Statement Regarding the HHS Secretary’s Section 1135 COVID-19 HIPAA Waiver

May 11, 2020

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Brief Summary of Analysis and Recommendations

There are two distinct types of HIPAA waivers in place during the COVID-19 national emergency: COVID-19-specific administrative waivers issued in March and April 2020, and a January 2020 waiver authorized by a 2004 statute.¹

COVID-19-specific administrative waivers: The three administrative waivers are the Telehealth waiver, the Business Associate waiver, and the Community Based Testing Sites waiver.

¹ In this document, when we say "statutory" HIPAA waiver, we mean a waiver expressly authorized by statute. Three HIPAA waivers -- Telehealth, Business Associate, and Community Based Testing Sites dating March 13, April 2, and April 9 respectively -- are administrative waivers.
**Statutory waiver:** Section 1135 of the Social Security Act gives the Secretary of HHS express authority to waive a variety of health regulatory requirements during a national emergency. That statute allows for waiver of some provisions of the HIPAA health privacy rule. When a HIPAA-related statutory waiver is in effect, HHS does not enforce selected provisions of the HIPAA privacy rule. In the past, hurricanes, floods, and other natural disasters created a need for the HIPAA waiver. The first time HHS used the statutory HIPAA waiver was for Hurricane Katrina in 2005.

The COVID-19 public health emergency, however, is not like Hurricane Katrina, and created a much different type of emergency. Instead of a HIPAA waiver geographically restricted to one or two affected states, and instead of a waiver period spanning a few weeks or months, the COVID-19 crisis involves the entire United States, and the crisis is likely to extend for a year or more.

What this means is that for all patients in healthcare settings covered by the waiver, HHS will not enforce important HIPAA privacy rights, including the right to confidential communications.

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The relevant part of this statute provides:

(b) Secretarial Authority To the extent necessary to accomplish the purpose specified in subsection (a), the Secretary is authorized, subject to the provisions of this section, to temporarily waive or modify the application of, with respect to health care items and services furnished by a health care provider (or classes of health care providers) in any emergency area (or portion of such an area) during any portion of an emergency period, the requirements of subchapters XVIII, XIX, or XXI, or any regulation thereunder (and the requirements of this subchapter other than this section, and regulations thereunder, insofar as they relate to such subchapters), pertaining to—

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(7) sanctions and penalties that arise from noncompliance with the following requirements (as promulgated under the authority of section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note)—

(A) section 164.510 of title 45, Code of Federal Regulations, relating to—

(i) requirements to obtain a patient’s agreement to speak with family members or friends; and

(ii) the requirement to honor a request to opt out of the facility directory;

(B) section 164.520 of such title, relating to the requirement to distribute a notice; or

(C) section 164.522 of such title, relating to—

(i) the patient’s right to request privacy restrictions; and

(ii) the patient’s right to request confidential communications.

Congress amended this section of law several times during the COVID-19 emergency. Section 102 of Public Law 116-123 gave the Secretary of HHS authority to temporarily waive or modify application of certain Medicare requirements with respect to telehealth services furnished during certain emergency periods. [https://www.govinfo.gov/link/plaw/116/public/123](https://www.govinfo.gov/link/plaw/116/public/123). Section 6010 of Public Law 116-127 clarified the Secretary’s authority regarding Medicare telehealth services furnished during the COVID–19 emergency period. [https://www.govinfo.gov/link/plaw/116/public/127](https://www.govinfo.gov/link/plaw/116/public/127). Neither amendment expanded the Secretary’s waiver authority with respect to HIPAA.
WPF suggests that the activation of the statutory HIPAA waiver carries with it more risks than HHS was able to consider when declaring the COVID-19 emergency and applying the waiver. While the statutory waiver works well during brief, geographically limited emergency situations, a national-level emergency that continues for one or more years requires a different approach. It should not be the case that so many patients in the U.S. lose some existing HIPAA privacy rights for a long and perhaps indefinite period. The current emergency has lasted long enough to ask for reconsideration of the effect on privacy rights.

**WPF recommends:**

- That the HHS Secretary end the statutory HIPAA waiver in a month or two or three, with the possibility of limiting the waiver in specific, discrete areas where the frequency of COVID-19 justifies a continued public health emergency.

- That the HHS Secretary seek comments from stakeholders on appropriate timing for limiting or ending the statutory waiver.

Debates about reopening the U.S. economy are ongoing. The guidance thus far calls for a phased lifting of restrictions, with attention paid to areas of flare-ups. This same reasoning should apply to the statutory HIPAA waiver. Patients of healthcare providers covered by the statutory waiver, whether treated for COVID-19 or otherwise, should not be deprived of HIPAA rights for so long. Instead, HHS should take a more granular approach that will not affect patients for longer than is necessary.

**Background on Statutory HIPAA Waiver as applied in the COVID-19 Crisis**

During a national emergency, the Secretary of Health and Human Services can waive sanctions and penalties that might be imposed for noncompliance with these five requirements in the HIPAA privacy rule:

1. The requirement to obtain a patient’s agreement to speak with family members or friends involved in the patient’s care (45 CFR 164.510(b))

2. The requirement to honor a request to opt out of the facility directory (45 CFR 164.510(a))

3. The requirement to distribute a notice of privacy practices (45 CFR 164.520)

4. The patient’s right to request privacy restrictions (45 CFR 164.522(a))

5. The patient’s right to request confidential communications (45 CFR 164.522(b))
The Secretary first exercised the Section 1135 HIPAA waiver authority on September 4, 2005, in response to Hurricane Katrina. In numerous subsequent hurricanes and other emergencies, the Secretary invoked the same waiver of HIPAA rules.

During the COVID-19 crisis, the first step to placing the statutory HIPAA waivers came on January 31, 2020, when the Secretary announced his determination that a public health emergency existed because of the “2019 Novel Coronavirus (2019-nCoV)” and that the emergency existed nationwide since January 27, 2020. Then on March 13, 2020, the Secretary used the authority under Section 1135 of the Social Security Act to apply the existing statutorily authorized waiver during the COVID-19 emergency. The March 13 waiver covered all five provisions that Section 1135(b)(7) identified. This action conformed to those taken the previous times when HHS invoked emergency HIPAA waivers.

Specifically, paragraph (7) of the March 13, 2020 announcement provides for the following waiver from five specific HIPAA requirements:

(7) sanctions and penalties that arise from noncompliance with the following requirements (as promulgated under the authority of section 264(c) of the Health Insurance Portability and Accountability Act of 1996)—

(A) section 164.510 of title 45, Code of Federal Regulations, relating to—
(i) requirements to obtain a patient’s agreement to speak with family members or friends; and
(ii) the requirement to honor a request to opt out of the facility directory;
(B) section 164.520 of such title, relating to the requirement to distribute a notice; or
(C) section 164.522 of such title, relating to—
(i) the patient’s right to request privacy restrictions; and
(ii) the patient’s right to request confidential communications.

This provision of law that authorized the HIPAA waiver during public health emergencies originated in Public Law 108-276, the Project Bioshield Act of 2004. The title of Section 9 of that Act is “Authority of the Secretary of Health and Human Services During


### Further Analysis of the Statutory HIPAA Waiver as Applied during the COVID-19 Crisis

The actual text of the March 13 HIPAA waiver is:

> Pursuant to Section 1135(b)(7) of the Act, I hereby waive sanctions and penalties arising from noncompliance with the following provisions of the HIPAA privacy regulations: (a) the requirements to obtain a patient’s agreement to speak with family members or friends or to honor a patient's request to opt out of the facility directory (as set forth in 45 C.F.R. § 164.510); (b) the requirement to distribute a notice of privacy practices (as set forth in 45 C.F.R. § 164.520); and (c) the patient’s right to request privacy restrictions or confidential communications (as set forth in 45 C.F.R. § 164.522); but in each case, only with respect to hospitals in the designated geographic area that have hospital disaster protocols in operation during the time the waiver is in effect.

The last clause is of special interest. It provides that the waiver applies in specific circumstances, namely:

> ..."only with respect to hospitals in the designated geographic area that have hospital disaster protocols in operation during the time the waiver is in effect." [note: emphasis added]

This is the same language used when the Secretary announced previous HIPAA waivers, typically in response to hurricanes, floods, fires, and natural disasters. For those emergencies, the limitation to hospitals within specific and narrow designated geographic areas made sense and acted to place reasonable bounds on the scope of the waiver. For many of the natural disasters, emergency conditions generally lasted for a limited time, for example, for days, weeks, or months.

In light of the original intent and language, the use of the statutory public health emergency authority for HIPAA in response to COVID-19 presents several novel circumstances.

- First, the COVID-19 public health emergency is nationwide.
- Second, the emergency is likely to continue for a significant period of time and perhaps for several years. At this stage, it is not predictable when the emergency might end.
- Third, since the emergency is nationwide, it is not clear what it means that the waivers are limited to "hospitals...that have hospital disaster protocols in operation." It is possible that HHS used the existing formulaic language when invoking the HIPAA waiver without considering its application to the COVID-19 circumstances.
Fourth, it is not clear that the justification for the waiver is limited to hospitals. Other health care providers may also provide COVID-19 services on an emergency basis.

There are several problems here that call for attention now that we are moving from the immediate response stage to assessing the need for adjustments more appropriate to a long-term emergency.

**Should the HIPAA waiver be limited to hospitals that have disaster protocols in place?**

Was it appropriate for the waiver to cover only hospitals and not other facilities providing testing or treatment for COVID-19? It may be that HHS’s use of the ritual language was not appropriate for the long term and may need reconsideration. When the waiver for hospitals is no longer justified, of course, then the need to apply the waiver to other providers may also not be a concern.

**Not all patients at hospitals are COVID-19 patients**

As invoked, the statutory waiver is not limited to COVID-19 patients, although it is understandable that there may be no practical way to distinguish between patients based on diagnosis. This means that the statutory waiver, as currently written, applies to all patients, at qualifying hospitals, including patients not treated for COVID-19. 7

Actions justified as an immediate response to a broad public health emergency may not make sense over a longer term. This may be especially true as health care facilities expand non-emergency treatment over time. By most estimates, the COVID-19 crisis will continue for a year and more. HHS needs to find a way to limit the scope of the waiver to those parts of the health care system, if any, that require it on a longer-term basis. Otherwise, the waiver impacts the privacy of all patients in the U.S. who seek any treatment at any HIPAA-covered entity during the duration of the crisis.

**Should the waiver of HIPAA rights continue indefinitely, including for COVID-19 patients?**

The broad purpose of the waiver is to lessen the administrative obligations of health care providers confronting overwhelming public health emergencies. However, the rights provided under the HIPAA privacy rule remain important and should be restored at some point. The question here is when should those rights be restored, given that the public health emergency may not end for the foreseeable future, and COVID-19 patients deserve the rights granted by the rule when the need for the waiver diminishes.

**Recommendations**

1. **HHS needs to adjust the statutory waiver now that it is clear that the emergency may last a long time.**

WPF proposes that the activation of the statutory HIPAA waiver carries with it more risks than HHS was able to consider when declaring the emergency and applying the waiver. While the statutory waiver works well during brief, geographically limited emergency situations, a national-level emergency that continues for one or more years

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7 We recognize that nothing requires hospitals covered by a waiver to deny patients the rights waived. Our concern is that many hospitals will take the path of least resistance and use the waivers too liberally.
calls for a different approach. It should not be the case that so many patients in the U.S. lose existing HIPAA privacy rights for what may be an indefinite period.

WPF recognizes the delicate balancing of interests necessary here, and we are not questioning actions taken at the initial moment of crisis. It is time, however, to look forward and to search for reasonable limits.

One way for the HHS Secretary to proceed is to propose ending the statutory HIPAA waiver in a month or two or three, perhaps with the possibility of limiting the waiver to specific, discrete areas where the frequency of COVID-19 justifies a continued public health emergency.

2. **HHS should seek stakeholder comments on appropriate limitations for a continued waiver, including the timing for limiting or ending the waiver.**

We recommend that the Secretary seek comments from stakeholders on appropriate timing for limiting or ending the waiver. This could be accomplished through a formal comment process to ensure transparency and responsiveness.

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*Note:* This discussion covers only the statutory HIPAA waiver cited. The Office of Civil Rights announced three additional circumstances in March and April, 2020 under which it would exercise its enforcement discretion for violations of HIPAA rules. These additional waivers, which in this document we call administrative waivers, cover telehealth, business associates, and community-based testing sites, raise other concerns that are not addressed here. WPF issued separate statements about the three administrative 2020 HIPAA waivers.8

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