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Outline of remarks made at the Summer Meeting of CALGB in Ottawa, Canada on June 23, 2001

MYTHS AND FACTS ABOUT THE FEDERAL MEDICAL PRIVACY REGULATION

Myth #1: The regulation will "jeopardize the quality and timeliness of patient care" and "drive a wedge between individuals and their care providers."

Sources: "Wedge" comment -- "HIPAA's Privacy Standards: Driving a Wedge Between Patients and the Health Field," by Marilou M. King, attorney representing the American Hospital Association (page 1).

"Quality of care" comment: Testimony of Blue Cross and Blue Shield Association before the Senate Committee on Health, Education, Labor, and Pensions, presented February 8, 2001 (page 11)("This standard...could jeopardize the quality and timeliness of patient care...")

Fact: The regulation will improve the quality of care and the patient/provider relationship. Concerns about lack of privacy now drive a wedge between patients and their providers and impede the provision of quality care because patients withhold information, avoid asking certain questions, or fail to seek care altogether. Among other benefits, the regulation creates the opportunity for patients and their health care providers to engage in a dialogue about how their information will be used and gives patients more control over uses and disclosures. This regulation will go a long way toward promoting confidence in the privacy of medical information and in the health care system.

Myth #2: "If a patient is sharing a room with another patient, which is often the case, physicians may be constrained to discuss openly vital care and treatment issues for fear of running afoul of HIPAA's many prohibitions." A similar charge being made is that "new sound-proof walls and offices may need to be built in health care facilities."

Sources: "Oral communications and single rooms" comment: Testimony of the American Hospital Association before the Senate Committee on Health, Education, Labor, and Pensions, presented February 8, 2001 (page 10). "Sound-proof" comment: Testimony of Blue Cross and Blue Shield Association before the Senate Committee on Health, Education, Labor, and Pensions, presented February 8, 2001 (page 7).

Fact: Health care professionals, and the hospitals in which they work, should take reasonable steps to make sure that conversations about one patient are not overheard by others. The regulation merely requires covered entities to "reasonably safeguard protected health information

from any intentional or unintentional use or disclosure that is in violation of the standards." Screens or curtains often separate patients from one another in hospital rooms to protect the privacy of patients. Health care professionals can and should modulate their voices so that private conversations can take place. This is true whether the conversation takes place in the patient's room or in the hallways, corridors, or elevators.

Myth #3: Family members and friends will no longer be able to pick up prescriptions for others at the pharmacy.

Source: "'As Craig Fuller has told me, the way it's set up right now, if you are married and you're too sick to go to the drug store, you can't send your spouse down to pick up your medicine,' [HHS Secretary] Thompson said during a National Chamber Foundation meeting March 1 in Washington, D.C." F-D-C Reports' Research Services, "Consulting NACDS," The Pink Sheet, March 5, 2001 (page 5).

Fact: The regulation explicitly provides that this common practice can continue. The regulation states that covered entities can use their professional judgment and experience with such practices so that family members, friends, and others may pick up items like filled prescriptions, medical supplies, or x-rays.

Myth #4: The "minimum necessary" standard will disrupt communications between providers involved in treating a patient. Some charge that providers treating patients will not be able to examine the patient's entire medical record.

Sources: "The minimum necessary rules may still place artificial limits on the ability of doctors to use and disclose health information for critical treatment situations – threatening the overall quality of care." Testimony of Blue Cross and Blue Shield Association before the Senate Committee on Health, Education, Labor, and Pensions, presented February 8, 2001 (page 11).

"The regulation includes a strong discouragement regarding the release of entire medical records of patients. The complete exchange of medical information is absolutely critical to assuring a patient receives the right treatment at the right time." Testimony of Blue Cross and Blue Shield Association before the Senate Committee on Health, Education, Labor, and Pensions, presented February 8, 2001 (page 11).

"Limiting the ability of teams of health professionals, and health profession trainees, in a hospital setting to use a patient's complete medical chart or freely discuss and communicate among themselves in the course of treating patients could be disruptive and potentially dangerous." Testimony of the Healthcare Leadership Council before the Senate Committee on Health, Education, Labor, and Pensions, submitted February 8, 2001 (page 5).

Fact: The regulation explicitly exempts from the "minimum necessary" standard all disclosures to providers for treatment purposes. It also exempts all requests by health care providers for information to be used for treatment purposes. As a result, information will flow freely between and among providers involved in treatment. Provisions in the regulation that require special justification for disclosing the entire medical record do not apply to treatment-related disclosures because they are not subject to the minimum necessary standard in the first place.

With respect to *uses* of health care information for treatment purposes, the regulation allows the use of the entire medical record when it is specifically justified as the amount that is "reasonably necessary" to accomplish the purpose of the use. A provider is only required to have a policy as to the amount of health information that is to be used: a case-by-case determination is not required or anticipated. In fact, HHS states in the preamble to the regulation that HHS "expect[s] that covered entities will implement policies that allow persons involved in treatment to have access to the entire record, as needed." 65 Fed. Reg. 82544.

Myth #5: Providers that disclose medical information for treatment purposes must meet the minimum necessary standard.

Source: "This exemption [from the minimum necessary standard] does not cover . . . 'disclosures by' providers." (emphasis added) Testimony of Blue Cross and Blue Shield Association before the Senate Committee on Health, Education, Labor, and Pensions, presented February 8, 2001 (page 11).

Fact: This assertion takes the minimum necessary exemption out of context. The general rule imposes the minimum necessary standard on covered entities, including providers, when they are "disclosing protected health information." The provision goes on to state: "This requirement does not apply to: . . . Disclosures to . . . a health care provider for treatment." When read as a whole, it is clear that the exemption applies to disclosures by health care providers.

Myth #6: The regulation will impede the training of medical students, in part because the regulation will not allow medical students to see a patient's entire medical record.

Source: The Association of American Medical Colleges has "grave concerns" about "the effects of the rule on medical and health education." "The AAMC supports the proposition that medical residents and medical and nursing students, as well as other health professions students, as necessary, should have unrestricted access to medical information of their patients . . . – a proposition that the rule seems to recognize, peculiarly, only with respect to psychotherapy notes." Testimony of the Association of American Medical Colleges before the Senate Committee on Health, Education, Labor and Pensions, presented on February 8, 2001 (pages 2, 4).

Fact: The regulation respects the important role that covered entities play in the training of medical students. It includes the following within the definition of "health care operations": "conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers." Therefore, once a provider obtains a consent, an individual's health information can be used not only for treating the patient but also for training medical students. Disclosures, for treatment purposes, to medical students providing health care services to patients would not be subject to the minimum necessary standard because such medical students would be considered "health care providers." Medical students — even those not actually considered "health care providers" because they do not furnish care — would be able to review a patient's entire medical record when the covered entity makes a policy determination that the entire medical record is "reasonably necessary to achieve the purpose" of training medical students.

Myth #7: Stakeholders have not had an opportunity to comment on the provisions requiring that health care providers obtain patient consent for treatment, payment, and health care operations purposes because such a provision was not in the proposed rule.

Source: "Our concern about this consent process is that is was not subject to meaningful notice and comment. Neither the AHA, nor other affected providers, had an opportunity to comment on how this potentially confusing and burdensome procedure would affect patient care or hospital operations. Therefore, it is only prudent to re-open the rule so that the pros and cons of HHS' imposed consent scheme can be fully considered." Testimony of the American Hospital Association before the Senate Committee on Health, Education, Labor, and Pensions, presented February 8, 2001 (pages 9-10).

Fact: It is true that HHS did not propose such an approach, but HHS made it clear in the proposed rule that it was interested in receiving comments on its approach to consent and on other approaches. Specifically, the proposed rule states: "We recognize . . . that other approaches could be of interest. We invite comments on whether other approaches to protecting individuals' health information would be more effective." (See 64 Fed. Reg. at 59941.) Since everything in the proposed rule was just that – a proposal – and since the question of actual consent or "statutory" consent was a key threshold issue, many stakeholders did submit comments on the proposed approach to individual consent. The failure of some organizations to take advantage of this opportunity is no reason to delay or reopen the regulation for additional comment. AHA's argument would lead to a never-ending cycle of comments, since every change adopted to a proposed regulation would necessitate yet another round of comments.

Myth #8: The regulation is so complex it is 1,500 pages long.

Source: U.S. News & World Report (Jan. 29, 2001, page 47) refers to the regulation as "the 1,500-page doorstopper."

Fact: The text of the actual regulation only covers 32 pages in the Federal Register. The preamble that precedes the regulation covers 337 pages in the Federal Register. Over half of the preamble is devoted to summarizing and responding to the more than 50,000 comments received by HHS.

Myth #9: "Health care providers would have to keep track of everyone who received medical information from them. Patients could demand an accounting of all of these disclosures."

Source: Amitai Etzioni, "New Medical Privacy Rules Need Editing," *USA Today* at 13A (February 22, 2001).

Fact: This is simply not true. Providers are *not* required by this regulation to keep an accounting of anyone within their own organization who has received (or had access to) medical information. This is because the accounting provision only covers "disclosures," which are defined as the sharing of health information with someone *outside* of an organization. Furthermore, the regulation specifically states that a provider does not have to keep account of information disclosed (i.e., shared with someone outside of the organization) for treatment, payment or health care operations. For example, a hospital would not have to keep track of health information sent to outside doctors providing follow-up care to patients. The result of these exclusions is that providers are required to account for only a narrow category of disclosures that primarily are *not related to health care*, such as those made to law enforcement personnel or pursuant to a request for documents in a lawsuit.

Myth #10: The regulation allows patients to demand that doctors correct their medical records.

Source: "We all would be the beneficiaries if the regulations as currently constituted were not allowed to go into effect until they are subject to an expeditious and thorough trimming and simplification. . . . And while patients should be allowed to see their medical records and attach their comments, they should not be allowed to demand that doctors "correct" the records." Amitai Etzioni, "New Medical Privacy Rules Need Editing," *USA Today* at 13A (February 22, 2001).

Fact: There is no provision allowing patients to demand that doctors "correct" their records. An individual may request that a provider (or other covered entity) *amend* his or her records and append or otherwise provide a link to the location of the amendment. There are several grounds under which a provider may deny such a request.

Myth #11: The final regulation requires disclosures of protected health information to a variety of federal government departments and agencies.

Source: "What has not been widely reported are the rule's new mandates requiring doctors, hospitals, and other health care providers to share patients' personal medical records with the federal government, sometimes without notice or advance warning. (See, for example, Federal Register, Vol. 65, No. 250, December 28, 2000, p. 82802, Sec. 160.310.) ... Handing sensitive medical records to federal departments and agencies that are ill-equipped to protect that information is not a solution; it is inviting abuse, errors, scandal, and tragedy." Letter from Dick Armey, House Majority Leader, to Secretary Thompson (dated March 5, 2001).

Fact: The regulation *requires* covered entities to make only two types of disclosures: (1) disclosures to the individual who is the subject of the protected health information and (2) disclosures to HHS for the purpose of enforcing the regulation. The regulatory section cited by Majority Leader Armey in his letter only requires disclosures to HHS for compliance purposes. It restricts such disclosures to that information that is "pertinent to ascertaining compliance with [the Privacy Rule]." Without this provision, HHS would have no way of determining whether a covered entity had complied with the regulation, making enforcement of the law impossible. Moreover, HHS is limited in what it can do with health information obtained in this fashion. The regulation prohibits HHS from disclosing such information except where necessary to ascertain or enforce compliance with the regulation or as required by other law. Under an executive order issued contemporaneously with the Privacy Rule, HHS is also prohibited from using protected health information concerning an individual discovered during the course of health oversight activities for unrelated civil, administrative, or criminal investigations.

The regulation does not require disclosures to any other person or entity, including to other federal agencies or departments. The regulation *permits* disclosures to government agencies only where the agency requesting or receiving the information has authority to request or receive the information through some other law.

Myth #12: The regulation will be too costly to implement.

Source: "An AHA-commissioned study, looking at hospital costs alone, found that the cost of only three key provisions of the proposed rule . . . could be as much as \$22.5 billion over five years." Testimony of the American Hospital Association before the Senate Committee on Health, Education, Labor, and Pensions, presented February 8, 2001 (page 6).

Fact: HHS estimates that the cost associated with implementing the privacy regulation (approximately \$17 billion over ten years) will be greatly offset by the cost savings associated with implementing HIPAA's transactions standards (approximately \$29 billion saved over ten years). If implemented together, as contemplated by Congress, consumers will benefit, health care organizations will benefit, and the health of our communities will benefit. Delay could actually be more costly for industry because it would need to redesign and retool systems a second time if privacy protections are not put in place along with the transactions standards.

Myth #13: Delay of the effective date and/or the compliance date is essential to give covered entities time to comply with the regulation.

Source: "The overwhelming financial impact of the final privacy rule is exacerbated by its overly aggressive implementation schedule." Testimony of the American Hospital Association before the Senate Committee on Health, Education, Labor, and Pensions, presented February 8, 2001 (page 3).

Fact: Covered entities are devoting substantial, precious resources to stopping the regulation from ever taking effect, rather than on a good-faith effort to begin the process of complying. There is no reason to delay the effective date. If HHS finds that there are any real and serious implementation problems with certain aspects of the regulation. HHS can remedy the situation without delaying the effective date. HHS has authority under HIPAA to modify the regulation after it takes effect to make changes that are "necessary in order to permit compliance."

Delay of the effective date will jeopardize the confidentiality of patients' medical information. Every day there are new advances in transmitting and storing health information in an electronic format. The HIPAA transactions standards encourage this movement. Fostering these technical advancements without adequate security and privacy protections in place is irresponsible.

Should any serious implementation problems develop in the future due to the two-year compliance time frame established by Congress in HIPAA, the industry can ask Congress to delay the compliance date.

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