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HEALTH LAW VITALS

A Healthcare Newsletter from Haynes and Boone, LLP

MAY 2016

QUICK SHOTS

CMS issues Final Rule regarding 60-day deadline for reporting and returning of overpayments. **Read more.**

HHS issues Final Rule modifying HIPAA to allow identification of people disqualified from possessing firearms due to certain mental health issues. **Read more.**

HHS begins next phase of audits of entities and business associates to determine compliance with HIPAA. **Read more.**

Alabama federal judge grants summary judgment for defendants in AseraCare False Claims Act case, finding that the DOJ could not predicate falsity on conflicting opinions of medical experts. **Read more.**

FTC releases new web-based tool for mobile health app developers. **Read more.**

OCR HIPAA Guidance for Mobile Health Developers

Kenya Woodruff and Jennifer Kreick

Kenya Woodruff

Jennifer Kreick

With the recent increase in health information technology, developers in this area are finding themselves facing a web of complex federal and state regulations and are often left with more questions than answers. However, the cost of hiring legal advisors and experts to help untangle this web can be insurmountable for some individuals and start-up companies. An interactive web platform released by the U.S. Department of Health & Human Services Office of Civil Rights ("**OCR**") could help those trying to navigate some of these difficult issues.

In October 2015, OCR launched a web platform for mobile health developers to help identify and address issues specific to developers of health information technology with regards to the Health Insurance Portability and Accountability Act ("**HIPAA**"). The site allows users to interact with OCR by submitting questions and receiving feedback directly from OCR and other users of the site and also acts as a repository for guidance and links helpful to mobile health developers. As explained on the site, OCR recognizes that there is "an explosion of technology using data about the health of individuals in innovative ways to improve health outcomes."[1] However, many developers of this technology may be unfamiliar with HIPAA and its regulations. OCR is using this site to understand what guidance on HIPAA regulations would be helpful to developers. If users wish to submit a question or comment, they must register with the site using their email address; however, their identities and email addresses remain anonymous to OCR.

In February 2016, OCR published a set of six specific scenarios on the site to assist developers in determining when HIPAA applies to them. OCR emphasized that the scenarios are highly dependent on the facts and circumstances, and that even a slight change in facts could change the analysis. For example, OCR stated that when a consumer downloads a health app to her smartphone and populates it with her own information (such as blood glucose levels and blood pressure readings she obtained herself using home health equipment), the app developer is not a business associate under HIPAA. OCR made clear that the developer in

this scenario is not creating, receiving, maintaining, or transmitting protected health information ("**PHI**") on behalf of a covered entity or business associate.

Likewise, if a consumer uses a health app that is designed to help her manage a chronic condition and then adds her own information to the app (even if she downloads the data from her doctor's electronic health record through a patient portal and then uploads it into the app), the developer is still not a business associate, because the consumer obtains the health information from her provider and then inputs it into the app for her own purposes.

OCR also stated that an app developer is not a business associate if a doctor recommends to a patient a particular app to track diet, exercise, and weight, and the patient downloads the app and uses it to send a summary report to her doctors before her next appointment. The developer is not a business associate because the developer is not creating, receiving, maintaining or transmitting PHI on behalf of a covered entity or business associate (note that the patient initiated the transmission to her physician). Thus, although the doctor recommended the app, there is no indication that the doctor hired the developer to provide services to patients involving PHI.

OCR's guidance clarifies that a developer becomes a business associate under HIPAA only when the developer provides goods or services to or on behalf of a covered entity or business associate that involve the use or disclosure of PHI. For example, OCR stated the following scenario would not render an app developer a business associate:

1. a consumer downloads a health app to her smartphone;
2. the consumer requests that her health care provider and the app developer enter into an interoperability arrangement that allows for secure exchange of the consumer's information between the provider's electronic health record and the app;
3. the consumer populates information on the app and directs the app to transmit the information to the provider; and
4. the consumer is able to access her test results from the provider through the app.

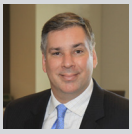
UPCOMING EVENTS

38th Annual Corporate Counsel Institute

Emerging Trends in Insurance 2016: Are You at Risk?

Micah Skidmore

May 5, 2016 | Dallas, Texas



Clear Law Institute

Developing an Effective Audit and Compliance Committee

Sean McKenna
Bill Marsh

May 10, 2016
Webinar

American Health Lawyers Association, Women's Leadership Institute

Mid Career Pivot: Career Transitions

Kenya Woodruff

May 16, 2016 | Nashville, Tennessee

Health Care Compliance Association Conference

Responding to a Compliance Investigation

Sean McKenna

June 3, 2016
Philadelphia, Pennsylvania

In this scenario, the app developer is providing a service to the consumer at the consumer's request and is not using or disclosing PHI on behalf of the covered entity. "The app developer is transmitting data on behalf of the consumer to and from the provider."[2] The interoperability agreement alone is not enough to make the app developer a business associate of the provider since "the arrangement exists to facilitate access initiated by the consumer."[3]

In contrast, an app developer would be a business associate of a provider if the provider "has contracted with app developer for patient management services, including remote patient health counseling, monitoring of patients' food and exercise, patient messaging, EHR integration and application interfaces."[4] The patient, at the direction of her provider, downloads the health app, and the information the patient inputs is automatically incorporated into the provider's electronic health record. In this scenario, the app developer contracts with the provider for certain services that involve the use and disclosure of PHI, and the app is a means for providing the services.

Similarly, an app developer is a business associate if an app is offered by a health plan and the app allows users in the network to request, download, and store health plan records and to check the status of claims and coverage decisions. The health plan "analyzes [the] health information and data about app usage to understand effectiveness of its health and wellness offerings."[5] However, the app developer would not be a business associate of the health plan if it offered a direct-to-consumer version of the app that consumers could use to store, manage, and organize their health records and to send health information to providers, because the product is not provided on behalf of a covered entity or business associate, as long as the app developer keeps the health information in the two versions of the app completely separate.

OCR's web platform provides a unique tool for developers and others in the mobile health industry to interact with OCR and also gain insight into OCR's enforcement perspective. As we continue to see health care technology developments, this platform will likely play an important role in developing and shaping OCR's guidance in this area. **View the web platform and guidance.**

*Portions of this text originally appear in *SMU Science and Technology Law Review*, Vol. XVIII.

[1] Dep't of Health & Human Servs., Office of Civil Rights, **OCR Invites Developers to Ask Questions about HIPAA Privacy Security**, (last visited Apr. 7, 2016).

[2] Dep't of Health & Human Servs., Office of Civil Rights, **Health App Use Scenarios & HIPAA** (Feb. 2016).

[3] *Id.*

[4] *Id.*

[5] *Id.*

New Reimbursement Requirements for Telemedicine Services in School Settings

Michelle "Missy" D. Apodaca and Lissette Villarruel

Michelle "Missy" Apodaca

Lissette Villarruel

On April 15, 2016, the Texas Health and Human Services Commission ("**HHSC**") adopted a Medicaid rule clarifying that physicians must be reimbursed for telemedicine services provided in school-based settings, if certain conditions are met (the "**Rule**"). The Rule becomes effective on May 15, 2016.

The Rule implements HB 1878, which was passed during the 84th Legislative Session. The Rule has been adopted amidst the recent support and expansion of telemedicine services as a method of increasing children's access to medical care. Telemedicine

services have become a focal point for innovative methods of health care delivery, as evidenced by its appearance in both the Senate and House interim charges as well as the recent House Committee on Public Health meeting on telemedicine in Texas.

Currently, regulations allow for the reimbursement of telemedicine and telehealth services under the Texas Medicaid program, subject to certain conditions and limitations. However, the Rule specifies the conditions under which physicians providing telemedicine services in school-based settings can be reimbursed by HHSC, regardless of whether the physician is the child's primary care physician.

Advance Consent

The Rule requires that consent from the parent or legal guardian be obtained before a child receives telemedicine services in a primary or secondary school-based setting. However, the HHSC has not provided guidance on how far in advance or how frequently that consent must be obtained.

Notification Requirements

If the patient has a primary care physician or provider, notification of the telemedicine service must be sent to the physician or provider, with the consent of the patient or the patient's parent or legal guardian. If the telemedicine service is provided in a primary or secondary school-based setting, the notification must include a detailed summary of the service provided.

If the patient does not have a primary care physician or provider and the telemedicine service is provided in a primary or secondary school-based setting, then the child's parent or legal guardian must be given (i) a detailed summary of the service provided and (ii) a list of primary care physicians or providers from which to select the child's primary care physician or provider.

Conditions for Reimbursement

The Rule specifies that telemedicine services offered in school-based settings are reimbursable if:

1. the physician is enrolled as a Medicaid provider;
2. the patient is a child, and the service is provided in a primary or secondary school-based setting;
3. the parent or legal guardian gives consent before the service is provided; and
4. a health professional is present with the patient during the treatment.

The adopted Rule amends Title 1, Section 354.1432 of the Texas Administrative Code and is published in the Texas Register. **View the adopted rule**. **View HB 1878**.

OSHA's Focus on Workplace Violence in the Healthcare Industry

Punam Kaji

Punam Kaji

The Occupational Safety and Health Administration ("**OSHA**") has taken a special interest in workplace violence and more specifically in patient interactions in the healthcare field. Two Haynes and Boone employment lawyers attended the American Bar Association ("**ABA**") Occupational Safety and Health Law Conference in March 2016. One of the panels focused entirely on "Workplace Violence in Healthcare," addressing the advisory guidelines issued by OSHA regarding workplace violence in the healthcare setting and OSHA's use of its General Duty Clause to fine employers and enforce its workplace violence guidance.

More on the General Duty Clause: The Occupational Safety and Health Act (the "**Act**") sets forth how

employers should provide a safe workplace. However, the broad General Duty Clause under section 5(1)(a) of the Act allows OSHA to cite and fine employers for failing to "furnish . . . a place of employment . . . free from recognized hazards that are causing or are likely to cause death or serious physical harm to employees." The Act does not specifically address workplace violence, thus, OSHA has used the General Duty Clause to cite employers for a failure to address workplace violence.

OSHA's Guidance on Workplace Violence in Healthcare: In April 2015, OSHA issued guidance ("**Guidance**") regarding workplace violence in the healthcare and social services industries, which have a higher rate of workplace violence. According to the Guidance, the Bureau of Labor Statistics reported that 27 out of the 100 employee fatalities in healthcare and social service settings that occurred in 2013 were due to assaults and violent acts. While the Guidance intends to help employers prevent dangerous situations, some panelists and attendees at the OSHA ABA Conference criticized the Guidance as creating rules for employers without going through the notice and comment process of administrative rulemaking. Some argue that OSHA should attempt to promulgate a rule regarding workplace violence rather than use the General Duty Clause.

OSHA Cites Employers for Workplace Violence under the General Duty Clause: OSHA has certainly used the General Duty Clause to cite and enforce its position on workplace violence. For example, in *Sec'y of Labor v. Integra Health Mgmt., Inc.*, OSHRC, No. 13-1124, OSHA cited a healthcare employer under the General Duty Clause after a patient with a violent history murdered an employee. OSHA claimed that the patient's violent history presented a known hazard that was not abated by the employer. An Administrative Law Judge affirmed the citations, and the employer appealed to the Occupational Safety and Health Review Commission ("**OSHRC**"). The case hinged on the patient's violent background, which was allegedly known to the employer. As a result of this case, healthcare employers should be particularly wary of situations involving patients with violent tendencies and the resulting obligation to protect the employee. In September 2015, the OSHRC requested briefing on whether the General Duty Clause was lawfully cited, which may add some clarity to this matter. The case is still pending review. Meanwhile, healthcare employers should be aware of this trending topic and how their obligations to provide a safe workplace may evolve.

Developments in the PPACA Contraceptive Coverage Controversy

Christopher Beinecke

Christopher Beinecke

Origins

Under the Patient Protection and Affordable Care Act of 2010 ("**PPACA**"), non-grandfathered group health plans subject to the PPACA's plan design mandates must provide a number of preventive services without cost sharing when the services are received in-network by a covered participant. The inability for a plan sponsor to engage in significant cost shifting and maintain grandfathered status has led to the number of grandfathered plans steadily dwindling over time. The PPACA itself did not directly define which preventive services were covered, instead it identifies them in four categories and outsources their identification as follows:

1. Preventive services receiving an A or B recommendation from the United States Preventive Services Task Force.

2. Immunizations as recommended for individuals by the Centers for Disease Control and Prevention.

3. Preventive services for infants, children, and adolescents recommended by the Health Resources and Services Administration.

4. Preventive services for women recommended by the Health Resources and Services Administration.

This drafting in the PPACA permitted the evolution and expansion of the prevented services mandate over time. The recommendations for preventive services for women eventually appeared and included a requirement that non-grandfathered plans cover a variety of contraceptive services for women starting with the first plan year beginning on or after August 1, 2012 (i.e., January 1, 2013 for calendar year plans).

The Religious Accommodation Compromise

Regulatory guidance released in 2013 exempted the group health plans of religious employers. Religious employers were narrowly defined as houses of worship, with no exemption for many religiously affiliated non-profit organizations or any for-profit organization, however religiously inclined it or its owners happened to be. The 2013 regulations permitted an accommodation for a non-profit, religiously affiliated organization that:

1. On account of religious objections, opposes providing coverage for some or all of any contraceptive services otherwise required to be covered;

2. Is organized and operates as a nonprofit entity;

3. Holds itself out as a religious organization; and

4. Self-certifies that it meets these criteria in accordance with the provisions of the final regulations.

The non-profit religiously affiliated organization would then provide a copy of the certification form to its insurance carrier or third-party administrator ("**TPA**"), who would arrange for the provision and payment of the mandated women's contraceptive services at no cost to the objecting organization. This cost absorption would then be offset by adjustments to the user fees paid by health insurance issuers in the federal public insurance marketplace. It is common for the same legal entity to operate as both an insurer and TPA or belong to a family of closely related legal entities who do, easing the payment by adjustments to the user fees.

Hobby Lobby's victory at the Supreme Court benefits closely held businesses whose owners object to providing the mandated contraceptive services (*Burwell v. Hobby Lobby Stores, Inc.*, 134 S.Ct. 2751 (2014)). The *Hobby Lobby* decision, and many objections about the certification process and its implications for the non-profit, religiously affiliated employers, resulted in further regulatory guidance appearing in August of 2014 (issued as final in 2015). This regulatory guidance softened the process by having a company notify the U.S. Department of Health & Human Services ("**HHS**") by letter that it was requesting the religious accommodation. HHS would then contact the insurer or TPA directly to complete the process. The regulatory guidance also expanded the accommodation to apply to closely held, for-profit entities objecting on religious grounds and defined them as:

1. Entities that are not a non-profit entity;

2. Having no publicly traded ownership interests; and

3. More than 50 percent of the value of the entity's ownership interest is owned directly or indirectly by five or fewer individuals. For this purpose, all of the ownership interests held by members of a family are treated as being owned by a single individual.

The Ongoing Dispute

The U.S. Supreme Court consolidated seven separate cases for review to determine whether the preventive

services mandate violates the Religious Freedom Restoration Act of 1993 ("**RFRA**"). This review is frequently reported in the media as the "Little Sisters of the Poor" case, which is one of the seven cases filed, although the case is officially known as *Zubrik v. Burwell*, because *Zubrik* was the first cased filed.

Under RFRA, the government is barred from imposing a substantial burden on the exercise of religious beliefs, unless the policy or program to be imposed is the least restrictive means the government could use to achieve a compelling government interest. The government argues that women's contraceptive services are a compelling government interest and that the accommodation approach was the least restrictive means to achieve it. Many employers eligible for the accommodation continue to object on the basis that the mandate amounts to a hijacking of their plan and continues to require them to participate in providing the women's contraceptive services that they object to on religious grounds.

The Development

The vacancy on the U.S. Supreme Court resulting from the unexpected death of Justice Scalia creates the potential likelihood for a 4-4 tie in *Zubrik*, which could be problematic due to the somewhat varying results of the lower court rulings for the seven cases. In an interesting development on March 29, 2016, the Supreme Court ordered additional briefs from both sides in *Zubrik* regarding the following issues:

1. How to use the religious non-profit entities' existing insurance providers, but without any involvement by the non-profits other than to have their own health plans without contraceptive benefits (if they wish).

2. How to assure that the coverage is available for the religious non-profit entities' employees through the insurer(s), but without requiring any notice by the non-profit entities.

3. How the religious non-profit entities would contract to provide health insurance for their employees and inform the insurer that they do not want the plan to include contraceptive coverage of the type to which they object on religious grounds. The non-profits would not be required to provide this coverage, pay for this coverage, or be required to provide any notice. The insurers would separately notify the non-profits' employees that the insurer will provide the coverage free of charge outside the non-profits' health plans.

4. Other proposals "along similar lines."

The religious non-profits welcome the move, as it appears to demonstrate the Supreme Court wants to consider options outside of providing the contraceptive coverage through the non-profits' health plans. The progress of and decision in *Zubrik* will be closely followed, not only for the impacts to the seven consolidated cases, but also for what impact, if any, it may have for closely held, for-profit religious employers.

U.S. Supreme Court Reviews the FCA Implied Certification Theory

Nicole Somerville and Phong Tran

Nicole Somerville

Phong Tran

On April 19, 2016, the U.S. Supreme Court heard oral arguments in *Universal Health Services, Inc. v. United States ex rel. Escobar*. The case will decide the fate of the "implied certification" theory of False Claims Act ("**FCA**") liability.

Normally, a defendant violates the FCA by submitting a false claim for payment to the United States. Under the implied certification theory, however,

a defendant may violate the FCA if it submits a proper claim for payment but nevertheless fails to comply with all governing statutory, regulatory, or contractual requirements that are conditions of payment. In these circumstances, the defendant is said to have "impliedly certified" compliance with those requirements merely by submitting the claim for payment.

For years, most courts refused to adopt the theory, concluding that it expanded the FCA beyond its statutory terms. But the First Circuit in *Universal Health* concluded that it could apply in certain circumstances. In that case, the parents of a patient who died from a seizure at a mental health clinic sued the owner-operator of the clinic, Universal Health Services, Inc. The parents alleged that the clinic was unlicensed and out of compliance with state regulations requiring supervision. The parents claimed that the clinic "impliedly certified" compliance with these requirements as a condition of payment every time it submitted a claim for Medicaid reimbursement. As a result, the parents alleged, the clinic had been defrauding Medicaid for years.

The district court dismissed the case. On appeal, the First Circuit reversed. The appellate court rejected distinctions between implied and express certification theories, and instead held that the principal inquiry is "whether the defendant, in submitting a claim for reimbursement, knowingly misrepresented compliance with a material precondition of payment." The court held that preconditions of payment need not be "expressly designated." Rather, it is a "fact-intensive and context-specific inquiry." Because the clinic failed to comply with regulations that "explicitly condition" government payment on compliance, the relators "have provided sufficient allegations of falsity to survive a motion to dismiss."

Universal Health appealed to the Supreme Court, which agreed to resolve two issues: (1) whether the implied-certification theory is viable; and (2) if so, whether liability should be limited to situations where the violation affects an "express" condition of payment.

At oral argument, the Court appeared to accept implied certification as a viable theory, but struggled with how to determine FCA liability when certain regulations are violated. Chief Justice Roberts, in particular, expressed concern that a broad interpretation could expose companies to the heightened risk that whistleblowers could "come in after the fact" and turn noncompliance with obscure regulations into allegations of fraud.

Regardless of the position the Court takes, the decision in *Universal Health* will affect healthcare providers and other contractors who do business with the government. A decision in *Universal Health* is expected by late June 2016.

We'd like to hear your feedback and suggestions for future newsletters. Please contact:

KENYA WOODRUFF
PARTNER | CO-CHAIR - HEALTHCARE PRACTICE GROUP
kenya.woodruff@haynesboone.com

SEAN MCKENNA
PARTNER | CO-CHAIR - HEALTHCARE PRACTICE GROUP
sean.mckenna@haynesboone.com