Deadline Here to Comply with HITECH Act’s Restrictions on Uses, Disclosures, and Requests for Protected Health Information

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Introduction

February 17, 2010, marks the one-year anniversary of the Health Information Technology for Economic and Clinical Health Act (HITECH), but not everyone has reason to celebrate. This anniversary date marks the deadline for covered entities, including health plans, health care providers, and health care clearinghouses, to comply with HITECH’s restrictions on the uses of, disclosures of, and requests for protective health information (PHI).

HITECH, an integral component of the American Recovery and Reinvestment Act of 2009 (ARRA), has been touted as the start of a new phase in the evolution of federal law governing the privacy and security of health information. Congress enacted HITECH with the intent to create a national infrastructure for the exchange of health information. HITECH’s “privacy” provisions establish a secure process for the electronic exchange of PHI by enhancing the existing privacy protections available under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Specifically, HITECH’s privacy provisions outline parameters for HIPAA’s “minimum necessary” standard, a key concept in HIPAA, which requires covered entities to make reasonable efforts to use, disclose, and request only the minimum amount of PHI needed

3 See ARRA, supra, note 1, at Title XIII, Subt. D, §13400(1). “Protected Health Information,” commonly referred to as “PHI,” is defined under 45 C.F.R. § 160.103 as “individually identifiable health information held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral.”
4 See ARRA, supra, note 1. Congress passed the American Recovery and Reinvestment Act of 2009 on February 13, 2009, at the urging of President Obama, who signed it into law four days later. Enacted as a direct response to the economic crisis, the ARRA has three immediate goals: (1) create new jobs as well as save existing ones, (2) spur economic activity and invest in long-term economic growth, and (3) foster unprecedented levels of accountability and transparency in government spending. See also United States Government, The Act, available at http://www.recovery.gov/About/Pages/The_Act.aspx.
5 ARRA, supra, note 1 at Title XIII, Subt. D.
7 HIPAA, supra, note 6 at 45 C.F.R. § 164.502(b)(1).
to accomplish the intended purpose of the use, disclosure, or request. As distinguished from HIPAA, HITECH imposes more restrictions on the use of PHI and utilizes a two-tiered approach for analyzing “minimum necessary” PHI. However, HITECH’s restrictions are under a sunset provision and are set to expire in about six months, or before August 17, 2010, the deadline when the U.S. Department of Health and Human Services (DHHS) is under a mandate to issue new guidance on the HIPAA “minimum necessary” standard. DHHS’ new guidance on the “minimum necessary” standard will then replace HITECH’s two-tiered approach.

Until DHHS issues the new “minimum necessary” guidance, covered entities should take heed and implement compliance policies to address HITECH’s restrictions as applicable to PHI. HITECH not only enhances the scope of the HIPAA privacy protections, but it also puts more teeth in HIPAA enforcement efforts with increased potential for audits, formal investigations and greater civil monetary penalties than for HIPAA violations. For the next six months, covered entities could potentially risk exposure to liability if they fail to implement appropriate measures to comply with HITECH’s new, but temporary, restrictions on the uses of, disclosures of, and requests for PHI.

Relationship Between HITECH and HIPAA

HITECH’s privacy provisions and HIPAA’s privacy provisions go hand-in-hand. HITECH not only cites and cross-references various HIPAA definitions and privacy provisions, but it also expressly states the HIPAA privacy rules governing PHI shall remain in effect to the extent they are consistent with the new HITECH privacy rules. DHHS is under a mandate to amend the HIPAA privacy rules, as necessary, to ensure consistency with HITECH.

HITECH’S Two-Tiered Approach for Determining “Minimum Necessary” Compliance

The “minimum necessary” standard for the use and disclosure of PHI is the central aspect of HIPAA’s and HITECH’s privacy provisions. Under HITECH, a covered entity will be compliant with the HIPAA “minimum necessary” standard for use, disclosure, and requests for PHI if the covered entity limits such PHI:

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8 See id. at §§ 164.502(b), 164.514(d); see also U.S. Dep’t of Health & Human Servs., Summary of the HIPAA Privacy Rule, OCR Privacy Brief, at 10, (May 2003), available at http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf.
9 ARRA, supra, note 1, at Title XIII, Subt. D, §13405(b)(1)(B), (C).
11 See generally ARRA supra, note 1, Title XIII, Subt. D.
12 ARRA, supra, note 1 at Title XIII, Subt. D, §13421(b).
13 Id.
…to the extent practicable, to the limited data set…or, if needed by such entity, to the minimum necessary to accomplish the intended purpose of such use, disclosure, or request, respectively.15

What does this mean? It means that covered entities must implement a two-tiered approach when analyzing and determining what PHI it can use, disclose, or request.

Under this rule, a covered entity must first limit any use of, disclosure of, and requests for PHI to a “limited data set” (LDS) to the extent it is practicable. If, however, the covered entity concludes that it needs more information than what is contained within the LDS, then it must analyze and determine what PHI is the minimum amount necessary to accomplish its intended purpose of such use, disclosure, or request, respectively.

First Tier – Restrict Use, Disclosure and Requests to Limited Data Set

HITECH does not define LDS, but rather, cross references HIPAA’s definition of the same term.16 Under HIPAA, a LDS is a subset of PHI, in which 16 specified direct identifiers of the individual, or the relatives, employers, or household members of the individual, have been removed.17 Although health information in an LDS is not directly identifiable, it may contain more identifiers than “de-identifiable data.”18

HITECH requires the LDS recipient to enter into a data use agreement,19 yet HITECH fails to reference the need for a data use agreement. Presumably, however, since a HIPAA data use agreement would be consistent with HITECH, the requirement for a data use agreement probably still stands.

Second Tier – Restrict Use, Disclosure and Requests to the “Minimum Necessary” to Accomplish the Intended Purpose

Most health care providers may find that it is not practical to use the LDS for purposes of payment and health care operations, and thus, will need to go through the process of analyzing and determining the “minimum necessary” PHI it can use. Despite the significance of the “minimum necessary” standard, neither HITECH nor HIPAA defines “minimum necessary.” While DHHS is expected to issue guidance on what constitutes “minimum necessary” by no later than August 17, 2010,20 during this interim period, covered entities are left to their own resources for implementing policies.

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15 ARRA, supra, note 1 at Title XIII, Subt. D, § 13405(b)(1)(A) (emphasis added).
16 ARRA, supra, note 1 at Title XIII, Subt. D, § 13405(b)(1)(A). HITECH defers to the HIPAA definition of “limited data set,” as defined in 45 C.F.R. § 164.514(e)(2).
17 HIPAA, supra, note 5 at 45 C.F.R. § 164.514(e)(2).
19 HIPAA, supra, note 5 at 45 C.F.R. § 164.514(e)(1), (4).
20 ARRA, supra, note 1 at Title XIII, Subt. D, § 13405 (b)(1)(B).
Hopefully, by now, most covered entities have existing HIPAA “minimum necessary” protocols, policies, and procedures in place and can rely on these as the baseline for revamping and updating the policies to comply with HITECH. Regardless of whether an entity is starting from scratch or simply needs to revise its policies, it is worthwhile to review previously published guidance documents from DHHS and its Office of Civil Rights (OCR) on the “minimum necessary” standard.\(^{21}\)

According to the OCR, the “minimum necessary” standard is derived from confidentiality codes and practices in common use today.\(^{22}\) It is based on the sound current practice that PHI should not be used or disclosed when it is not necessary to satisfy a particular purpose or carry out a function.\(^{23}\) The OCR separately addresses policies and procedures for uses, disclosures of, and requests for PHI, and advises covered entities to evaluate their practices and enhance safeguards as needed to limit unnecessary or inappropriate access to and disclosure of PHI, as follows:\(^{24}\)

**Uses of PHI:** Covered entities must develop and implement policies and procedures that identify: (1) the persons or classes of persons within the covered entity who need access to the information to carry out their job duties, (2) the categories or types of PHI needed, and (3) the conditions appropriate for such access.\(^{25}\) Where the entire medical record is necessary, the covered entities’ policies and procedures must state so explicitly and include a justification.\(^{26}\)

**Disclosures and Requests for PHI:** Covered entities must also establish and implement policies and procedures for routine, recurring disclosures or requests.\(^{27}\) Such policies and procedures must limit the PHI disclosed or requested to that which is the minimum amount necessary for that particular type of disclosure or request.\(^{28}\) Individual review of each disclosure or request is not required.\(^{29}\)

For non-routine, non-recurring disclosures or requests, covered entities must develop reasonable criteria for determining and limiting the disclosure or request to only the minimum amount of PHI necessary to accomplish the purpose of the non-routine disclosure or request.\(^{30}\) Non-routine disclosures and requests must be reviewed on an individual basis and limited accordingly.\(^{31}\)

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\(^{22}\) Id.

\(^{23}\) Id.

\(^{24}\) Id.

\(^{25}\) Id.

\(^{26}\) Id.

\(^{27}\) Id.

\(^{28}\) Id.

\(^{29}\) Id.

\(^{30}\) Id.

\(^{31}\) Id.
It is significant to note that, under HIPAA as distinguished from HITECH, a covered entity is permitted discretion to reasonably rely on the judgment of certain parties requesting the disclosure as complying with the minimum necessary standard. HITECH seemingly prohibits this discretionary reliance, and instead, imposes the duty solely on the covered entity to determine what constitutes the minimum necessary to accomplish the intended purpose for such disclosure.

Conclusion

There is an approximate six-month window from the time HITECH’s new “minimally necessary” restrictions become effective on February 17, 2010, until the time they will expire on or before the deadline of August 17, 2010, when DHHS must issue its new guidance on what constitutes “minimally necessary” for purposes of using, disclosing or requesting PHI. Even though these restrictions will be short-lived, they should not be overlooked. Covered entities need to take steps to update and revise their HIPAA “minimally necessary” PHI policies and procedures to ensure compliance with the same, or otherwise, they may face the potential for greater civil monetary penalties than under HIPAA.

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32 Id.
33 ARRA, supra, note 1 at Title XIII, Subt. D, § 13405(b)(2).