

**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](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](mailto: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.*

[FR Doc. E9-20340 Filed 8-25-09; 8:45 am]

**BILLING CODE 4160-01-S**

Dated: August 18, 2009.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. E9-20575 Filed 8-25-09; 8:45 am]

**BILLING CODE 4163-18-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **National Center for Complementary and Alternative Medicine**

#### **Announcement of Wellness Workshop**

**ACTION:** Notice.

**SUMMARY:** The National Center for Complementary and Alternative Medicine (NCCAM) invites the research community to participate in a workshop focused on wellness.

The purpose of this workshop is to review several measures of wellness, identify their strengths and weaknesses, and make recommendations on how best to capture the construct. This information will help NCCAM guide development of questions for the 2012 National Health Interview Survey.

The Workshop will take place on September 25, 2009. Those interested in CAM research are particularly encouraged to attend.

**Background:** The National Center for Complementary and Alternative Medicine (NCCAM) was established in 1999 with the mission of exploring complementary and alternative healing practices in the context of rigorous science, training CAM researchers, and disseminating authoritative information to the public and professionals. NCCAM funds research grants that explore the science of CAM. For more information, see <http://nccam.nih.gov/grants/whatnccamfunds/>.

**Participating:** The public is invited to attend and observe this workshop. Those interested in attending are required to RSVP via e-mail to Edward Culhane Jr. at [culhane@mail.nih.gov](mailto:culhane@mail.nih.gov) with their name, affiliation, e-mail and phone number. Space constraints limit the number of attendees at this workshop and participation will be on a first come, first served basis. For more information about what will be covered at the workshop, see <http://nccam.nih.gov/news/events/>.

**FOR FURTHER INFORMATION CONTACT:** To request more information, visit the NCCAM Web site at <http://nccam.nih.gov/news/events/>, call 301-594-3391 (Edward Culhane Jr.) or e-mail at [culhane@mail.nih.gov](mailto:culhane@mail.nih.gov).

## **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) 498-6235.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the CDC and the Agency for Toxic Substance and Disease Registry.

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]

BILLING CODE 4140-01-M

## 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 Administration regulation, private credentialing and accreditation issues as well as telecommunications issues, changes in technology or any other barriers that affect the delivery of telehealth services. During the extension

CTeL will continue assessing clients' needs to develop technical assistance products as well as a means for marketing these products, maintaining its Web site, providing technical assistance to new and existing telehealth organizations, implementing special projects that involve collaboration among the RTRCs, conducting quarterly roundtables with the RTRC's, planning and inviting the RTRCs to participate in the biannual collaboration meetings. CTeL will also ensure that the RTRC's are adequately represented at all telehealth conferences and events. CTeL will share its expertise in legal and regulatory issues at conferences, work shops and roundtables, including the OAT Annual Telehealth Workshop.

HRSA will hold another full and open competition for the National Telehealth Resource Center in 2010.

#### FOR FURTHER INFORMATION CONTACT:

Dena S. Puskin, Sc.D., Director, or Monica Cowan, Public Health Analyst, Office for the Advancement of Telehealth, Office of Health Information Technology, Health Resources and Services Administration, Room 7C-26, 5600 Fishers Lane, Rockville, MD 20857; phone 301-443-3682 (Puskin) or 301-443-0076; e-mail [dpuskin@hrsa.gov](mailto:dpuskin@hrsa.gov) or [mcowan@hrsa.gov](mailto:mcowan@hrsa.gov).

Dated: July 16, 2009.

**Mary K. Wakefield,**

*Administrator.*

[FR Doc. E9-20518 Filed 8-25-09; 8:45 am]

BILLING CODE 4165-15-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

#### Privacy Act of 1974; Report of an Altered System of Records; Sanitation Facilities Construction Individual Applicant Records; System Number 09-17-0004

**AGENCY:** Department of Health and Human Services (HHS), Indian Health Service (IHS).

**ACTION:** Notice of an Altered System of Records (SOR).

**SUMMARY:** Pursuant to the provisions of the Privacy Act of 1974, as amended, 5 U.S.C. 552a(e)(4), the IHS has amended and is publishing the proposed alteration of a SOR, System No. 09-17-0004, "Sanitation Facilities Construction Individual Applicant (SFCIA) Records." Under the provisions of the Indian Sanitation Facilities Act, Public Law 86-121 (42 U.S.C. 2004a), IHS is charged with carrying out the