O R A C L E
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Direct Liability of Business Associates

In 2009, Congress enacted the Health Information Technology for Economic and Clinical Health (HITECH) Act,**1** making business associates of covered entities directly liable for compliance with certain requirements of the HIPAA Rules. Consistent with the HITECH Act, the HHS Office for Civil Rights (OCR) issued a final rule in 2013 to modify the HIPAA Privacy, Security, Breach Notification, and Enforcement Rules.2 Among other things, the final rule identifies provisions of the HIPAA Rules that apply directly to business associates and for which business associates are directly liable.3

As set forth in the HITECH Act and OCR's 2013 final rule, OCR has authority to take enforcement action against business associates only for those requirements and prohibitions of the HIPAA Rules as set forth below.

Business associates are directly liable for HIPAA violations as follows:

1st Failure to provide the Secretary with records and compliance reports; cooperate with complaint investigations and compliance reviews; and permit access by the Secretary to information, including protected health information (PHI), pertinent to determining compliance.4

2nd Taking any retaliatory action against any individual or other person for filing a HIPAA complaint, participating in an investigation or other enforcement process, or opposing an act or practice that is unlawful under the HIPAA Rules.5

3rd Failure to comply with the requirements of the Security Rule.6

4th Failure to provide breach notification to a covered entity or another business associate.7

5th Impermissible uses and disclosures of PHI.8

6th Failure to disclose a copy of electronic PHI (ePHI) to either the covered entity, the individual, or the individual's designee (whichever is specified in the business associate agreement) to satisfy a covered entity's obligations regarding the form and format, and the time and manner of access under 45 C.F.R. §§ 164.524(c)(2)(ii) and 3(ii), respectively.9

7th Failure to make reasonable efforts to limit PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.10

8th Failure, in certain circumstances, to provide an accounting of disclosures.11

9th Failure to enter into business associate agreements with subcontractors that create or receive PHI on their behalf, and failure to comply with the implementation specifications for such agreements.12

10th Failure to take reasonable steps to address a material breach or violation of the subcontractor's business associate agreement.13

For example, where the business associate's agreement with a covered entity requires it to provide an individual with an electronic copy of his or her ePHI upon the individual's request and the business associate fails to do so, OCR has enforcement authority directly over the business associate for that failure. (*See* No. 6 above.)

By contrast, OCR lacks the authority to enforce the "reasonable, cost-based fee" limitation in 45 C.F.R. § 164.524(c)(4) against business associates because the HITECH Act does not apply the fee limitation provision to business associates. A covered entity that engages the services of a business associate to fulfill an individual's request for access to their PHI is responsible for ensuring that, where applicable, no more than the reasonable, cost-based fee permitted under HIPAA is charged. If the fee charged is in excess of the fee limitation, OCR can take enforcement action against only the covered entity.

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Potential Advantages and Disadvantages of Electronic Instructions for Use (eIFUs) for Medical De-vices

Questions? Request more information from our specialists

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EMERGO BY UL SUMMARY OF KEY POINTS:

- India has become the latest medical device market whereby regulators have begun accepting electronic indications for use (eIFU) for registrations.
- Manufacturers can realize advantages of utilizing eIFU but should consider how eIFU may impact other design, labeling and user interface issues.
- Markets including the US and European Union already recognize eIFU for medical device premarket submissions.

Recently, the Indian Ministry of Health & Family Welfare granted that instructions for use (IFU) for medical devices and equipment can take an electronic form, thereby eliminating the need for printed instructions.

In doing so, India joined a growing list of other markets including the US and the European Un-ion that allow instructions to take this form; a form that is widely being called an eIFU (electron-ic instructions for use). This action is likely to be replicated by many more regulators who recognize that an eIFU saves paper and offers some usability advantages as compared to printed instructions.

Advantages of eIFU

What are some of the potential advantages of an eIFU?

- Availability. Paper IFUs can become separated from their associated devices, such as a dialysis machine or blood gas analyzer. The IFU could be lost or placed in a remote storage location and, therefore, effectively unavailable to the device user at the point of use/care. An eIFU stands a chance of remaining accessible to kit users if the manufacturer assembling it supplies it with integrated, electronic instructions. Presuming a means to display the eIFU at the point of use/care, the content should be persistently available.
- Interactivity. eIFUs open the door to more advanced, interactive design. Whereas a paper IFU is a static resource, an eIFU can incorporate dynamic elements, such as animations and confirmations pertaining to pending and completed steps. An eIFU can even incorporate voice prompts and provide direct access to a help line via the Internet.
- Durability. While printed documents might be subject to wear (e.g., tearing, fading, abrasion, staining, bio contamination), eIFUs are not.
- Adaptability. eIFUs can be easily changed and updated. If there is a technical flaw in a printed IFU, it can become an ordeal to fix it, often requiring a new version that brings with it high pro-duction and distribution costs. An eIFU can be updated periodically via the Internet, which offers great economies, speed, and assurance that text and graphical instructions are updated as needed.
- Local language. eIFUs can handily present content in many possible languages, leaving it to the user to choose as she might when arriving at a webpage that presents many language options.

eIFU disadvantages to consider

What are some of the potential disadvantages of an eIFU, or outright obstacles to instructions assuming an electronic form? Here are a couple of important considerations:

- (Also) Availability. Even for eIFUs that are compatible with various devices such as smartphones, tablets and laptop computers, one can envision scenarios in which a means to display the eIFU at the point of use/care is unlikely to be available. This could be the case for many devices (e.g., certain incubators, syringe pumps, sphygmomanometers) that do not have an embedded computer display suited to displaying instructions, perhaps due to a device's small size or need to continuously display critical information that should not be displaced by instructions. Also, in emerging and developing markets, the spread of eIFUs may be inhibited by lack of access to suitable technology. And one more concern is that it might be time consuming to access an eIFU embedded in a device's software user interface, requiring the users to navigate to the instructions via multiple steps.
- Parallel access. In cases in which eIFU content appears on a device's primary screen, it might become awkward or even untenable for the user to switch back and forth between instructional content and a device's primary user interface in order to sort through a particular task requiring guidance. Moreover, warnings that might normally be continuously present when using a print-ed IFU would only be present intermittently, potentially reducing their effectiveness at critical junctions of device use. Of course, this problem is eliminated if an eIFU is presented on a supplemental display (i.e., a tablet computer).
- Design quality. For some companies, it is enough of a challenge to design printed instructions that are legible, readable, clear, concise, and accurate. In fact, shortcomings in the design of IFUs are well chronicled and have led regulators to issue guidance on how to create good ones. Turning IFUs into eIFUs might fulfill many needs but also pose new challenges. Such challenges include presenting the instructional content in accordance with a simple conceptual model that people immediately "get;" partitioning instructions properly and logically among multiple screens; and enabling intuitive and swift navigation among various eIFU sections. And, some of the same challenges associated with designing printed instructions remain, including differentiating information according to its importance; displaying graphics where they can be more helpful and pleasing than text; presenting warnings in an attention-getting manner; and ensuring narrative content is clear and comprehensible by the intended users. Manufacturers need to take care not to change the instructions in a manner that changes a device's user interface to the degree that it requires a new round of human factors validation testing and regulatory approval.

Making instructions electronic opens the door to interactive elements that can greatly improve their utility, but this requires an investment in high-quality user interface and instructional material de-sign. Meanwhile, printed instructions are not an endangered species. There will always be a place for them in a world in which many medical devices will not be computerized themselves and a viewing screen is not nearby. Even though most users will own a handheld or tabletop device on which they could display an eIFU, some users will undoubtedly feel more comfortable and confident with a paper version in-hand; one that enables them to quickly browse a Table of Contents, highlight key points or make hand-written notes in the margin, and earmark pages--even if in a "low-tech" manner.

Labeling and user interface issues

And now, a final word about eIFUs. They are unquestionably here to stay, and will without doubt become more sophisticated, interactive and widespread. Still, keep in mind that instructions for use (including eIFUs) are part of a device's "labeling," which is part of a device's user interface in the US FDA's view. Properly performed human factors testing is important, whether the instructions are written on paper or on a smartphone.

FDA accepts patient labeling supplied in several formats, including patient brochures and leaflets, user manuals and videos.

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Design Control Documentation is important from the start.

The FDA cited a Wilkesboro, North Carolina device manufacturer following a July 2018 inspection that revealed problems with the firm's design control procedures.

Hinson and Hale Medical Technologies' design control procedures didn't define quality system requirements for design documents and records, the investigator found.

The agency said it needed the missing documentation to support a 510(k)-marketing application. "The firm's missing design plans were necessary to ensure that the supporting device test records submitted with the 510(k) were complete and accurate," the FDA said.

Microsoft is going to ship a full Linux kernel in Windows 10 a.k.a HELL has frozen over solid.

Available in testing this summer

By Tom Warren@tomwarren May 6, 2019, 7:24pm EDT

Microsoft has surprised many in the Linux developer community in recent years. Surprises have included bringing things like adding the Bash shell to Win- dows, or native OpenSSH in Windows 10, and even in- cluding Ubuntu, SUSE Linux, and Fedora all in the Windows Store. Microsoft is now going even further, with plans to ship a full Linux kernel directly in Windows 10.

"Beginning with Windows Insiders builds this Summer, we will include an in-house custom-built Linux kernel to underpin the newest version of the Windows Subsystem for Linux (WSL)," explains Microsoft pro- gram manager Jack Hammons. "The kernel itself will initially be based on version 4.19, the latest long-term stable release of Linux. The kernel will be rebased at the designation of new long-term stable releases to ensure that the WSL kernel always has the latest Linux good- ness."

Microsoft's integration of Linux in Windows 10 will interface with a user space installed via the Windows Store. It's a big shift for Microsoft and marks the first time that the Linux kernel will be included as part of Windows. It sounds like this Linux kernel integration will be available later this year, with a Windows 10 update that's codenamed 19H2.

For developers it should dramatically improve the performance of Microsoft's Linux subsystem in Windows. Microsoft is also promising to update this kernel through Windows Update, and it will be fully open source with the ability for developers to create their own WSL kernel and contribute changes.

In the near past or light years ago in computer time, Microsoft called Linux a "cancer" in the computer world! *Fake news.* The fact is AI developers use Linux and will not use Windows OS. Dell has released four new laptops with Linux OS for AI developers. Write this on the bathroom wall "In time Linux will become 'the' OS for all."

R. I. P.

Let's all take a moment to remember this wonderful cat who passed at age 7. She helped millions of people smile all over the world - even when times were tough.