

Holt Anderson

U.S. Food and Drug Administration Leveraging -- Collaborating with Stakeholders

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Background:

1. NCHICA is a unique, 501(c)(3) nonprofit organization with 150+ members representing providers, health plans, professional societies and associations, pharmaceutical research, academic medical research, contract research, technology and communications vendors and state and federal agencies.
2. NCHICA's focus is on the implementation of secure information and communications technology to improve the delivery and the efficiency of health care.
3. Currently there are projects underway that deal with the secure use of the Internet to gather, transmit and provide access to sensitive health information.
4. NCHICA has been dealing with the development and use of registries for a number of years including secure Internet access to immunization records and the electronic collection of standardized emergency department information for community assessment and best practice development.
5. NCHICA is part of a five-state consortium developing PKI policies, procedures and best practices for application in healthcare. These efforts are funded by a multi-year grant from the Robert Wood Johnson Foundation.
6. NCHICA has been a leader in the area of privacy, confidentiality and security of information for over five years.
7. The professional societies and associations that are members of NCHICA are adopting a common vision of "Paperless, person-centered health records by 2010" that includes a fundamental principle that "... prompt access to complete and accurate information will improve the quality of care through the communication of patient wishes and prevention of mishaps related to drug interactions, allergies, transmissible diseases, etc."

The Opportunity:

NCHICA proposes to undertake discussions with the FDA that will:

1. lead to a strong collaboration between the FDA and NCHICA to develop an understanding of the policies, practices, technology and implementation issues that will enable the secure monitoring and reporting of adverse events and the improvement of care consistent with NCHICA's vision and mission; and
2. undertake pilot and demonstration projects to put into practice the lessons learned in the step above; and
3. to collaborate with the FDA in the dissemination of the results and best practices arising from the projects described above.

Next Steps:

Develop a joint project plan that meets the approval of the appropriate authorities of both the FDA and the NCHICA Board of Directors.

Contact Information:

W. Holt Anderson, Executive Director
North Carolina Healthcare Information & Communications Alliance, Inc.

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NCHICA

NC Healthcare Information & Communications Alliance, Inc.

PO Box 13048, Research Triangle Park, North Carolina 27709-3048

Voice: 919.558.9258 ext. 27 E-mail: holt@nchica.org www.nchica.org