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Medical Privacy Issues
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Good morning. Mr. Chairman, Senator Gregg, and members of the committee, my name is Sam Karp. I am the Chief Information Officer of the California HealthCare Foundation. The Foundation is an independent philanthropy, committed to improving California's health care delivery and financing systems. Thank you for the opportunity to testify today on an issue we believe is fundamental to improving the quality of health care.

Over the past five years the Foundation has supported a range of activities - from research studies, surveys, educational publications, guides, workshops and conferences - to heighten awareness and understanding of the need to establish strong safeguards to protect the confidentiality and security of personal health information, both on- and offline. Our work is motivated by the belief that unless patients, and consumers generally, have confidence that the confidentiality of their health information is guaranteed, progress being made to develop better information systems to improve care and monitor and assess the quality of care will be thwarted. [The Foundation's work on health privacy can be found on our Web site at www.chcf.org.]

California HIPAA Privacy Implementation Survey

In December 2001, the Foundation commissioned the National Committee for Quality Assurance (NCQA) and the Georgetown University Health Privacy Project to survey health care organizations operating in California to see how implementation efforts are proceeding under the HIPAA Privacy Rule. The survey was intended to distinguish between the real and perceived barriers to compliance and to use the results of the survey to inform policymakers and the public debate.

The survey represents the views of 100 health care organizations that do business in California, including 29 hospitals, 19 physician groups, 26 health plans, and 26 other organizations, such as disease management organizations, clearinghouses, medical management groups, behavior health care organizations and researchers. The organizations that took part in this survey are fairly representative of entities potentially affected by the Privacy Rule. Some of the organizations surveyed also operate in states other than California.

The survey was conducted in January and February 2002, prior to the March 27, 2002 release by Department of Health and Human Service (HHS) of the proposed rule modifications (NPRM).

When reviewing the findings of the survey it is important to note that the State of California has a history of strong patient confidentiality laws. Health care organizations operating in California generally have more experience operationalizing privacy protections than most of the rest of the

nation.

The Survey Findings

The survey identified the following key findings:

1. Planning is proceeding; implementation progress varies.
2. The consent requirements are somewhat workable.
3. Minimum necessary requirements are somewhat workable.
4. Information needed for quality assessment thought to be limited by the consent and minimum necessary requirements.
5. The business associate requirements are viewed as burdensome.
6. Resources are needed to assist preemption analysis.
7. Compliance efforts are not fully funded.
8. There is a general need for clarifications and/or modifications.

1. Planning Is Proceeding; Implementation Progress Varies

Ten months into a two-year compliance period, when asked about specific actions taken toward implementation, 81% of respondents have developed a strategic plan, 67% indicated they have conducted a gap assessment, and 52% have started to develop and implement readiness initiatives. Twelve percent of respondents reported completion of their readiness initiatives. Hospitals report having made the most progress to date, with Physician Groups having made the least progress. (See Table 1.) Payors with a Medicaid product were less likely than Payors with commercial products to have developed a strategic plan (64% to 92%), conducted a gap assessment (50% to 92%), or developed a readiness initiative (29% to 67%).

Seventy-seven percent of respondents indicated they had designated a Privacy Official, as defined by HIPAA. Eighty-seven percent of those that had designated a Privacy Official also report they had identified the human resources within their organization needed to prepare for HIPAA compliance. Again, Payors with a Medicaid product were less likely (50% to 92%) than Payors with commercial products to have designated a Privacy Official and also less likely (63% to 91%) to have identified the human resources needed to prepare for HIPAA.

Organizational challenges frequently identified by respondents included implementation, staff education, cost, time, and information technology.

2. The Consent Requirements Are Somewhat Workable

Overall, 51% of total respondents felt that the consent requirements were somewhat workable. Twenty-nine percent felt they were either workable (19%) or very workable (10%), while 20% felt they were less than workable (13%) or not workable at all (7%). (See Figure 1.)

Hospitals, Others and Physician Groups were more likely to feel the consent requirements were somewhat to very workable (90%, 81%, and 79% respectively) than Payors (68%). Respondents who had developed/completed a readiness initiative, developed a strategic plan or conducted a

gap assessment were more likely than their counterparts to feel that the consent requirements were workable.

Forty-six percent of survey respondents believe that the Privacy Rule will be useful in assuring patient confidentiality rights and achieving consistent national standards for confidentiality, however, 47% of respondents expressed concern about the paperwork burden.

Although the final rule required consent to be obtained only one time, many respondents expressed confusion or concern about the practicability of tracking revocations and limitations on consent. There was concern that as a result, some covered entities would require patients to sign a consent form every time they sought treatment and that patients would be overwhelmed and confused as a result.

Many respondents expressed concern that the burden of implementing consent would take time and money away from patient care. Respondents also expressed concern that covered entities would err on the side of caution and refuse to release information for fear of violating HIPAA.

All respondents were asked to indicate what they deemed useful about the consent requirements, and what areas of the consent requirements caused them concern.
Regarding aspects of the consent requirements that were useful:

§ 30% said that the requirements were useful in assuring patient rights.
§ 16% felt the requirements would provide national standards and increase consistency among providers.
§ 16% said that there was nothing useful about the requirements.

Regarding areas of concern related to the consent requirements:

§ 19% of respondents cited continuity of care.
§ 14% cited confusion about consent among patients, employees, and physicians.
§ 9% cited cost.

Payors were more likely to cite confusion about consent as an area of concern.

Respondents were asked whether available tools and technologies could be used to implement four areas: 1) initial consent, 2) revocations of consent, 3) limitations on consent, and 4) accounting of disclosures. Implementing initial consent was thought to be the easiest and tracking limitations to consent the most difficult. It should be noted that between 17 and 25% of respondents did not know how to respond and were excluded from the results.

Physician Groups were more likely than Hospitals, Payors, and Others to feel that available technologies could not be used for tracking initial consent. Of those who did know, 53% of respondents felt that initial consent could definitely be tracked.
For revocations of consent, more than a quarter (28%) of respondents felt that they could not be tracked with available tools and technologies. Forty-five percent thought they could be tracked with available tools and technologies.

Overall 37% of respondents thought that limitations on consent could be tracked, while 35% of respondents thought they could not be tracked with existing tools. Only 30% of Hospitals and 32% of Payors felt that limitations on consent could be tracked with existing tools.

Twenty-nine percent of respondents thought that accounting of disclosure could not be tracked with existing tools, while 43% thought that they could be tracked. Physician Groups (33%) and Payors (33%) were more likely to say that they could not be tracked.

3. Minimum Necessary Requirements Are Somewhat Workable

Overall, 58% of respondents felt that the minimum necessary requirements are somewhat workable. Twenty-three percent felt they were workable (18%) or very workable (5%), while 19% felt they were either less than workable (15%) or not workable at all (4%).
Physician Groups were slightly more likely to see the minimum necessary requirements as workable, with Payors and Others slightly less likely to see them as workable. As with the consent requirements, respondents who had developed a readiness initiative or strategic plan or had conducted a gap assessment were more likely than their counterparts to feel that the minimum necessary requirements were workable.

4. Information Needed For Quality Assessment Thought To Be Limited By The Consent And Minimum-Necessary Requirements

When asked if they thought the consent requirements would enhance or limit the flow of information needed to assess health care quality, 58% of respondents thought that the consent requirements would somewhat limit (51%) or greatly limit (7%) the flow of information needed to assess quality of care. Thirty-two percent of respondents felt the consent requirements would have no affect on the flow of information, while 10% percent felt the consent requirements would enhance (9%) or greatly enhance (1%) the flow of information. Sixty-five percent of Hospitals and 65% of Others felt that the consent requirements would somewhat or greatly limit the flow of information, while 42% of Physician Groups and 44% of Payors felt that the consent requirements would have no effect on the flow of information.

Those respondents that felt the consent requirements would somewhat or greatly impact the flow of information needed to assess health care quality were asked to indicate in what way the consent requirements would impact assessment of health care quality. There were 60 open-ended responses to this question:

§ 30% of respondents answering the questions felt that there would be process complications or additional burden associated with paperwork.
§ 17% felt there would be confusion over requirements; 15% felt patient factors, such as revoking consent, would limit the flow of information and interrupt the continuity of care.
§ 6% felt that there would be inadequate transfer/flow of information needed for patient assessment.

Inadequate time was a common theme in the responses. Hospitals were more likely to cite process complications, paperwork burden, and patient factors as limiting the flow of information, while Payors tended to cite confusion over requirements as limiting the flow of information.

With respect to the minimum necessary requirements, the findings were less clear. While 45% of respondents' thought this requirement would greatly limit or somewhat limit the flow of information needed to assess the quality of health care, another 45% thought that the minimum necessary requirements would have no impact. Ten percent of respondents thought the requirements would somewhat enhance (9%) or greatly enhance (1%) the flow of information.

Physicians and Payors expressed similar concerns that the minimum necessary requirement would negatively affect the flow of information for payment, delivery, and assessment of care. It appears that the belief that quality would be affected is related to the fact that the consent requirements in the final rule would not permit providers to share Personal Health Information (PHI) with health plans for the plans' quality assurance activities.

There was generally a lack of clarity about the permissibility of disclosures for quality assessment purposes. Respondents did not seem to understand the permitted uses and limitations of PHI within and between covered entities.

5. The Business Associate Requirements Are Viewed As Burdensome

The time and cost associated with contracting with business associates was a significant issue for respondents. Seventy-two percent felt there would be a substantial to large time burden to implement the business associate requirements; more than half of respondents said the cost of implementing these requirements was substantial to large.

When asked if they believe that the regulations clearly define who constitutes a business associate, 65% of all respondents thought the regulations were clear. While 81% of Physician Groups thought the regulations were clear, only 50% of Payors agreed. While most respondents likely have existing contractual relations, the initial burden of recontracting is believed to be high. There is also disagreement and lack of understanding about the level of oversight and due diligence required by covered entities over their business associates.

6. Resources Are Needed To Assist Preemption Analysis

Fourteen percent of respondents did not know whether they had conducted any preemption analysis. Of those who did know, more than half have not identified the laws in the states in which they do business that either are or are not preempted by HIPAA. When asked how they were planning to identify and track these laws, most respondents indicated that they hoped outside sources would develop and track preemption issues or that they were expending significant resources hiring outside legal assistance. Assistance provided by HHS with regard to preemption analyses would ease the burden on covered entities.

7. Compliance Efforts Are Not Fully Funded

With respect to funding, only 21% of respondents said that their compliance efforts were fully

funded. More than half of respondents indicated that their HIPAA compliance efforts were only partially funded or not funded at all. When asked whether they think the anticipated costs of complying with the Privacy Rule will eventually be offset by savings expected from implementing other components of HIPAA (e.g., the Transaction and Code Set regulations), 31% to 32% of respondents said they did not know. Of those that said they did know, 48% expect no savings, 22% expect some savings but not within the next 5 years, and 26% expect some savings within 3to 5 years.

While 51% of respondents reported a lack of funding, it is also important to keep in mind that many respondents have not developed a strategy or conducted a gap analysis of their organizations and this may have an impact on their knowledge of the funding requirements. The survey results also indicated there is a great deal of money being spent on redundant legal and outside consultant analysis of the regulations and compliance efforts.

8. There Is A General Need for Modifications And/Or Clarifications

Seventy-eight percent of respondents felt that HHS needed to provide clarifications or make modifications to the final Privacy Rule. Many responders requested clarifications with respect to consent, minimum necessary, the definition and rules concerning business associates, the rules concerning communications, marketing and funding, and preemption. Others wanted clarification around research rules and how the regulations apply to disease management organizations.

Conclusion

The clear message from this survey is that there is a lot of work still to be done to address areas of confusion, misinterpretation and to make the rules generally more workable.

1. If you are a supporter of the Privacy Rule, the survey suggests it cannot be fully or successfully implemented, without clarifications and possible modifications.

2. On the other hand, there is substantial evidence that progress is being made in implementation, so that removing key provisions of the rule does not seem justified.

Today, nearly 20% of Americans practice some form of privacy-protective behavior that puts their own health at risk or creates financial hardships. These behaviors include: paying out-of-pocket when insured to avoid disclosure; not seeking care to avoid disclosure to an employer; giving inaccurate or incomplete information on a medical history; asking a doctor to not write down the health problem or to record a less serious or embarrassing condition; or, simply not seeking care at all.

It is in everyone's best interest to see that these rules are implemented.

Again, thank you for this opportunity to testify today. I am happy to answer any questions you may have.