Submitted by Feb. 17, 2009

Proposed Policy:

1a. Title: **D4: THE NEED FOR UNIVERSAL EHR AND PUBLIC HEALTH INFORMATION SYSTEMS BASED ON OPEN SOURCE CODE**

1b. Keywords: Open Source Electronic Health EHR Public Linkage

1c. Overriding Concern: To improve the efficiency, safety, and quality of health care of the individual, by establishing universal electronic health records (EHR), and to improve the public health by developing a national health information (HIT) infrastructure that includes seamless communication of anonymized medical and demographic information between the point of care and public health entities, without compromising the privacy of personally identifiable health and other information or the confidentiality of the doctor-patient relationship, in keeping with the goals of Executive Order 13335 of April 27, 2004, and the American Recovery and Reinvestment Act of 2009.

2. Relationship of this Policy to Existing APHA Policies: None.

3. Problem Statement. Almost five years after Executive Order 13335,[1] health care providers in the United States continue to lag behind those of other developed countries in the adoption of the electronic health record (EHR),[2] a cornerstone of health information technology (HIT). Universal adoption of HIT will significantly improve the safety, efficiency, and quality of health care in the United States, and benefit the public health. The current Administration has re-committed to the goal of universal EHR by 2014.[3] Funding under the American Recovery and Reinvestment Act of 2009 is expected to be on the order of $20B, but it is unclear how even that amount of money is going to help us reach that goal, including the achievement of interoperability and the protection of individually identifiable information, without a fundamental shift in strategy. Cost– sometimes prohibitive– to providers, lack of meaningful interoperability among multiple proprietary systems, failure to agree on meaningful protection

of privacy, and concerns about the security of digitally stored health information, will continue to stall the adoption of universal EHR, without such a shift.

The availability of integrated open source EHR and public health data management systems, with adequate protections of patient privacy, at nominal cost to providers and appropriate public health entities is the fundamental shift in strategy that is needed. Meaningful input into the design of these information systems on the part of consumers is practically non-existent at this time, and can only be achieved by making the software code public (i.e., open source code), and the establishment of a governing consortium like that proposed in H.R. 6898, and consistent with provisions of the American Recovery and Reinvestment Act (H.1, and S.336, http://thomas.loc.gov (last access 2/10/09).[4] The stimulus package, signed by the President on 2/17/09 promises to "ensure transparency in promotion of a nationwide health information technology infrastructure," and to provide for "meaningful public input" into its development. The architecture of any proprietary EHR system, primarily in the form of source code, is known only to the company that makes and sells it. Code has a way of invisibly controlling the lives of EHR users and their patients in ways they don't always understand, or even know about,[5] all the more reason why software for the national HIT infrastructure should be open source and transparent.

The idea of implementing open source in the national HIT infrastructure is not new. In June of 2005, Doctor David Brailler, National Coordinator for Health Information Technology, proposed a set-aside for open source systems. This initiative was successfully opposed, ostensibly, on the contention that government should not be involved, and should let the free market decide what is best.[6]

Thus far, the free market has accomplished relatively little toward the goal of universal EHR in the past five years, much less that of interoperability. One observer notes, "Amazingly 15 years of e-Health standards have brought us no closer to *ubiquitous* sharing of even the most basic health data . . . Why? . . . We have not defined the necessary *framework* . . ."[7] The idea of introducing open source into the national HIT infrastructure re-surfaced this past September, in the form of H.R. 6898, co-sponsored by Reps. Stark (D-CA) and Camp (R-MI).[8] This proposed legislation was opposed by the Health Information Management Systems Society (HIMSS).

Protection of patient privacy and the confidentiality of physician-patient communications are essential to optimal medical care. The law makes specific exceptions where public health concerns trump the privacy concerns of individuals. The protections of patient privacy should be integral to the design of EHR systems and governed in a transparent way by those who design and maintain those systems, with meaningful input from consumer groups, and from providers who see them in the clinic or at the bedside from day to day. Government has no place in deciding the limits of patient privacy beyond the needs of the public health. At the time of this writing, Congress is needlessly bogged down in a debate about the limits of patient privacy, when it really ought to be concentrating on the current global financial crisis and the threat of depression.[9] Even though HIMSS opposed H.R. 6898, it earlier released a white paper, *Evaluating Open Source Software for Health Information Exchange* (www.himss.org/content/files/HIE_FY08_Open_Source.pdf p. 9), that contains the statement,

> A recent study demonstrated that a substantial number of projects in the U.S. Department of Defense and in the Intelligence communities have been implemented using open source software and that security considerations were critical in making the choice. *If anything, use of open source software enhances*

security [italics added].[10]

Open source cannot compete in the market without significant capital behind it. That is where the government comes in. In fact, the Veterans Administration EHR, VistA, is an open source EHR that is one of the most widely used EHR systems today, and could be adapted for use by non-governmental providers.[10] With $20B to invest in a national HIT infrastructure, our government would be well advised to embrace open source software. In doing so, it would be much better positioned to achieve the goal of universal EHR by 2014, and more likely than not at a cost well below $20B.

"The government ought to mandate open source products based on open source reference implementations to improve security, get higher quality software, lower costs, higher reliability– all the benefits that come with open software."[11] Specifically as to EHR, India seems to have recognized this some time ago.[12]

3a. Scientific Issues – None (other than technical/legal issues presented herein). Evidence for the Problem: see #3. Poor adoption. Not even PACS (MRI and CT imaging software) are interoperable. Consumers, consumer advocates, and providers continue to have concerns about the limits of patient privacy and the security of digitally stored health information.

3b. Political/Resource Issues May involve testimony before Congress.

3c. Ethical Issues Protection of individually indentifiable information.

3d. Opposing Arguments/Evidence The major arguments used to bolster opposition to the use of open source code, will undoubtedly be that it will remove incentives for innovation. Other, compelling but somewhat arcane, arguments are set forth in the attached letter, which should be self-explanatory.[14]

Ultimately what the APHA should weigh, is not whether governmental adoption of open source HIT should create a level playing field for software companies, but whether the policy herein proposed will achieve the goal of universal adoption of HIT by 2014 at a reasonable cost. An important consideration is the cost to providers of such a system. It doesn't make sense to just give $20B to providers to purchase EHR systems that they wouldn't ordinarily purchase. If we do that, we will not be much closer to universal EHR in 2014 than we are now.

4. Proposed Recommendations Statement. The American Public Health Association supports law and public policy consistent with the Department of Health and Human Services making available (1) an open source EHR application to qualified providers at nominal cost; (2) an open source public health data management application to public health entities designated by the Secretary; and (3) open source health information technology that provides for seamless data exchange between health care providers and designated public health agencies by way of these applications, provided that such technology have intrinsic systems for the protection of individually identifiable information, acceptable to consumers except as required by law.

Further, the American Pubic Health Association supports law and public policy that will establish a public-private entity to govern the development of such open source software, which entity will have meaningful representation of consumers, providers, public health entities,

technical experts, legal experts, and other groups as designated by the Secretary, such as payers, employers, and research institutions.

Further, the American Public Health Association supports law and public policy that requires the above-described public-private entity to establish open standards and specifications that, as much as possible, permit proprietary EHR systems to exchange data with the above-mentioned open source EHR and public health data management applications, and with each other, so as to facilitate innovation, yet maintain the utility of legacy EHR systems.

Further, that all open source applications as mentioned herein be, as much as possible, platform-independent, i.e. capable of adaptation and updating in different operating environments or systems.

4a. Alternative Strategies None.

5. Action Steps Publish and transmit a report of this Policy Statement to the President of the United States, and to the Secretary of Health and Human Services, along with a statement urging the adoption of the policies outlined herein.

6. References See endnotes.

Section C. Implementation Suggestions (*Optional*) See #5

References

Submitted by Feb. 17, 2009

1. Executive Order No. 13335, Incentives for the Use of Health Information Technology and Establishing the Position of the National Health Information Technology Coordinator, April 27, 2004, www.archives.gov/federal-register/executive-orders/2004.html (last access 2/5/09), 69 FR 24059, May 5, 2004.
2. DesRoches C, Campbell E, et al, Electronic Health Records in Ambulatory Care— A National Survey of Physicians, NEJM 2008;**359**:50-60 http://content.nejm.org/cgi/content/full/NEJMsa0802005 (last access 1/24/09).
3. American Recovery and Reinvestment Act of 2009 (H.1, H.R. 679, and S.336, at the time of this writng, http://thomas.loc.gov, last access 2/9/09).
4. See excerpts in Note 8, H.R. 6898, and the HIT Policy and HIT Standards Committees, established by the American Recovery and Reinvestment Act of 2009, Sec. 3002(c)(2) and Sec. 3003(c)(2), respectively, " . . . [that] shall at least reflect providers, ancillary healthcare workers, consumers, purchasers, health plans, technology vendors, researchers, relevant Federal agencies, and individuals with technical expertise on health care quality, privacy and security, and on the electronic exchange and use of health information."
5. This language paraphrases that of Professor Lessig, who might well have been talking about EHR. "Code-based regulation– especially of people who are not themselves technically expert– risks making regulation invisible. Controls are imposed for particular policy reasons, but people experience those controls as nature." *See* Lawrence Lessig, CODE, VERSION 2.0, Basic Books, New York, 2006 (p. 138).
6. Letter to David Brailler, MD, ONCHIT, 7/18/05, from Melanie Wyne, Executive Director, Initiative for Software Choice, previously available at www.softwarechoice.org, attached.
7. Thomas Beale, open EHR: An open Health Computing Platform for Europe, EFMI, 10 Sep 2008, http://www.openehr.org/downloads/presentations/EFMI_2008_openEHR.zip last access 1/25/09).
8. See HR6898 (http://www.govtrack.us/congress/bill.xpd?bill=h110-6898 also see http://thomas.loc.gov last

accessed 2/20/09) Sec. 3001, (c)(4), introduced before the 110th Congress on 9/15/08, which read:

(c)(4) FEDERAL OPEN SOURCE HEALTH IT SYSTEM.—

(A) IN GENERAL.—The National Coordinator shall provide for coordinating the development, routine updating, and provision of an open source health information technology system that is either new or based on an open source health information technology system,such as VistA, that is in existence as of the date of the enactment of this title and that in compliance with all applicable standards (for each category described in paragraph (2)(A)) that are adopted under this subtitle. The National Coordinator shall make such system publicly available for use, after appropriate pilot testing, as soon as practicable but not later than 9 months after the date of the adoption by the Secretary of the initial set of standards and guidance under section 3003(c).

(B) CONSORTIUM.—In order to carry out subparagraph (A), the National Coordinator shall establish, not later than 6 months after the date of the enactment of this section, a consortium comprised of individuals with technical, clinical, and legal expertise open source health information technology. The Secretary, through agencies with the Department, shall provide assistance to the consortium in conducting its activities under this paragraph.

(C) AUTHORIZATION TO CHARGE NOMINAL FEE.—The National Coordinator may impose a nominal fee for the adoption of a health information technology system developed or approved under subparagraph (A). Such fee shall take into account the circumstances of smaller providers and providers located in rural or other medically under

served areas.

(D) OPEN SOURCE DEFINED.—In this paragraph, the term 'open source' has the meaning given such term by the Open Source Initiative [www.opensource.org (last access 1/27/09)].

For reasons which may be obvious, the Health Information Management Systems Society voiced strong opposition to this provision, just days after it was introduced in Congress. It is a safe bet that the medical community did not oppose this provision.

9. See Ellen Nakashima, *Lobbying War Ensues over Digital Health Data,* WASHINGTON POST, February 10, 2009, www.washingtonpost.com/wp-dyn/content/article/2009/02/09/AR2009020903263_pf.html last access 2/10/09.

10. www.himss.org/content/files/HIE_FY08_Open_Source.pdf p. 9, last access 2/10/09).

11. http://worldvista.org (last access 2/10/09).

12. Scott McNealy, Sun Microsystems, news.bbc.co.uk/2/hi/technology/7841486.stm (last access 1/25/09).

13. *See* Jim Dowling and Seif Haridi, *Developing a Distributed Electronic Health-Record Store for India* http://ercim-news.ercim.org/content/view/444/656/ last access 2/7/09).

14. Note 6, above.

Submitted by:

Bruce L. Wilder MD MPH JD
APHA Member No. 9852221
Office Address:
436 Seventh Avenue, Suite 1050
Pittsburgh, PA 15219-1827
Tel 412 683-6015
bwild@interprofessional.com
APHA Affiliation: HIIT SPIG