Pennsylvania Medical Society®

MEMORANDUM

To: Senator Mike Folmer and members of the Senate Communications & Technology Committee

From: Marilyn, J. Heine, MD, President, Pennsylvania Medical Society

Subject: Senate Bill 8

Date: March 7, 2012

The Pennsylvania Medical Society appreciates the opportunity to offer comments in conjunction with the Senate Communications & Technology Committee's March 7, 2012 public hearing on Senate Bill 8. We also look forward to the opportunity to continue to work with the committee as you advance this significant legislation toward consideration by the committee, which we understand may take place later this month.

While our comments are primarily directed toward the confidentiality provisions of Senate Bill 8, we would also offer a couple general comments and questions.

First, the bill makes no provision for what happens after the authority expires on December 31, 2018. Will it be renewed through a sunset review process, or will there be a successor entity, and if so what sort of entity is envisioned?

Second, the legislation calls for the participation of "health care providers" on the advisory committees. In view of the critical role physicians will play in implementing and using the health information exchange, we believe that the legislation should require the specific participation of physicians on the advisory groups.

Now, to our more detailed comments regarding the confidentiality provisions of Senate Bill 8.

Section 701 and definitions in section 102

Our understanding is that the intent of the confidentiality section in SB 8 is to allow exchange of protected health information (PHI) for treatment purposes via a health information exchange (HIE) consistent with the federal HIPAA rules,[1] with three exceptions:

[1] 45 C.F.R. § 164.500 *et seq*.

Right to opt-out – HIPAA generally permits health care providers to disclose PHI for treatment, payment, or health care operation (TPO) purposes without any patient consent.[2] HIPAA requires that patients be given notice, via a notice of privacy practices, that such disclosures may occur[3] and further requires that patients be given the opportunity to request restrictions on such disclosures.[4] However, HIPAA generally does not require the health care provider to agree to a requested restriction on TPO disclosures.[5] If the health care provider nonetheless agrees to a restriction on disclosures for TPO purposes, the provider generally must honor the agreement, but even in that case, there is a "break-the-glass" exception for emergency care.[6] The HITECH law also effectively amended HIPAA to require health care providers to honor requests to not disclose self-pay services to the patient's insurer, but the rules allowing health care providers to refuse confidentiality requests in the case of disclosures for TPO purposes otherwise still apply.[7] In contrast, section 701(a)(2) of SB 8 would require health care providers to both notify patients that they may opt-out of disclosures and to honor patient opt-outs, at least in the case of disclosures via an HIE.

Minimum necessary requirement – As a general rule, HIPAA requires that health care providers make reasonable efforts to limit allowed disclosures of PHI to the minimum necessary for the intended purpose.[8] However, HIPAA recognizes a number of exceptions. Of importance here, there is no minimum necessary requirement for disclosures for treatment purposes. For example, a physician could forward a patient's entire record to a consulting physician without scrutinizing what aspects are necessary for the consultant to see. In contrast, section 701(a)(1) of SB 8 imposes a minimum necessary requirement for disclosures for treatment purposes, at least in the case of those disclosures via an HIE.

Super-protected information – HIPAA does not pre-empt state and federal laws that impose more stringent confidentiality requirements. Certain information is super-protected under various state and federal laws. In Pennsylvania, this includes HIV-related information,[9] drug and alcohol abuse treatment information,[10] and certain mental health treatment information.[11] These laws generally require a signed patient authorization for disclosure. While there are certain exceptions for disclosures made for treatment purposes, the super-protected exceptions are not as broad as the HIPAA exception for treatment purposes. SB 8 would keep in place a requirement for specific patient authorization for HIV-related information and drug and alcohol abuse treatment information only.

Comments

Definition of "health information." Section 102 defines this term as follows:

> "Health information." Oral or recorded information in any form or medium that meets all of the following:

[2] 45 C.F.R. § 164.502(a)(1)(ii) & § 164.506.
[3] 45 C.F.R. § 164.520(b)(1)(ii)(A).
[4] 45 C.F.R. § 164.522(a)(1)(i)(A).
[5] 45 C.F.R. § 164.522(a)(1)(ii).
[6] 45 C.F.R. § 164.522(a)(1)(iii).
[7] 42 U.S.C.A. § 17935.
[8] 45 C.F.R. § 164.502(b)(1).
[9] 35 P.S. § 7601.
[10] 71 P.S. § 1690.101.
[11] 50 P.S. § 7101 *et seq*; 55 Pa. Code § 5100.1 *et seq*.

(1) Is created or received by a health care provider, health care plan, employer, payer or public health authority.

(2) Relates to:

(i) the past, present or future physical or mental health condition of an individual ***and is provided to the individual***; or

(ii) the past, present or future payment for the provision of health care to an individual.

The bold and italicized words above words make no sense in the context. It appears that this definition was derived from the definition of "health care" in the HIPAA regulations,[12] but that some words were deleted. Following the HIPAA definition, the following should be substituted for the highlighted language: ***"or the provision of health care to an individual."***

Definition of HIE – Section 102 defines HIE as "the electronic movement of health information between various entities according to nationally recognized standards" (emphasis added). This definition is far too vague. Our principal concern is that it could be interpreted to apply to a universal medical record of a physician practice or health system composed of multiple separate entities, or even an electronic medical record shared by multiple physicians in a practice if "entity" is viewed as including individuals. This must be considered in the context of the opt-out and minimum necessary requirements as well as other additional requirements that may be imposed on HIEs by the Authority created under the act. The reference to "nationally recognized standards" also may present a problem in certain contexts. For example, we assume that the Authority will be requiring HIEs to meet nationally recognized standards. Are HIEs exempt from such requirements if they are deficient?

Consistency with HIPAA – We support the intent to allow exchange of PHI for treatment purposes via a HIE consistent with the federal HIPAA rules. The free flow of information among a patient's treating health care providers is critical for quality care. While generally allowed under HIPAA, certain state laws and regulations can be interpreted to create barriers. For example, the hospital regulations prohibit hospitals from sharing patient information "outside the hospital" without the patient's signed consent.[13] The confidentiality provisions of the medical board regulations likewise lack clarity on this issue. Although the regulations of the osteopathic board include an explicit exception for treatment purposes,[14] the medical board regulations do not, allowing only exceptions only "as authorized or required by statute."[15] Ideally, the ability of health care providers to make disclosures for treatment purposes would be clarified. While this may have been the intent of SB 8, the problem is that the language does not accomplish this. Section 701 simply says that "this act" does not require patient consent for disclosure for treatment purposes (assuming no opt-out). It should reference all state laws other than those that apply to super-protected information (HIV status, drug and alcohol abuse treatment information, and mental health information protected under the Mental Health Procedures Act).

Right to opt-out – We generally support the opt-out requirement as long as concerns are addressed, relating to the definition of an HIE and the undue administrative burden of notice and implementation. While the right to opt-out is not required by HIPAA, some patients may have concerns about security

[12] 45 C.F.R. § 160.103.
[13] 28 Pa. Code § 115.27.
[14] 49 Pa. Code § 25.213(c).
[15] 49 Pa. Code § 16.61(2).

breaches. We read the bill as limiting the opt-out right to disclosures to an HIE, as section 701(b)(3) refers to the patient's right to deny release of PHI "to the health information exchange." However, section 701(a) may create some confusion on this issue and interpreted as limiting disclosures in other contexts. Ideally, this should be clarified. We certainly do not want a result where, for example, a physician office needs to get a patient's consent every time the patient's PHI is given to a consulting physician in another office.

Opt-out notice – During the eHealth Collaborative discussions, the consensus was that notice of the right to opt-out could be given via standard language in HIPAA notice of privacy practices. To avoid undue administrative burden, HIPAA only requires that health care providers make available their notice of privacy practices and to obtain a signed acknowledgement of receipt of the notice, once.[16] Typically, this occurs at the first encounter. Thereafter, the health care provider is allowed to modify its notice of privacy practices without further specific notice or patient acknowledgement. [17] Paragraphs (b)&(c) of section are 701 are vague as to whether this contemplated process would be permitted. A further technical point is that the title of paragraph (c) should be "notice to patients" rather than "notice to parents."

Opt-out form – Section 701(c) provides: "The notice shall be signed, dated and witnessed by the patient, or the patient's representative, should the patient choose to execute a denial of release." This is confusing as written and is not consistent with the contemplated process described above. Under HIPAA, patients need only sign the acknowledgement of notice once and may have done that prior to the effective date of the act. There should be no need for a second signed acknowledgement of notice. The only patient signature needed should be a signed opt-out when the patient desires to do so.

Provider-specific opt-outs – During the eHealth Collaborative discussions, the consensus was that any opt-out would apply to all health care providers. It further was contemplated that any health care provider who received a signed opt-out would forward that information to the Authority, which, in turn, would put appropriate mechanisms in place to preclude sharing of the patient's PHI via the HIE. However, paragraphs (b)&(c) of section 701 seem to contemplate provider-specific opt-outs. That could be problematic, as health care providers receiving information on a patient via the HIE might not know that they are being given only part of the story. Also, if the process is changed so that opt-outs apply to all health care providers, why impose on health care providers the administrative burden of collecting and forwarding opt-outs to the authority? The authority should provide a mechanism for patients to direct submit their opt-outs to the authority.

Selective opt-outs – During the eHealth Collaborative discussions, the consensus was that patients should not be permitted to selectively opt-out, i.e., they could not exclude specific PHI from the HIE (other than super-protected PHI). The rationale is that technology has not advanced to the point to permit selective opt-outs. However, section 701(a)(2) is at best ambiguous on this issue and may be interpreted as allowing selective opt-outs.

PHI created prior to the effective date of the act – What happens in the case of PHI created prior to the effective date if there is no subsequent patient encounter? Consider this scenario: a physician receives a request to transmit to an emergency department the PHI of a patient whom the physician last saw five

[16] 45 C.F.R. § 164.520(c)(2).
[17] 45 C.F.R. § 164.530(i)(2)(ii) & 164.520 (b)(1)(v)(C).

years before the effective date of the act. Under this timeline, the patient never would have been presented with the opportunity to opt-out. Can the physician send the PHI?

Break-the-glass exception – As noted, patients can opt-out of disclosure of their PHI via the HIE. There is no "break-the-glass" exception for emergency care. Patients may later regret their opt-out. However, to date, we have supported this concept as a matter of patient autonomy.

Minimum necessary requirement – Guidance should be obtained from physicians as to whether the minimum necessary requirement in section 701(a)(2) will present an undue burden. As discussed above, HIPAA does not impose a minimum necessary requirement for disclosures for treatment purposes. Also, HIPAA includes provisions that make compliance with the minimum necessary requirement less burdensome on health care providers when the request comes from another covered entity, e.g., a health plan seeking PHI for payment purposes. In situations where a covered entity requests PHI and the minimum necessary requirement is applicable, the covered entity must limit the request to that which is reasonably necessary to accomplish the purpose for which the request is made.[18] Furthermore, a covered entity receiving a request for PHI from another covered entity may assume that the request meets the minimum necessary requirement if such reliance is reasonable under the circumstances.[19] The first option should be to eliminate the minimum necessary requirement in this section to the extent that it applies to exchanges for treatment purposes. As an alternative, the bill should contain some provision to make it less burdensome.

Specific authorization for certain super-protected information – We recognize that extending the implied consent to super-protected information is not feasible practically or legally. We also understand that there may be opposition from groups who advocate for strict confidentiality of this information. Plus, in the case of drug and alcohol abuse treatment, there are federal confidentiality requirements that often apply.[20] State law cannot preempt those federal requirements.[21] On the other hand, the super-protected information requirements may thwart an effective HIE. Super-protected information generally is not segregated in a patient's medical record. For example, even assuming that a patient's HIV test results could be easily segregated and excluded from disclosure via the HIE, other aspects of the patient's medical record could also be protected HIV-related information. A medication list could reveal the status of an HIV-positive patient. Likewise, a prescription written for Antabuse would reveal alcohol abuse treatment. This type of information might be in a primary care physician's patient records. It is not limited to being prescribed by drug and alcohol abuse treatment centers. Finally, we note that there is a quality concern when physicians lack full information on the patient's health status. As noted, we don't have an obvious solution for this conundrum, but believe the point should be considered.

Scope of super-protected release – Section 701(a) requires that a release allowing disclosure of the covered super-protected information "relate only to that information." Would this allow a patient to sign a single release applicable to any request via the HIE or must the patient sign a release for each request? The language is not clear on that issue.

Mental health information – As noted, certain mental health information is super-protected under Pennsylvania law. Specifically, the Mental Health Procedures Act (MHPA) protects "all involuntary

[18] 45 C.F.R. § 164.514(d)(4)(i).
[19] 45 C.F.R. § 164.514(d)(3)(iii).
[20] 42 C.F.R. § 2.1 *et seq*.
[21] 42 C.F.R. § 2.20.

treatment of mentally ill persons, whether inpatient or outpatient, and for all voluntary inpatient treatment of mentally ill persons."[22] The consensus is that the MHPA protections only apply to care rendered by licensed facilities. However, the protection follows the records of the care and would, for example, apply to covered records transmitted to the patient's primary care physician and incorporated in the office chart. In any event, we are curious as to why this information is not specifically referenced in section 701(a)(3), which requires a specific patient authorization for other types of super-protected information. The applicable law and regulations do include a treatment exception. The MHPA allows disclosures without patient consent to "those engaged in providing treatment for the person."[23] The regulations allow "relevant portions or summaries [to be released to] those actively engaged in treating the individual, or to persons at other facilities … when the person is being referred to that facility and a summary or portion of the record is necessary to provide for continuity of proper care and treatment."[24] A narrow read would limit the treatment exception to those involved in providing mental health care to the patient. However, a broader read would include persons seeking the information for other purposes, e.g., an emergency physician in need of the patient's medication list. Was mental health care was not included because the drafters subscribe to the broader interpretation?

Psychotherapy notes – The HIPAA provision allowing disclosure of PHI for TPO purposes is severely restricted in the case of psychotherapy notes.[25] This would most likely apply to only a small group of physicians. However, the implication in section 701(a) that patient authorization is not required to disclose psychotherapy notes to another health care provider is incorrect when HIPAA is considered.

Payment purposes – Section 701 does not specifically address disclosures to health plans, employers, government entities, etc. for payment purposes. Ironically, paragraph (a) imposes restrictions on disclosures for treatment purposes, but not payment purposes. Even though HIPAA permits disclosures for payment purposes, the exception for payment purposes is not as liberal; the minimum necessary requirement does apply in the case of disclosures for payment purposes.

[22] 50 P.S. § 7103; 55 Pa. Code § 5100.4.
[23] 50 P.S. § 7111(a)(1).
[24] 55 Pa. Code § 5100.32(a)(1).
[25] 45 C.F.R. § 164.508(a)(2).