

HR 2991 Review by NC CACHI

Background: NCHICA was requested by the Congressional office of Rep. David Price (NC 5th District) with a request to provide input on HR 2991 "Independent Health Record Trust Act of 2007." NCHICA, in turn, requested the members of the NC Consumer Advisory Council on Health Information to individually review and comment on this bill which they did during their scheduled monthly meeting on February 21st.

The following comments represent the individual comments of the members and not a consensus position of the Council or of NCHICA. Council members agreed that, if requested, they would convene as a Council and provide a consensus position at a future date but it was observed that discussions of the reviews among the members in attendance at this meeting showed a significant amount of consistency of viewpoint and opinion about the strong and weak points of the bill.

Other members of NC CACHI who commented verbally may supplement this document with their written comments at a later date.

Reviewer #1 commented as follows:

1. I would suggest that within the definition of Affirmative Consent there be examples that are compliant and not compliant to this definition so as to bring more clarity to the definition.
2. Under --- No limitation on membership --- there is no mention of impacts to membership such as subscriptions fees or participation fees. I would suggest that there be no financial obligation to participate.
3. Under --- Fiduciary Responsibility --- it states "... the IHRT shall have a fiduciary duty to act for the benefit and in the interests of such participant and of the IHRT as a whole." There may a conflict of interest in acting on behalf of both the participant and the IHRT.
4. Under --- Penalties --- in my humble opinion these penalties do not seem enough of a deterrent. Depending on the monetary possibilities ---- some organizations may be willing to pay a fine of \$50,000 and perhaps spend 5 years or less in prison.
5. There is no stipulation of enforcement of compliancy to the Act.
6. Part III under HIPAA Privacy Regulations may be quite costly. I would suggest a standard format.
7. Part iv) Notification of sensitive information. It states "... unless the user certifies that the participant has been notified of such information." "Notified" seems nebulous here. A definition of notified is not included in the Act.
8. Under "(3) RULES FOR SECONDARY USES OF RECORDS FOR RESEARCH AND OTHER PURPOSES.— (A) IN GENERAL.—With respect to the electronic health record of an IHRT participant (or specified parts of such electronic health record) maintained by an IHRT, the IHRT may sell such record (or specified parts of such record)" The possible revenue incurred from selling the record may far exceed the penalties. Additionally there seems to be no enforceable measures/ penalties of non-compliance by third party entities.
9. Under (2) TREATMENT OF STATE LAWS.— (A) IN GENERAL.—Except as provided under subparagraph (B), the provisions of a privacy protection agreement entered into between an IHRT and an IHRT participant shall preempt any provision of State law (or any State regulation) relating to the privacy and

confidentiality of individually identifiable health information or to the security of such health information." If the State Law is more strict than the Federal Law the State Law should prevail.

10. Under ---- Financing of Activities ---- the charge to participate along with the high risk of privacy and security of the data involved coupled with the selling of the data seem to be counterproductive to encouraging participation in the IHRT.
11. Under ---- "REQUIRED DISCLOSURES.—The sources and amounts of revenue derived under subsection (a) for the operations of an IHRT shall be fully disclosed to each IHRT participant of such IHRT and to the public." There seems to be no audit and control measures for disclosures.
12. There is a requirement for the "ESTABLISHMENT OF INTERAGENCY STEERING COMMITTEE" however there are no time and oversight stipulations.
13. Under ---- (e) REGULATIONS PROMULGATED BY FEDERAL TRADE COMMISSION.—The Federal Trade Commission shall promulgate regulations based on, at a minimum, the following factors: (1) Requiring that an IHRT participant, who has an electronic health record that is maintained by an IHRT, be notified of a security breach with respect to such record, and any corrective action taken on behalf of the participant." There seems to be no audit and control measures for breaches. There is no definition of "notified".
14. Under ---- COMPLIANCE REPORT -- There is a requirement to report number of violations and corresponding actions but it is unclear as to how to report these and to whom.
15. In my humble opinion the ability for great profit with minor risk of penalties for non-compliance is throughout this Bill. Therefore even though I am an avid proponent of electronic health records I would elect not to participate in an IHRT as the Bill is currently written.

Reviewer #2 commented as follows:

SEC. 4. Establishment, certification, and membership of independent health record trusts .

(a) Establishment .—Not later than one year after the date of the enactment of this Act, the Federal Trade Commission, in consultation with the National Committee on Vital and Health Statistics, shall prescribe standards for the establishment, certification, operation, and interoperability of IHRTs to carry out the purposes described in section 2 in accordance with the provisions of this Act.

Comment: the establishment of standards required to fully to enable IHRTs is a very large and complex task that will involve numerous stakeholders. The industry has been working on this for many years. I question the ability to provide this in 1 year.

(b) Certification .—

(1) Certification by FTC .—The Federal Trade Commission shall provide for the certification of IHRTs. No IHRT may be certified unless the IHRT is determined to meet the standards for certification established under subsection (a).

Comment: how does this relate to EHR certification currently provided by the Certification Commission for Healthcare Information Technology (CCHIT), does it overlap, will there be 2 certifications required for health records?

(4) establish standards for the interoperability of health information technology to ensure that information contained in such record may be shared between the trust involved, the participant, and authorized EHR data users, including for the standardized collection and transmission of individual health records (or portions of such records) to authorized EHR data users through a common interface and for the portability of such records among independent health record trusts; and

Comment: the establishment of standards required to fully to enable IHRTs is a very large and complex task that will involve numerous stakeholders. The industry has been working on this for many years. How will the FTC accomplish this?

Reviewer #3 commented as follows:

Here's my list re our discussion of HR2991 yesterday.

1. In general I applaud the idea behind this bill.
2. I agree with many of the comments #1 made and I would echo #2 comments about the purpose of the bill.
3. I would like to better understand how this bill would affect existing arrangements - WebMD, Microsoft initiative, Google,....
4. I don't understand the financial model at all. The vague references to selling of data are troublesome. One scenario I envision, and it's already happening, is targeted advertisements and alerts to both the consumer and the provider. Note this can be done without disclosing the personal information to the advertiser, and might not even be considered a disclosure.
5. I questioned the use of the FTC as the regulatory agency, though I have in general found their rule making to be much clearer than some other federal agencies.
6. Penalties for violation are inadequate and enforcement is not spelled out. I did not mention it yesterday, but the proposed law does not allow for private cause for action, and since it would trump state laws which might allow that, it could take away some consumers rights.
7. Where state privacy protection laws are stronger, they should trump this legislation.
8. Consumer interests are inadequately represented by having only one consumer representative on the advisory board.

9. I would like to see something more about the consumers' right to terminate the agreement, lock records, and even, especially in the instance of egregious breaches by an IHRT, to purge records.

10. There should be safeguards for the orderly transfer of custodial duties in the event that an IHRT ceases operation.

For comparison, some may be interested in NC's Identity Protection Act, <http://www.ncleg.net/Sessions/2005/Bills/Senate/pdf/S1048v6.pdf>, which gives consumers the right to sue for civil damages in the event of disclosure and to place a security freeze on their records.