

COST OF REGISTRATION—Continued

Affiliation	Fee
Non-Government (SoCRA Member)	\$575.00
Non-Government (Non SoCRA Member)	\$650.00

If you need special accommodations due to a disability, please contact Marie Falcone (see *Contact*) at least 7 days in advance of the workshop.

Registration Instructions: To register, please submit a registration form with your name, affiliation, mailing address, telephone, fax number, and e-mail address, along with a check or money order payable to "Socra." Mail to: SoCRA, 530 West Butler Ave., suite 109, Chalfont, PA 18914. To register via the Internet, go to http://www.socra.org/html/FDA_Conference.htm. FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**). The registrar will also accept payment by major credit cards (VISA/MasterCard/AMEX only). For more information on the public workshop, or for questions on registration, contact the Society of Clinical Research Associates at 800-762-7292 or 215-822-8644, FAX: 215-822-8633, or e-mail: SoCRAmail@aol.com.

SUPPLEMENTARY INFORMATION: The public workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The workshop will provide those engaged in FDA-regulated (human) clinical trials with information on a number of topics concerning FDA requirements related to informed consent, clinical investigation requirements, institutional review board (IRB) inspections, electronic record requirements, and investigator initiated research. Topics for discussion include the following:

- What FDA Expects in a Pharmaceutical Clinical Trial;
- Adverse Event Reporting—Science, Regulation, Error, and Safety;
- Part 11 Compliance—Electronic Signatures;
- Informed Consent Regulations;
- IRB Regulations and FDA Inspections;
- Keeping Informed and Working Together;
- FDA Conduct of Clinical Investigator Inspections;
- Meetings With FDA: Why, When, and How;
- Investigator Initiated Research;

- Medical Device Aspects of Clinical Research;
- Working With FDA's Center for Biologics Evaluation and Research; and
- The Inspection is Over—What Happens Next? Possible FDA Compliance Actions.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The public workshop helps to achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (21 U.S.C. 393) which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The public workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121), as outreach activities by Government agencies to small businesses.

Dated: August 18, 2009.

David Horowitz,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Public Health Informatics (BSC, NCPHI)

Correction: The notice was published in the **Federal Register** on August 18, 2009 [Volume 74, Number 158] [page 41712]. The "Matters To Be Discussed" has been revised: The board will discuss public health informatics issues related to the H1N1 virus; CDC public health informatics strategies and goals, including future program activities; and how the board can provide informatics scientific input to CDC.

Contact Person for More Information: Dr. Scott McNabb, National Center for Public Health Informatics, CDC, 1600 Clifton Road, NE., Mailstop E-78, Atlanta, Georgia 30333, Telephone (404) 498-6427, Fax (404) 498

Dated: August 12, 2009.

Richard Nahin,

Senior Advisor for Scientific Coordination and Outreach, National Center for Complementary and Alternative Medicine, National Institutes of Health.

[FR Doc. E9-20309 Filed 8-25-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Office of Health Information Technology, Office for the Advancement of Telehealth

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice of non-competitive supplemental funding to Center for Telehealth & E-Health Law.

SUMMARY: The Health Resources and Services Administration (HRSA) is issuing non-competitive supplemental funding under the Office of Health Information Technology, Office for the Advancement of Telehealth, Telehealth Resource Center Grant Program to ensure that the Center for Telehealth & E-Health Law, the National Telehealth Resource Center (NTRC) in Washington, DC, can continue to provide much needed technical assistance services to the Regional Telehealth Resource Centers (RTRCs), HRSA grantees and new and existing telehealth organizations in order to address legal and regulatory barriers to the effective implementation of telehealth technologies at the State and national level.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: Center for Telehealth & E-Health Law.

Amount of the Non-Competitive Supplemental Funding: \$225,000.

Project Period: The original project period for this grant is September 1, 2008, through August 31, 2009.

Period of Supplemental Support: September 1, 2009, through August 31, 2010.

Authority: This activity is under the authority of the Health Care Safety Net Amendments of 2002, section 330I(d)(2) of the Public Health Service Act as amended.

Catalogue of Federal Domestic Assistance Number: 93.211.

Background

The purpose of the National Telehealth Resource Center is to support the RTRCs and other relevant

organizations by providing technical assistance to address the policy, legislative, and regulatory barriers that affect telehealth services at the national and State levels, to give guidance to new programs in the development and implementation of an effective sustainable telehealth program and serve as a resource for existing programs regarding changes in technology or other issues affecting telehealth in a State or region. The necessary requirements to serve as a NTRC involve the organization's ability to recognize critical policy, legislative, and regulatory barriers to the deployment of effective telehealth technologies. The NTRC should have a means to facilitate the transfer of knowledge between telehealth programs and others in the field. Additional requirements are the establishment of an effective plan to meet the demands for technical assistance, conduct on-going analysis of the market for its services and track evolving trends in the market. The NTRC has to address the following areas in relation to telemedicine and the exchange of health information across institutions: State and Federal regulations regarding privacy, security, reimbursement, licensure, Internet practice, telecommunications, technology safety, etc.

Justification for Non-Competitive Supplemental Funding

The Telehealth Resource Center Grant Program competition yielded 17 applicants requesting to serve as a Regional Telehealth Resource Center. HRSA received no applications for the National Telehealth Resource Center (NTRC). Since no organization applied to serve in the capacity as a NTRC, it is urgent that the Center for Telehealth & E-Health Law (CTeL) continue to provide its services until next year without disruption when HRSA can conduct a new competition for the provision of these services.

CTeL has served as the National Telehealth Resource Center since September 2006. Continued funding from HRSA will allow CTeL to continue convening telehealth leaders from around the nation to discuss key legal and regulatory issues facing the telehealth industry. CTeL will continue to monitor and analyze State and national legislation, such as reimbursement, licensure, privacy, security and confidentiality, Food and Drug