WRITTEN COMMENTS SUBMITTED BY
KEVIN J.F. FITZGERALD, HEALTH CARE COUNSEL, GENERAL ELECTRIC COMPANY
ON BEHALF OF
THE ERISA INDUSTRY COMMITTEE
BEFORE THE
NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS
SUBCOMMITTEE ON PRIVACY AND CONFIDENTIALITY
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INTRODUCTION:

Thank you for the opportunity to submit the following written comments regarding implementation of the final HIPAA regulation on health information privacy. While it is not possible to address these issues in depth within this document, ERIC would be pleased to participate in follow-up activities to develop them in more detail.

THE ERISA INDUSTRY COMMITTEE:

The ERISA Industry Committee (ERIC) is a non-profit association committed to the advancement of employee retirement, health, and welfare benefit plans of America's largest employers. ERIC represents exclusively the employee benefits interests of major employers all of which provide comprehensive retirement, health care coverage and other economic security benefits directly to some 25 million active and retired workers and their families. The association has a strong interest in proposals affecting its members' ability to deliver those benefits, their cost and their effectiveness, as well as the role of those benefits in the American economy.

GENERAL COMMENTS:

1. *The current environment could hardly be worse: the economic slowdown and rapidly increasing health care costs have left many employers will few available resources for compliance efforts.*

2. *Widespread uncertainty among employers sponsoring group health plans regarding the regulation's requirements is further delaying investment in compliance efforts.*

3. *Of the many issues vexing employers, outlined below, the most pervasive problem is the utterly unworkable preemption rule contained in the regulation and its underlying statutory provision.*

4. *For the foreseeable future, the government should concentrate on educating covered entities about how to come into compliance, and providing ample opportunities for self-correction, rather than seeking to penalize non-compliance.*

5. *ERIC members have expressed strong interest in establishing a working group to meet with government experts on a periodic basis to discuss ongoing compliance issues.*

ERIC'S RESPONSE TO THE SPECIFIC QUESTIONS POSED BY NCVHS:

1. *What outreach, education, and technical support programs are needed from OCR [HHS Office for Civil Rights, which is responsible for enforcing the privacy regulation], including suggestions for OCR priority setting?*

There is a broad consensus among ERIC members that more guidance is needed specifically addressing employers' concerns because employers administering group health plans are responsible for ensuring their plans' compliance even though they are not themselves covered entities. To date, ERIC members who have attended various courses and seminars have found them to be of limited use because "experts" who participated in the drafting of the statute or regulation did not anticipate many of the issues employers are facing and have had few answers for the numerous tough questions being posed.

ERIC suggests that a variety of new or enhanced programs be considered, including (but not limited to) the following:

- Website specifically for employers sponsoring group health plans, with fact sheets and FAQs designed specifically for employer plan sponsors
- Prerecorded primers on employer groups health plan sponsors' obligations under the regulation
- An open line of communication, such as an informal employer plan sponsor hotline, to ensure easy access to information
- Additional town meeting-style opportunities for consultation
- Convening of a technical working group of private sector experts to meet with government representatives on a periodic basis to identify issues and assist in the formulation of guidance

2. *What areas are especially in need of guidance from OCR? What difficulties are providers and plans experiencing coming into compliance?*

There is considerable uncertainty among ERIC members with respect to the status of certain activities under the regulation, including whether such activities constitute a health plan or a health care provider. For example, employers are having particular difficulty understanding the regulation's applicability to and requirements for:

- on-site and off-site company-sponsored health clinics
- administration of flu shots
- health surveillance activities (*e.g.*, regarding toxic exposure, drug use, pre-employment physical exams)
- fitness centers

- health promotion and health risk assessment programs
- disease management programs
- employee assistance programs (EAPs)

Although the primary purpose of many of these activities is not to provide treatment, under certain circumstances they can lead to treatment or lead to the collection of information later used to provide treatment. Even those activities that do have treatment as a primary purpose generally do not engage in the types of transactions that are the subject of the regulation.

Current guidance is problematic because it is transaction-oriented, suggesting that if a particular activity could give rise to a covered transaction under certain circumstances, the entire activity must comply with the regulation to ensure that the requirements will be met if a covered transaction ever occurs. It would be inordinately expensive for employers to have to comply with the requirements of the privacy regulation for activities that do not ordinarily engage in the types of transactions subject to the regulation just because they might engage in such transactions under certain special circumstances.

Therefore, ERIC members have indicated that it would be especially helpful if guidance further clarified:

- the distinction between providing medical care and promoting good health such that activities that do not provide, or are not primarily intended to provide, medical treatment are not considered health plans and not subject to the regulation
- that the definition of health plan be limited to activities that routinely engage in covered transactions and exclude activities that only incidentally engage in such transactions under non-routine circumstances
- that the definition of excepted benefits includes all activities conducted in on-site clinics, and that the exception includes off-site clinics as well
- that disease management vendors are conducting health plan operations, not research subject to additional restrictions
- the status of flexible spending accounts
- that first report of injury be deleted from the regulation
- that health care provider who are company employees and acting in an employer-related capacity (*e.g.*, occupational health nurses) are not subject to the rule

ERIC members are also struggling with the firewall requirements contained in the regulation. One of the fundamental problems the regulation poses for employers is the fact that a group health plan is generally not a tangible entity, like an insurance company, but a contract that is carried out by company employees and third party vendors. In addition, ERISA imposes some of its legal obligations on the plan and plan fiduciaries, while other obligations are imposed on the employer sponsoring the plan.

As a result, certain activities that may superficially appear to be exclusively plan functions (*e.g.*, eligibility determinations, fulfillment of COBRA enrollment and notice requirements, the issuance of HIPAA certificates of creditable coverage, etc.) are often subject to a mixture of both employer and plan legal obligations, making the imposition of a firewall between employer and plan functions difficult

(if not impossible). Moreover, in order to reduce cost and increase efficiency, many employers provide health, disability and other welfare benefits through a single integrated benefit plan. The regulation needs to be interpreted and applied in a way that recognizes these practical and legal realities and does not require the wholesale restructuring of employer and plan functions.

Finally, ERIC members have expressed strong interest in safe harbors for "minimum necessary," for hybrid entities, and for employer advocacy on behalf of employees, as well as for adoption of a pharmacy transaction standard that parallels the identification data fields of other health claims transactions

3. *What "best practices" are being done in the industry? Are compilations of best practices available and how are successful implementation strategies being disseminated?*

ERIC members are aware of few, if any, compilations of best practices from an employer-sponsored group health plan perspective. Although there appear to be some best practice materials relating to insurance industry compliance, they do not address many of the issues faced by employers. Because most employers are still in the planning phase of their preparations, there is little or no information available about successful implementation strategies.

4. *What are the available resources for HIPAA compliance (especially no or low cost ones) including those from professional organizations and trade associations? What helpful websites are entities using? What other work has been done and is in the public domain?*

ERIC members are aware of some licensable materials, including some that include model policies and forms, but much of this material was prepared relative early and is relatively basic. For example, members mentioned the HIPAA Summit Conference and related website, the NCHICA Early View Privacy Tool, a book recently published by the American Medical Association, and a training module prepared by The Legal Knowledge Company[1] as materials they had seen or used.

5. *How are covered entities approaching the privacy rule training mandate?*

Most employer group health plan sponsors are still assessing and/or planning how they will train their trainers; they do not expect to commence general training until next year. Some are reviewing customizeable web-based training modules. Most are finding that available training materials need to be significantly customized for their specific operations. ERIC believes that the training requirement needs to be interpreted flexibly so as not to constrain the many different means by which individuals can be effectively trained.

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[1] ERIC has not reviewed any of these materials and does not endorse or otherwise express an opinion regarding their quality or accuracy.

6. *Are there any models for public (Federal, state, and local) -private partnership development? How should covered entities go about coalition building and developing consensus procedures?*

There appear to be some public-private partnership efforts among state-regulated entities, but we are unaware of any similar efforts involving employer plan sponsors. ERIC has offered its own members the opportunity to participate in a series of meetings and conference calls to review the requirements of the regulation and to exchange information among peers regarding the issues they face and possible responses. We expect to continue these periodic activities well into next year.

A number of ERIC members have expressed interest in convening and participating in an expert working group that would meet with government representatives on a period basis to identify issues and recommend solutions. ERIC would be pleased to facilitate the organization of such a group

7. *How are entities managing to do the state/Fed preemption analysis fundamental to HIPAA integration and compliance? How should we address the integration of HIPAA and other federal and state laws?*

ERIC argued in its comments on the proposed regulation that the preemption provision was untenable and urged a different approach. Experience has been as bad, if not worse, than our expectations.

Most employers lack the resources to conduct the extensive legal analysis required. Although licensable materials are available that purport to have conducted a comprehensive preemption analysis, purchase of such materials (at considerable expense) does not obviate the need for a plan sponsor to conduct its own supplemental analysis

Even plan sponsors with sufficient resources find there is so much uncertainty regarding the requirements of federal and state law that many have concluded it is impossible for them to determine, with any degree of confidence, how applicable state and Federal rules interact. Even where they are relatively confident that they can determine the requirements of both state and federal law, the lack of uniform rules prevents plan sponsors with plan participants in multiple jurisdictions from having uniform disclosure policies, notices and business associate contracts.

ERIC believes that three affirmative steps are called for to rectify this situation:

- **!** A clear and unambiguous statement that the HIPAA privacy rules do not amend, modify or in any way limit ERISA preemption of state privacy laws with respect to group health plans;
- **!** Establishment of a formal administrative preemption determination process or consensus best practice process for determining the interaction of federal and state law; and
- **!** Amendment of the underlying statutory provision to establish uniform federal privacy standards

8. *Can you assess the accuracy and quality of the information and services of vendors and consultants, especially as they pertain to small providers and health plans?*

There appears to be significant variation in approach among vendors, especially with regard to whether certain employer-sponsored activities should be treated as a provider or as a business associate under the regulation. Most vendors' understanding is general and not fact/situation-specific because they do not have direct knowledge of the operational needs of different employers.