

3104. Comments regarding this proposed action will be accepted until September 23, 2009.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

[FR Doc. E9-20288 Filed 8-21-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information Relevant to the Regionalization of Emergency Medical Care Delivery Systems and Demonstration Model Development

AGENCY: Department of Health and Human Services, Office of the Secretary.

ACTION: Notice.

SUMMARY: This is a time-sensitive Request for Information (RFI) issued by the Emergency Care Coordination Center in the Office of the Assistant Secretary for Preparedness and Response on behalf of the Council on Emergency Medical Care (CEMC) and the Federal Interagency Committee on Emergency Medical Services (FICEMS)—collectively known as the Emergency Care Enterprise (ECE). The information requested is meant to ascertain key concepts, best practices, and operational approaches to support regionalized, comprehensive and accountable emergency care and trauma systems. The information will be analyzed by the ECCC to help guide the development of demonstration programs that design and evaluate innovative models of regionalized, coordinated and accountable emergency care and trauma systems.

ADDRESSES: Responses to this RFI may be submitted electronically to eccc@hhs.gov by COB September 30th 2009.

FOR FURTHER INFORMATION CONTACT: For further information on this RFI or the Emergency Care Coordination Center (ECCC), please contact Melicia Seay, Program Analyst, by e-mail at melicia.seay@hhs.gov or by phone at 202-260-1383.

SUPPLEMENTARY INFORMATION: The Emergency Care Coordination Center (ECCC) was created in order to: (1) Lead an enterprise to promote and fund research in emergency medicine and trauma health care, (2) promote regional partnerships and more effective emergency medical systems in order to enhance appropriate triage, distribution, and care of routine community patients, and (3) promote local, regional, and State emergency medical systems' preparedness for and response to public

health events. The office addresses the full spectrum of issues that have impact on care in hospital emergency departments, encompassing the complete continuum of patient care from the pre-hospital environment to disposition from emergency or trauma care. The Office coordinates with existing executive departments and agencies that perform functions relating to emergency medical systems in order to ensure unified strategy, policy, and implementation.

The issue of regionalization is one of great interest across academic and clinical communities and is frequently touted as a potential solution to healthcare reform. The Future of Emergency Care reports published by the Institute of Medicine in 2006 recommended the establishment of a demonstration program to promote coordinated, regionalized, and accountable emergency care delivery systems. As demonstrated by existing systems for trauma, cardiac arrest, and stroke patients, regionalized emergency care systems help get the right patients to the right hospitals in the right amount of time, improve patient outcomes, and reduce costs. These systems typically require careful coordination amongst 9-1-1 dispatch, pre-hospital emergency medical services, EMS system medical direction, categorization/designation of medical facilities, interfacility transfer protocols, data collection/analysis, and ongoing system-wide quality improvement.

Yet regionalization of emergency care remains poorly defined and often misunderstood, with competing definitions, a variety of organizational and financial structures, and a lack of understanding regarding the implementation, evaluation, feasibility, and long term consequences of regional emergency care. Even amongst the State Trauma Systems, for instance, there is wide-scale variability in terms of resourcing mechanisms, support levels, functionality, and systems-wide interoperability. While some states have data mechanisms in place to monitor emergency care system status including medical facility bed availability and patient tracking, these systems vary in terms of management, sophistication and purpose, often collecting and reporting different data without uniform data definitions or agreement on which data should be collected.

The ECCC, in coordination with the CEMC and FICEMS, aims to demonstrate model systems for Emergency Care through the development of regionalization demonstration projects that will provide information and lessons learned while

generating guidance for the nationwide deployment of regionalized and accountable emergency care delivery systems.

Issues on Which Information Is Requested

The ECCC seeks input regarding regionalization of emergency care, with a focus on identification of the challenges and opportunities that could be addressed through federally funded national demonstration projects. The scope of emergency care being considered is defined as beginning with an event, disease, or condition that causes an individual to seek care through EMS or in an ED setting and ending with departure from the ED (either by admission to another hospital department, through discharge from the ED, or via transfer to another hospital).

We welcome your comments, research findings, and/or practical experience on the following topics that can be used both to enhance our knowledge of regional emergency care networks and to help formulate guidance and strategies for potential Federal programs to develop regional emergency care systems. Please provide concise responses in the context of regionalization to any or all of the following topics.

A. Existing Models. Please describe existing trauma or EMS regions in terms of characteristics such as: overall structure and organization, boundaries and geography, governance or oversight mechanisms and authorities, triage-transfer protocols, sustained financial support and provider reimbursement, data collection procedures, resource tracking, and communication/coordination of relationships amongst State leadership, 9-1-1 services and/or EMS system medical direction, individual regions, etc. If desired, include opinions regarding the overall functioning and effectiveness of existing systems.

B. Analysis of Current Practices in Regionalized Clinical Care. Whether at the local, State, or inter-State level, please provide suggestions and justifications as to which existing systems or specific elements of regionalized care models specifically merit further investigation, development, or targeted alteration and which clinical conditions are most suitable to regionalized care delivery. Please provide specific evidence where available and applicable.

C. Communications Infrastructure. Please provide information on appropriate data elements that should be incorporated within regionalization systems to provide for situational

awareness on resource availability. List the measurable variables and data elements that you believe need to be defined and captured in order to effectively support regional delivery of care. Also include any suggestions as to which common data elements, at a minimum, should be included within a standardized data language to facilitate, encourage, and improve the support and integration of the various state resource tracking mechanisms.

D. Opportunities and challenges in regionalized care delivery. Please share your opinions on the potential benefits, obstacles, drawbacks, and consequences (both intended and unintended) of regionalized healthcare models, providing specific evidence where feasible. If possible, elaborate on the effects regionalization may produce on providers' financial viability, patient access to care, healthcare service utilization rates, disaster preparedness efforts, and response capabilities.

E. Evaluation of regionalized care delivery systems. Please provide comments on how regionalized care systems can be objectively assessed and evaluated, including suggestions on appropriate measures of programmatic success or failure and opinions on which data sources could be used to establish compliance with regional performance benchmarks. Where possible, also list measurable ways to assess regionalization's impact with regard to health outcomes, including factors such as morbidity and mortality, time-to-care, condition-specific treatment, quality of care, patient safety, etc.

F. Adaptation of regionalization to emergency medical care. Given the legal requirement to screen and stabilize ED patients, the need for time-sensitive, high-quality care in emergency settings, and the diversity of patient populations and geographic locations, please provide insights or commentary on how the concept of regionalization could be adapted and/or customized to fit the unique aspects of emergency medical care.

G. Additional information. Please provide any additional opinions, suggestions, or comments as to how the ECCC and the Emergency Care Enterprise can shape demonstration projects of regionalized, coordinated, and accountable systems of emergency care to effectively utilize limited resources, facilitate information management and flow, increase the efficiency and effectiveness of the emergency healthcare delivery system, and enhance the overall quality of care provided.

Please indicate which type of institution or organization you are primarily affiliated with (using the following categories):

- Academia;
- Small Business;
- Healthcare Facility;
- Trauma or EMSS region;
- Federal Government;
- State Government;
- Healthcare Professional;
- Patient Advocacy Group;
- Other (briefly define).

This request for information is for planning purposes only and shall not be interpreted as a solicitation for applications or as an obligation on the part of the government. The government will not pay for the preparation of any information submitted or for the government's use of that information.

Dated: August 14, 2009.

Nicole Lurie,

Assistant Secretary for Preparedness and Response, Rear Admiral, U.S. Public Health Service.

[FR Doc. E9-20162 Filed 8-21-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0360]

Agency Information Collection Activities; Proposed Collection; Comment Request; FDA Public Health Notification Readership Survey (formerly known as "Safety Alert/Public Health Advisory Readership Survey")

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA Public Health Notification Readership Survey.

DATES: Submit written or electronic comments on the collection of information by October 23, 2009.

ADDRESSES: Submit electronic comments on the collection of

information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3793.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

FDA Public Health Notification Readership Survey (formerly known as Safety Alert/Public Health Advisory Readership Survey) (PHS Act, Section 1701 (a)(4)); OMB Control Number 0910-0341-Extension

Section 705(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21