. Those tasks include assessing needs, selecting and negotiating with a system vendor or reseller, and implementing workflow changes to improve clinical performance and, ultimately, outcomes. Past experiences have shown that without robust technical assistance, many EHRs that are purchased are never installed or are not used by some providers.

Section 3012 of the Public Health Service Act (PHSA), as added by the HITECH Act, authorizes a Health Information Technology Extension Program to make assistance available to all providers, but with priority given to assisting specific types of providers. By statute, the health information technology extension program (or “Extension Program”) consists of a National Health Information Technology Research Center (HITRC) and Regional Extension Centers (or “regional centers”).

The major focus for the Centers’ work with most of the providers that they serve will be to help to select and successfully implement certified electronic health records (EHRs). While those providers that have already implemented a basic EHR may not require implementation assistance, they may require other technical assistance to achieve “meaningful user” status. All regional centers will assist adopters to effectively meet or exceed the requirements to be determined a

“meaningful user” for purposes of earning the incentives authorized under Title IV of Division B. Lessons learned in the support of providers, both before and after their initial implementation of the EHR, will be shared among the regional centers and made publicly available.

The HITECH Act prioritizes access to health information technology for uninsured, underinsured, historically underserved and other special-needs populations, and use of that technology to achieve reduction in health disparities. The Extension Program will include provisions in both the HITRC and regional centers awards to assure that the program addresses the unique needs of providers serving American Indian and Alaska Native, non-English-speaking and other historically underserved populations, as well as those that serve patients with maternal, child, long-term care, and behavioral health needs.

II. Detailed Explanation and Goals of the Program

The HITECH Act directs the Secretary of Health and Human Services, through the Office of the National Coordinator for Health Information Technology (ONC), to establish Health Information Technology Regional Extension Centers to provide technical assistance and disseminate best practices and other information learned from the Center to support and accelerate efforts to adopt, implement and effectively utilize health information technology. In developing and implementing this and other programs pursuant to the HITECH Act, ONC is consulting with other Federal agencies with demonstrated experience and expertise in information technology services, such as the National Institute of Standards and Technology.

We propose that the goals of the regional center program should be to:

- Encourage adoption of electronic health records by clinicians and hospitals;
- Assist clinicians and hospitals to become meaningful users of electronic health records; and
- Increase the probability that adopters of electronic health record systems will become meaningful users of the technology.

The HITECH Act states that “the objective of the regional centers is to enhance and promote the adoption of health information technology through—

(A) Assistance with the implementation, effective use, upgrading, and ongoing maintenance of health information technology,

including electronic health records, to healthcare providers nationwide;

(B) broad participation of individuals from industry, universities, and State governments;

(C) active dissemination of best practices and research on the implementation, effective use, upgrading, and ongoing maintenance of health information technology, including electronic health records, to health care providers in order to improve the quality of healthcare and protect the privacy and security of health information;

(D) participation, to the extent practicable, in health information exchanges;

(E) utilization, when appropriate, of the expertise and capability that exists in Federal agencies other than the Department; and

(F) integration of health information technology, including electronic health records, into the initial and ongoing training of health professionals and others in the healthcare industry that would be instrumental to improving the quality of healthcare through the smooth and accurate electronic use and exchange of health information.”

To achieve the centers’ statutory objectives, we propose to establish regional centers to offer to all providers in a designated region access to information and to some level of assistance. The regional centers will become, upon award, members of a consortium that will be coordinated and facilitated by the Health Information Technology Research Center (HITRC) that the Secretary is directed to establish by Section 3012(b) of the PHSA as added by the HITECH Act. Whereas research and analysis of best practices regarding health IT utilization rests primarily with the HITRC, dissemination and implementation of those best practices learned from the HITRC will rest with the regional centers.

Per Section 3012(c)(4) of the PHSA as added by the HITECH Act, each regional center shall “aim to provide assistance and education to all providers in a region but shall prioritize any direct assistance first to the following:

- Public or not-for-profit hospitals or critical-access hospitals.
- Federally qualified health centers (as defined in section 1861(aa)(4) of the Social Security Act).
- Entities that are located in rural and other areas that serve uninsured, underinsured, and medically underserved individuals (regardless of whether such area is urban or rural).

- Individual or small group practices (or a consortium thereof) that are primarily focused on primary care.”

Regional centers will therefore, as a core purpose of their establishment, furnish direct, individualized, and (as needed) on-site assistance to individual providers. This intensive assistance is, per statute, to be prioritized to providers identified in the statute. We expect that on-site assistance will be a key service offered by the regional centers to providers prioritized by the statute for direct assistance, and will represent a significant portion of the regional centers’ activities.

Because of the nationwide scope of the Medicare and Medicaid payment incentives for adoption and meaningful use of certified EHRs, the Extension Program should provide at least a minimal level of technical assistance across the nation. We propose that the minimal level of support must include the provision of unbiased information on mechanisms to exchange health information in compliance with applicable statutory and regulatory requirements, and information to support the effective integration of health information exchange activities into practice workflow.

It is expected that each regional center will provide technical assistance within a defined geographic area, and that each defined geographic area will be served by only one center. At a minimum, the support should consist of materials designed to be widely and rapidly disseminated, both for provider self-study and for use by entities other than regional centers that have an interest and the ability to provide some assistance and information to providers adopting health IT.

As required by Section 3012(c)(8) of the Public Health Service Act as added by the HITECH Act, all regional centers will be evaluated to ensure they are meeting the needs of the health providers in their geographic area in a manner consistent with specified statutory objectives. All lessons learned from these efforts will be exchanged across regional centers, and with other stakeholders, including but not limited to other federal programs, to promote the availability of highly effective support to providers across the nation. All regional centers will be expected to use the lessons learned as important, but not the only, information to guide their internal self-evaluation and ongoing improvement processes.

A. Criteria for Determining Qualified Applicants

Section 3012(c)(2) of the PHSA as added by the HITECH Act requires that:

“Regional centers shall be affiliated with any United States-based nonprofit organization, or group thereof, that applies and is awarded financial assistance under this section. Individual awards shall be decided on the basis of merit.” In addition, we propose the following requirements and preference criteria.

Required Criteria may include:

- Define the geographic region and the provider population within that region it proposes to serve.
- Describe proposed levels and approaches of support for prioritized and other providers to be served.
- Address how the applicant would structure its organization and staffing to enable providers served to have ready access to reasonably local health IT “extension agents” and provide training and on-going support for these critical workers.
- Demonstrate the capacity to facilitate and support cooperation among local providers, health systems, communities, and health information exchanges.
- Demonstrate that the applicant is able to meet the needs of providers prioritized for direct assistance by Section 3012(c)(4) of the PHSA as added by the HITECH Act.
- Propose an efficient and feasible strategy to furnish deep specialized expertise (in such areas as organizational development, legal issues, privacy and security, economic and financing issues, and evaluation) broadly to all providers served and intensive, individualized, “local” presence from an interdisciplinary extension agent to smaller groups of providers assigned to individual agents.

Preference Criteria may include:

- We propose to give preference to proposed regional center organizational plans and implementation strategies incorporating multi-stakeholder collaborations that leverage local resources. The local stakeholders and resources that applicants may wish to consider including in some combination, though not limited to, the following: Public and/or private universities with health professions, informatics, and allied health programs; state or regional medical/professional societies and other provider organizations; federally recognized state primary care associations; state or regional hospital organizations; large health centers and networks of rural and/or community health centers; other relevant health professional organizations; the regionally relevant state Area Health Education Center(s); health information exchange organizations serving providers in the

region; the Medicare Quality Improvement Organization(s)(QIO(s) serving providers that the proposed regional center aims to serve; state and tribal government entities in the center's geographic service area including, but not limited to, public health agencies; libraries and information centers with health professional and community outreach programs; and consumer/patient organizations.

- As noted below, we propose to give preference to applicants identifying viable sources of matching funds. Viable sources could include grants from states, non-profit foundations, and payment for services from providers able to make such payment. For example, Medicaid providers could choose to contract with a regional center in lieu of a corporate vendor for implementation and meaningful use support services, for which costs are reimbursable under Section 1903 of the Social Security Act, as amended by the HITECH Act. A regional center could also, theoretically, seek to establish itself as a first-choice source of assistance that would realize net retained earnings on service to non-prioritized providers and use those retained earnings as a source of matching funds for its grant-funded activities.

B. Maximum Support Levels Expected To Be Available to Centers Under the Program

Given current national economic conditions, we propose to exercise the option in the HITECH Act to not require matching funds for awards made in FY 2010. We will encourage use of matching funds and the coordination of existing resources to strengthen proposals for regional centers and potentially expand the number of providers that can be assisted. Review criteria may be established that give preference to proposals including matching funds but that do not automatically preclude otherwise technically meritorious proposals that do not include matching funds.

We propose using ARRA funding for two-year awards made in FY2010 and furnishing providers in awardees' areas with robust support. While we expect the actual ARRA funding awarded per center will vary based on the number and types of providers proposed to be served, and the amount of matching funds proposed by each regional center, we anticipate an average award value on the order of \$1 million to \$2 million per center. The maximum award value we anticipate making available to any one regional center is \$10 million. Funding may also be approximately allocated to

the regional centers in relative proportion to the numbers of prioritized direct assistance recipients identified in the HITECH Act.

C. Procedures To Be Followed by the Applicants

Timelines

This notice makes public and invites comments on the draft description of the regional centers program and is not a solicitation of proposals to serve as extension centers under this program. The Federal Government will award funding for the regional centers through a solicitation of proposals, after considering the comments obtained through this notice. The availability of this solicitation will be broadly announced through appropriate and familiar means, including publication in the **Federal Register** of a Notice of the solicitation's availability. This announcement of the solicitation will provide further details on the finalized requirements and application process for regional centers, pursuant to and in compliance with all applicable statutes and regulations, including but not limited to the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Applicants well prepared to provide robust extension services will likely need at least two months to provide high quality proposals. It is expected, however, that other potential applicants will need more time to prepare proposals.

We propose to make initial awards for regional centers as early as the first quarter of FY2010 and continuing through the fourth quarter of FY2010. Multiple, closely spaced proposal submission dates will be established to allow each geographic area to begin receiving benefit of a regional center as soon as possible. We believe this approach is necessary to allow areas with well prepared applicants to begin work sooner, without excluding from consideration those areas where the best applicants require more time to convene a multi-stakeholder collaboration to develop a robust proposal that includes a viable organizational plan and implementation strategy. We solicit comment on our phased approach to proposal submission dates and issuance of awards.

The target timeframe for awards is intended to enable regional centers to begin supporting provider adoption in time for providers to receive incentive payments with respect to Fiscal Year (hospitals) or Calendar Year (physicians) 2011 and 2012, when potential Medicare incentives are greatest.

D. Comments on Draft Description

ONC requests comments on this draft description of the regional centers within the Extension Program. Please send comments to the address, for receipt by the due date, specified at the beginning of this notice.

Dated: May 22, 2009.

Charles P. Friedman,

Deputy National Coordinator for Health Information Technology.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-0923-09BR]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an e-mail to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden 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 on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Registration of individuals with Amyotrophic Lateral Sclerosis (ALS) in the National ALS Registry—New—Agency for Toxic Substances and Disease Registry (ATSDR), Coordinating