ROBERT GELLMAN
Privacy and Information Policy Consultant **202-543-7923**
419 Fifth Street SE **bob@bobgellman.com**
Washington, DC 20003 **www.bobgellman.com**

Policy Misdiagnosis: The Myth of Patient Consent in the Clinton HIPAA Health Privacy Rule

Version 1.5
May 9, 2017

Abstract: It is a myth that the Bush Administration's changes to President Clinton's HIPAA privacy rule significantly affected the role of consent for health information disclosures for treatment, payment, or health care operation purposes. In practice, consent for these disclosures under the Clinton rule was not meaningful. Separately, the Bush changes corrected a loophole that would have greatly expanded the use of health information for marketing.

Introduction and Summary

Although the federal health privacy rule known as HIPAA (Health Insurance Portability and Accountability Act) is only 15 years old, not many are aware of its origins. The story of the early days of the HIPAA rule is important because it gave birth to a myth that the first version of the privacy rule provided for robust patient consent and that a later version of the rule weakened that consent provision. It is the purpose of this document to review the history, dispel that myth, and show why the second version of HIPAA is more protective of privacy than the first version.

The Department of Health and Human Services issued the first final version of the HIPAA privacy rule at the end of 2000, just before the end of the Clinton Administration. The incoming Bush Administration made changes, and the health care sector began compliance with second final version of the privacy rule, as modified by the Bush Administration, in 2003. The Bush changes are the source of the misunderstanding.

Some look back on the Clinton version of HIPAA as providing a grand, privacy-affirming policy because it appeared to require patient consent for disclosures for treatment, payment, and health care operations. However, it is a myth that the Clinton version of HIPAA offered patient consent that was meaningfully better than the version of the rule that the Bush Administration put into effect. This is so because in fact, the Clinton policy offered patients no real ability to decline to consent to uses and disclosures for treatment, payment, and health care operations. The difference between the Clinton and Bush policies on consent was largely procedural.

In addition, the Clinton policy allowed all covered entities to use patient information for third party marketing purposes without patient consent and only subject to a later opt-out by the patient. If implemented, the Clinton marketing policy would have damaged the privacy of patients by allowing much health information to pass beyond the privacy protections in the HIPAA privacy rule and into the hands of marketers and database vendors. The Bush version of

HIPAA changed the marketing rule to prevent use or disclosure for third-party marketing without advance approval from the patient.

On balance, the Bush version of the rule was more protective of patient privacy because (1) there was no meaningful difference between the way that the Bush rule treated disclosures for treatment, payment, and health care operations and the way the Clinton rule treated those disclosures; and (2) because it prevented nonconsensual uses for third party marketing. The change in the Clinton marketing rule by the Bush Administration represented a major improvement in patient privacy.

Background and Procedural History

The Department of Health and Human Services published two separate final HIPAA privacy rules. One came during the Clinton Administration, and the second during the Bush Administration. This document reviews elements of the two versions of the final HIPAA privacy rule that pertain to obtaining consent for the use and disclosure of protected health information for treatment, payment and health care operations. HIPAA practitioners often refer to these three activities as TPO (treatment, payment, and health care operations). It is the TPO disclosures that are at the heart of the Clinton HIPAA consent myth.

As used in the HIPAA privacy rule, *consent* refers to the process by which a patient[1] gives approval for the use and disclosure of protected health information for TPO. The rule uses the term *authorization* to refer to the process by which a patient gives approval to the use and disclosure of protected health information for any purpose other than TPO. These two terms became the source of confusion, and some use the terms incorrectly or interchangeably. While a distinction between *consent* and *authorization* remains in the rule, the difference is not material.

HHS first published the HIPAA health privacy rule for comment during the Clinton Administration on November 3, 1999.[2] HHS published the final HIPAA health privacy rule on December 28, 2000.[3] This publication happened just a few weeks before the end of the Clinton Administration. HHS intended that effective date for the rule would be sixty days after Federal Register publication. The compliance date – when covered entities had to comply with the rule – was two years later.

However, under 5 U.S.C. § 801, a rule cannot normally take effect until the later of 60 days following publication in the Federal Register or the date on which Congress receives a report of the rule from the agency that issued the rule. [4] Because of an error, Congress did not receive the required congressional report until February 13, 2001. That date was after the end of the Clinton Administration and after the start of the Bush Administration.

---

[1] HIPAA uses the term *individual* to refer to data subjects protected by the rule because not all data subjects are patients (e.g., the beneficiary of a health insurance policy may not be a patient). However, it is common practice to refer to HIPAA data subjects as *patients*, and this paper uses the common terminology. The term also covers the patient's authorized representative.

[2] http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/1999nprm.pdf.

[3] http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/prdecember2000all8parts.pdf.

[4] https://www.law.cornell.edu/uscode/text/5/801.

The Clinton failure to submit the proposal on time may have contributed to the ability of the Bush Administration to reconsider the rule. Although the Bush Administration later modified the rule, the compliance date did not change. The rule required covered entities to comply two years after the date of submission to the Congress, or on April 14, 2003.[5]

On February 28, 2001, the Bush Administration sought public comment on the final Clinton rule.[6] A year later, on March 27, 2002, HHS published for comment modifications to the final Clinton rule.[7]

Finally, on August 14, 2002, HHS published the final rule with the Bush Administration modifications to the Clinton rule.[8] The current rule is codified at 45 C.F.R. Parts 160, 162, 164.[9]

The Clinton Rule on Consent for TPO

The final Clinton rule generally allowed a covered entity to use or disclose protected health information (PHI) for treatment, payment, and health care operations (TPO) pursuant to a written patient consent.[10] The rule allowed non-consensual uses and disclosures for TPO (1) if a health care provider has an indirect treatment relationship with a patient; (2) the patient is an inmate of a prison; (3) under certain emergency treatment situations; (4) if treatment is required by law but the provider cannot obtain the necessary consent; or (5) if communications barriers prevent obtaining consent.[11] The first of the consent exceptions – indirect relationship – applies to a

---

[5] http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/dates.pdf.
[6] http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2001_register&docid=01-4811-filed.pdf.
[7] http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/2002proposedmods.pdf.
[8] http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/privrulepd.pdf.
[9] http://www.ecfr.gov/cgi-bin/text-idx?SID=97b92e5463dabeb76fb0ec990d8c6340&mc=true&tpl=/ecfrbrowse/Title45/45CsubchapC.tpl.
[10] 45 C.F.R. § 164.502. Uses and disclosures of protected health information: general rules.
(a) Standard. A covered entity may not use or disclose protected health information, except as permitted or required by this subpart or by subpart C of part 160 of this subchapter.
(1) Permitted uses and disclosures. A covered entity is permitted to use or disclose protected health information as follows:
(i) To the individual;
(ii) Pursuant to and in compliance with a consent that complies with § 164.506, to carry out treatment, payment, or health care operations;
(iii) Without consent, if consent is not required under § 164.506(a) and has not been sought under § 164.506(a)(4), to carry out treatment, payment, or health care operations, except with respect to psychotherapy notes;
(iv) Pursuant to and in compliance with an authorization that complies with § 164.508;
(v) Pursuant to an agreement under, or as otherwise permitted by, § 164.510; and
(vi) As permitted by and in compliance with this section, § 164.512, or § 164.514(e), (f), and (g).
[11] § 164.506. Consent for uses or disclosures to carry out treatment, payment, or health care operations.
(a) Standard: consent requirement. (1) Except as provided in paragraph (a)(2) or (a)(3) of this section, a covered health care provider must obtain the individual's consent, in accordance with this section, prior to using or disclosing protected health information to carry out treatment, payment, or health care operations.
(2) A covered health care provider may, without consent, use or disclose protected health information to carry out treatment, payment, or health care operations, if:
(i) The covered health care provider has an indirect treatment relationship with the individual; or
(ii) The covered health care provider created or received the protected health information in the course of providing health care to an individual who is an inmate.

significant number of health care activities. Still, the Clinton requirement for affirmative patient consent applied to most treatment and payment activities.

The Clinton consent rule included two important implementation specifics. The rule provided that a health care provider may condition treatment on an individual's signing of a consent that met the requirements of the rule. The second provision allowed a health plan to condition enrollment in the plan on the signing of a consent that met the requirements of the rule.[12]

Had the rule been implemented as written by the Clinton Administration, it is highly likely that nearly all health care providers and that all health plans would have insisted that patients sign consents for TPO uses and disclosures as a condition of treatment or enrollment. It is also likely that health plans would have required providers to obtain patient consent as a condition of participating in the health plan's network.

Prior to the HIPAA privacy rule, it was common for patients to be asked to sign consent forms when they visited a doctor's office. In a typical consent form, a patient authorized the provider to disclose "any or all information" to a health insurer and to others. Patients signed the forms, often without reading or understanding the forms. Patients rarely had the opportunity to negotiate changes to the forms. If patients changed the form on their own, their changes had little or no effect on actual practice.

In a pre-HIPAA paper, I wrote about the shortcoming of consent as a method for protecting patient privacy. I called it the *paradox of informed consent*. The paradox is that "giving the patient more of a say in the disclosure of health records for payment results in the patient having less actual control." The explanation reflects the state of health care payments in the late 1990s.

---

(3)(i) A covered health care provider may, without prior consent, use or disclose protected health information created or received under paragraph (a)(3)(i)(A)-(C) of this section to carry out treatment, payment, or health care operations:

(A) In emergency treatment situations, if the covered health care provider attempts to obtain such consent as soon as reasonably practicable after the delivery of such treatment;

(B) If the covered health care provider is required by law to treat the individual, and the covered health care provider attempts to obtain such consent but is unable to obtain such consent; or

(C) If a covered health care provider attempts to obtain such consent from the individual but is unable to obtain such consent due to substantial barriers to communicating with the individual, and the covered health care provider determines, in the exercise of professional judgment, that the individual's consent to receive treatment is clearly inferred from the circumstances.

(ii) A covered health care provider that fails to obtain such consent in accordance with paragraph (a)(3)(i) of this section must document its attempt to obtain consent and the reason why consent was not obtained.

(4) If a covered entity is not required to obtain consent by paragraph (a)(1) of this section, it may obtain an individual's consent for the covered entity's own use or disclosure of protected health information to carry out treatment, payment, or health care operations, provided that such consent meets the requirements of this section.

(5) Except as provided in paragraph (f)(1) of this section, a consent obtained by a covered entity under this section is not effective to permit another covered entity to use or disclose protected health information.

[12] 45 C.F.R. § 164.506 (b). Implementation specifications: general requirements. (1) A covered health care provider may condition treatment on the provision by the individual of a consent under this section.

(2) A health plan may condition enrollment in the health plan on the provision by the individual of a consent under this section sought in conjunction with such enrollment.

> Because third party payment is the rule today rather than the exception, the signing of a consent form is not an event that triggers concern or suspicion. Written by insurance companies and health care providers, consent forms allow broad disclosure without any conditions or restrictions. Health care providers – who may share their patients' concern about confidentiality – nevertheless want to be sure that they can make disclosures necessary for payment. The effect of the informed consent model is to protect the interests of all parties except the patient.[13]

The Clinton rule did not give patients any clear rights to refuse demands by a provider or an insurer. The Clinton rule did not require providers or plans to negotiate terms governing the use and disclosure of PHI for TPO. If a provider or insurer asked a patient to sign a consent form, the patient who refused to sign the form as presented could be denied treatment or coverage.

In effect, the Clinton rule gave patients the theoretical right to refuse to sign a consent form, but the price of not signing was denial of treatment or insurance. The policy might be called *sign or die*. The patient who refused to sign the consent could be lawfully denied treatment by any covered health care provider and coverage by any health insurer. The right to consent under these circumstances is a figment. Coerced consent is not consent.[14]

Keep in mind that while the Clinton rule offered the appearance of a right to consent to use and disclosure for TPO, the rule also allowed for many non-consensual uses and disclosures.[15] The non-consensual uses and disclosures included those (1) required by law; (2) for public health activities; (3) for health oversight activities; (4) for judicial and administrative proceedings; (5) for specified law enforcement purposes; (6) for research purposes; (7) for national security and intelligence activities; and others. The Bush rule retained all of these non-consensual uses and disclosures with minor adjustments. Thus, neither the Bush nor the Clinton versions relied exclusively on patient approval for the use and disclosure of PHI. Both allowed for many non-consensual uses and disclosures. The biggest difference on consent, at least nominally, between the two versions related to consent for uses and disclosures for TPO.

The Bush Rule on TPO Uses and Disclosures

The Bush Administration changed the Clinton approach to uses and disclosures for TPO. In place of the requirement that a patient sign a consent form to allow the uses and disclosures for TPO, the Bush rule provided that uses and disclosures for TPO could be made without patient consent. In explaining the change when publishing the final rule in 2002, the Department of Health and Human Services discussed some of the practical problems that would have resulted from had consent been required:

---

[13] Robert Gellman, *The Privacy of Health Information and the Challenge for Data Protection*, presented at the Eighth International Conference of the Observatory "Giordano Dell'Amore" on the Relations Between Law and Economics, Stresa, Italy (May 1997), http://bobgellman.com/rg-docs/rg-health-consent-97.pdf.

[14] By contrast, treatment generally cannot be denied in either the Clinton or the Bush version of the privacy rule if a patient refuses to sign an authorization for other types of disclosure.

[15] See 45 C.F.R. § 164.512.

* Pharmacists would not have been able to fill a prescription, search for potential drug interactions, determine eligibility, or verify coverage before the individual arrived at the pharmacy to pick up the prescription if the individual had not already provided consent under the Privacy Rule.

* Hospitals would not have been able to use information from a referring physician to schedule and prepare for procedures before the individual presented at the hospital for such procedure, or the patient would have had to make a special trip to the hospital to sign the consent form.

* Providers who do not provide treatment in person may have been unable to provide care because they would have had difficulty obtaining prior written consent to use protected health information at the first service delivery.

* Emergency medical providers were concerned that, if a situation was urgent, they would have had to try to obtain consent to comply with the Privacy Rule, even if that would be inconsistent with appropriate practice of emergency medicine.

* Emergency medical providers were also concerned that the requirement that they attempt to obtain consent as soon as reasonably practicable after an emergency would have required significant efforts and administrative burden which might have been viewed as harassing by individuals, because these providers typically do not have ongoing relationships with individuals.

* Providers who did not meet one of the consent exceptions were concerned that they could have been put in the untenable position of having to decide whether to withhold treatment when an individual did not provide consent or proceed to use information to treat the individual in violation of the consent requirements.

* The right to revoke a consent would have required tracking consents, which could have hampered treatment and resulted in large institutional providers deciding that it would be necessary to obtain consent at each patient encounter instead.

* The transition provisions would have resulted in significant operational problems, and the inability to access health records would have had an adverse effect on quality activities, because many providers currently are not required to obtain consent for treatment, payment, or health care operations.

* Providers that are required by law to treat were concerned about the mixed messages to patients and interference with the physician-patient relationship that would have resulted because they would have had to ask for consent to use or disclose protected health information for treatment, payment, or health care operations, but could have used or disclosed the information for such purposes even if the patient said no.[16]

[16] http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/privrulepd.pdf, 67 Fed. Reg. 53209 (Aug. 14, 2002).

Experience in the State of Maine with a patient consent regime supports the concerns expressed by HHS. In 1998, a Maine health privacy law required written consent for many health disclosures. The patient consent law was so unpopular and impractical that the Maine legislature suspended the law shortly after it took effect. The revised law replaced many of the requirements for written consent with expanded authority for nonconsensual disclosures.[17] The new Maine law provided for nonconsensual treatment and payment disclosures.

The Bush rule added two features. First, it *allows* a covered entity to obtain consent from a patient for TPO uses and disclosures.[18] Thus, any covered entity that chooses to operate under a TPO consent regime is free to do so. It appears that few do today. Second, the rule generally requires a direct treatment provider to make a good faith effort to obtain a written acknowledgment of receipt of the provider's notice of privacy practices.[19] Thus, when a patient appears in a doctor's office for treatment, the patient should be presented with a form to sign.

However, there is often misunderstanding about the meaning of the signature. Many patients and many receptionists think that the form is an authorization for disclosure of PHI, and they think that a signature is mandatory. However, the rule does not actually require that a patient sign the acknowledgement. Signing the acknowledgement has little legal significance. Some question the value and the expense of obtaining these mostly meaningless signatures. The collection of a signature has become its own ritual activity, frequently disconnected from actually offering or providing the patient with a copy of the notice of information practices.

The Bush rule did not change one partially relevant aspect of the Clinton HIPAA privacy rule. HIPAA provides that stronger state laws ("more stringent") remain in effect and that the federal rule does not preempt the state law.[20] Thus, HIPAA did not preempt any state law requiring affirmative patient consent for TPO.

The Clinton Rule on Marketing

The Clinton rule permitted several uses for communications with patients that might be seen as marketing uses.[21] One allowed face-to-face communication made by a covered entity to a patient. Another allowed promotional gifts of nominal value provided by the covered entity.

---

[17] See Robert Gellman, *Consent for Disclosure of Health Records: Lessons from the Past* (2007), http://bobgellman.com/rg-docs/RG-Maine-1998.pdf.

[18] 45 C.F.R. § 164.506(b)(1).

[19] 45 C.F.R. § 164.520(c)(2)(ii).

[20] 45 C.F.R. § 160.203.

[21] 45 C.F.R. § 164.514(e)(1) Standard: uses and disclosures of protected health information for marketing. A covered entity may not use or disclose protected health information for marketing without an authorization that meets the applicable requirements of § 164.508, except as provided for by paragraph (e)(2) of this section.
(2) Implementation specifications: requirements relating to marketing. (i) A covered entity is not required to obtain an authorization under § 164.508 when it uses or discloses protected health information to make a marketing communication to an individual that:

(A) Occurs in a face-to-face encounter with the individual;

(B) Concerns products or services of nominal value; or

(C) Concerns the health-related products and services of the covered entity or of a third party and the communication meets the applicable conditions in paragraph (e)(3) of this section.

These remained substantially unchanged in the Bush rule and are not at issue here.

However, the Bush Administration prohibited another class of marketing activities that the Clinton rule allowed – the third party marketing provision. This third party marketing provision in the Clinton rule allowed a marketing communication to a patient that concerns the health-related products and services of the covered entity *or of a third party* if the communication meets the applicable conditions. The conditions were that the marketing communication must (1) identify the covered entity making the communication; (2) disclose any payment to the covered entity for making the communication; (3) provide an opt-out except for general communications via newsletter or the equivalent; and (4) explain why a communication based on health condition targeted the individual.

The scope of the Clinton third party marketing provision was broad. Any covered entity could make marketing communications to an individual at the behest of any third party. Covered entities include health care providers, health plans, and health care clearinghouses. When a patient visits a physician, information about that encounter could routinely be shared with a health plan, pharmacy, pharmacy benefit manager, one or more laboratories, x-ray facility, health care clearinghouse, and others. A family of four with routine health care encounters could easily have relationships with dozens of covered entities. Under the Clinton rule, every one of those covered entities (and, perhaps, their business associates as well) could use PHI to make marketing communications. To opt-out of further marketing, that family might have to send dozens of opt-out requests, some to indirect providers previously unknown to the family.

Information about a patient who responded to a marketing communication could easily leak out from the privacy protections of HIPAA and become available without restriction for additional use and disclosure. Consider a diabetic patient targeted by a pharmaceutical manufacturer through a communication from the patient's health care provider. If the patient responded to the communication directly to the pharmaceutical manufacturer, the manufacturer would know by

---

(ii) A covered entity may disclose protected health information for purposes of such communications only to a business associate that assists the covered entity with such communications.

(3) Implementation specifications: requirements for certain marketing communications. For a marketing communication to qualify under paragraph (e)(2)(i) of this section, the following conditions must be met:

(i) The communication must:

(A) Identify the covered entity as the party making the communication;

(B) If the covered entity has received or will receive direct or indirect remuneration for making the communication, prominently state that fact; and

(C) Except when the communication is contained in a newsletter or similar type of general communication device that the covered entity distributes to a broad cross-section of patients, enrollees, or other broad groups of individuals, contain instructions describing how the individual may opt out of receiving future such communications.

(ii) If the covered entity uses or discloses protected health information to target the communication to individuals based on their health status or condition:

(A) The covered entity must make a determination prior to making the communication that the product or service being marketed may be beneficial to the health of the type or class of individual targeted; and

(B) The communication must explain why the individual has been targeted and how the product or service relates to the health of the individual.

(iii) The covered entity must make reasonable efforts to ensure that individuals who decide to opt out of receiving future marketing communications, under paragraph (e)(3)(i)(C) of this section, are not sent such communications.

virtue of the targeting that the patient had diabetes, along with any other status or conditions specified by the targeting conditions (e.g., age, other diagnoses, type of insurance, current treatment, etc.) agreed to by the health care provider. Any patient information in the hands of that pharmaceutical manufacture would not be subject to HIPAA or any other health privacy law. The information could be freely sold, shared, and used for the remainder of the patient's life. The Clinton third-party marketing policy may have been the most anti-privacy feature of the HIPAA rule.

The third party marketing provision was too much for the Bush Administration. The Bush changes to the marketing provisions made the rule clearer, simpler, and more privacy protective. The first change eliminated entirely the possibility of non-consensual marketing communications on behalf of third parties. That was a major advance for privacy. Other changes were relatively modest, clarifying the definition of marketing and requiring an express patient authorization for marketing communications.[22]

Conclusion

The written patient consent required by Clinton Administration's rule for uses and disclosures of PHI for TPO was not a meaningful consent. It was not true consent because any patient refusing to sign a standard consent form could be denied treatment by a health care provider or enrollment by a health insurer. Under those conditions, the ability to consent is illusory. It is a Hobson's choice, a coerced consent. Nearly all patients would have no choice at all. The Bush rule basically took away the illusion of consent.

Further, the Clinton rule allowed any covered entity to use patient information for marketing of third party goods and services without patient authorization and subject to an opt-out. The Clinton marketing rule would have allowed much patient information to leak into the databases of marketers and others not subject to the HIPAA privacy rule or any privacy law. The Bush Administration dropped the Clinton marketing rule and replaced it with a more standard provision that required express patient authorization.

The Bush Administration's change to the TPO consent rule did not meaningfully change patient rights, while its change to the marketing rule was a substantial improvement for patient privacy. On balance, the Bush Administration changes on consent for TPO and for marketing represented a significant gain for the privacy of patients.

The argument here is a narrow one. The argument should not be read to suggest that the HIPAA rule is without flaws; that the Bush changes are uniformly good or that the Clinton rule was uniformly bad; that there either is or is not a role for consent in controlling the use and disclosure of patient information. On these broader subjects, there is much to debate.

Finding the right balances between the interests of individual patients, the interests of other participants in the health care system, and the interests of the public at large remains a challenge for health privacy and for the health care system in general. There are many different

[22] 45 C.F.R. § 164.508(a)(3). The Bush rule dropped the marketing provisions in the Clinton rule that had been at 45 C.F.R. § 164.514(e). It also made modest changes to the definition of marketing.

perspectives on striking those balances. However, it should not be assumed that patient consent for TPO disclosures always is good or practical, benefits patients, or is actually something that patients really want.