

Health Law UPDATE

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Ridesharing May Be a Swing and a Miss at Increasing Access to Health Care

Over the past two years, a wave of hospitals, insurance carriers, and practice groups have signed ridesharing agreements in an effort to offer free transportation services to patients to counter no-show medical appointments.

Lyft and Uber are the two big players in these health care ridesharing deals, along with software companies such as Hitch Health, a Minneapolis startup that is pitching clinics and health systems on the idea that making it easier to get to appointments can improve the quality of care and also lower costs. While Lyft and Uber provide the ride, Hitch Health aims to facilitate easy access by patients to these ridesharing services. The company's software connects with a health care provider's electronic health record to identify patients who could benefit from the program and automatically sends a text message offering a ride.

Unfortunately, [a new study from Penn Medicine researchers](#), published in JAMA Internal Medicine, found that offering a free ride to Medicaid patients for an upcoming medical appointment did not, in fact, reduce the rate of missed appointments. The study, which included nearly 800 West Philadelphians who were Medicaid patients at one of two Penn Medicine primary care practices, found that the missed appointment rate for those offered a free ride and those not offered a ride was virtually the same: 36.5 percent and 36.7 percent, respectively. The findings suggest that ridesharing may not deliver the return on investment for which some are hoping.

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House Subcommittee Energizes Push for Opioid Legislation

On March 22, 2018, the U.S. House of Representatives' Energy and Commerce Health Subcommittee concluded [two days of hearings](#) on 25 bills to combat the growing [opioid crisis](#).

The subcommittee heard from the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the Substance Abuse and Mental Health Services Administration (SAMHSA), and other industry stakeholders.

Significantly, Dr. Scott Gottlieb, the FDA Commissioner, indicated that the FDA was investigating ways to limit the number of opioids being prescribed and dispensed. This included possibly revising opioid packaging and labeling to ensure that dosage and duration were consistent with evidence-based guidelines, using unit dose blister packs to encourage shorter duration and fewer leftover pills that could be misappropriated, requiring specific documentation to prescribe above a specific quantity of pills, and educating providers about proper prescribing guidelines. Dr. Gottlieb also stated that the FDA had tripled its import investigators to assist in interdiction of illegal or unlabeled drugs, including fentanyl. To further these efforts, the FDA is seeking to expand its authority to seize or refuse entry into the U.S. of such illegal or unlabeled drugs.

The Subcommittee is one of a number of House and Senate committees seeking bipartisan support to address the opioid crisis.

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U.S. Surgeon General Issues Advisory on Naloxone and Opioid Overdose

As part of our nation's continued focus on the opioid epidemic, the Surgeon General of the U.S. Department of Health and Human Services issued an [advisory](#) earlier last month, urging individuals to become trained in administering the overdose-reversal drug naloxone. The Attorney General stated:

I, Surgeon General of the United States Public Health Service, VADM Jerome Adams, am emphasizing the importance of the overdose-reversing drug naloxone. For patients currently taking high doses of opioids as prescribed for pain, individuals misusing prescription opioids, individuals using illicit opioids such as heroin or fentanyl, health care practitioners, family and friends of people who have an opioid use disorder, and community members who come into contact with people at risk for opioid overdose, knowing how to use naloxone and keeping it within reach can save a life.

In the Advisory, the Attorney General discusses the contributing factors to the opioid epidemic over recent years and the increase in overdose deaths from prescription and illicit opioids. "These highly potent opioids are being mixed with heroin, sold alone as super-potent heroin, pressed into counterfeit tablets to look like commonly misused prescription

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opioids or sedatives (e.g., Xanax), and being mixed (often unknowingly) with other illicit drugs like cocaine or methamphetamine. The resulting unpredictability in illegal drug products is dramatically increasing the risk of a fatal overdose.” The Attorney General explained another contributing factor is the increase in the number of prescriptions written for high doses of opioids for long-term chronic pain management, and the increased risk of accidental overdose and drug-alcohol or drug-drug interactions.

The Attorney General emphasizes expanding awareness and availability of the opioid antagonist naloxone that is used to temporarily reverse the effects of an opioid overdose and, when timely given, can save a life. According to the Attorney General, “increasing the availability and targeted distribution of naloxone is a critical component of our efforts to reduce opioid-related overdose deaths and, when combined with the availability of effective treatment, to ending the opioid epidemic.”

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OIG Examines Vulnerabilities in Home Health Surveys

The United States Department of Health and Human Services, Office of Inspector General (OIG) recently issued a risk alert on the home health agency (HHA) survey process.

Medicare conducts onsite surveys of HHAs to ensure that they are in compliance with Medicare standards. In selecting patient homes for review, Medicare relies on patient lists supplied by the HHAs. OIG is concerned that the HHAs may alter the lists to leave off potentially problematic patients. Surveyors confirmed they are unable to determine whether the lists are complete at the time of the surveys, so they rely on the HHAs to provide accurate data.

In reviewing a sample of the patient lists, OIG realized that Medicare beneficiaries were missing from many of the lists provided by the HHAs. Out of 28 lists reviewed, 19 were complete and nine were missing patients. In one instance, the list was missing 90% of the HHA’s active patients. A related concern is that HHAs appear to be discharging patients to avoid surveyor scrutiny and readmitting them later in the year.

OIG identified the following opportunities for improvement in the survey process:

- Additional data sources could be used in generating the lists.
- Reviews could be done retrospectively based on actual claims data.
- Surveyors could monitor HHAs as the lists are retrieved.

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States Voice Opposition to Proposed Federal Data Breach Law

A bipartisan group of 32 state Attorneys General have written an open letter to Congress urging federal lawmakers to abandon a proposed federal data breach notification law. The bipartisan bill, the Data Acquisition and Technology Accountability and Security Act, which has been proposed in the House Financial Services Committee, aims to develop a standard

streamlined nationwide reporting system for companies collecting personal data and to create steps companies must take to report certain kinds of data breaches to law enforcement officials. Under the Act, which comes in the wake of the massive Equifax data breach, liability would only be triggered if a reasonable risk that the breach of data security has resulted in identity theft, fraud, or economic loss to any consumer,” at which point companies would be required to report to the Federal Trade Commission and state Attorneys General, the entities responsible for policing the law.

The group of state Attorneys General argues, however, that the Act would water down more stringent state laws that require prompt notification so consumers can avoid identity theft, fraud, or losing money in the first place, and would allow companies to avoid disclosing hacks unless consumers are also the victim of a crime. The Attorneys General also argue that despite large nationwide data breaches, most data breaches occur at the local, intrastate level, and the Act would limit states’ abilities to address these breaches. The Act has also been panned by consumer advocate groups who say that the Act raises the bar when companies have to report data breaches, contains provisions exempting insurers and credit agencies despite their checkered history, and would preempt state laws that cover sources of data not protected in the Act, such as online accounts and the internet.

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STATE UPDATE

Data Breaches Spur State Regulatory Probes

Recent high-profile data breaches such as those that occurred at Equifax have sparked heightened interest from state regulators, including the New Jersey Attorney General’s Office. See, for example, our HIPAA Corner article on page 3, summarizing a New Jersey Attorney General action in response to a data breach. Inquiries lodged by state Attorneys General after notification of a data breach incident nearly [doubled nationwide, from 37 in 2016 to 64 in 2017. Non-Attorney General inquiries also jumped from 29 to 43 last year.](#)

Late last year, the New Jersey Attorney General released for the first time [annual statistics on cyber breaches](#). Former Attorney General Christopher S. Porrino announced that 676 data breaches were reported in 2016, affecting more than 116,000 New Jersey accountholders. The former NJ Attorney General also highlighted legal actions taken in 2017 by the Division of Law and the Division of Consumer Affairs to address data breaches. They included a \$2.5 million dollar payout from Vizio Inc, a \$1.1 million settlement with Horizon Healthcare Services, and a \$680,000 payout from Target Corp. as the result of a multistate investigation.

Several factors are driving states’ growing interest in this space, including the lack of consistent action at the federal level with regard to data security, the rise of multistate enforcement actions that have given regulators the funds to invest in forensic firms and advisors that provide a clearer picture of the overall data security of entities under investigation, and the exponential growth of large-scale data breaches affecting thousands of citizens.

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New Jersey Legislative Update

Governor Murphy Expands Medical Marijuana Program—On January 23, 2018, Governor Phil Murphy issued an executive order, [Executive Order 6](#), mandating the Department of Health and the State Board of Medical Examiners to review all aspects of the New Jersey medical marijuana program to remove any potential obstructions. As a follow-up to the executive order, the Governor [unveiled a report](#) on March 23, 2018 from the Department of Health that outlines short, mid-, and long-term changes to the medical marijuana program. The Department of Health report recommends a mix of direct Department of Health actions, regulatory changes, and statutory reforms to create a more “compassionate, progressive program,” according to Governor Murphy. The report expands the list of medical conditions covered under the medical marijuana program, including anxiety, chronic pain related to musculoskeletal disorders, chronic pain of visceral origin, migraines, and Tourette’s Syndrome. In addition, the registration fee for participation in the medical marijuana program will be cut from \$200 bi-annually to \$100 bi-annually.

Separately, on March 5, 2018, bill A3437 was introduced in the New Jersey Assembly to make various revisions to the requirements of New Jersey’s Compassionate Use of Marijuana Act. The bill would expand qualifying conditions for medical marijuana; require issuance of additional dispensary permits; revise requirements for physicians to authorize qualifying patients; and revise application, ownership, and operational requirements for alternative treatment centers.

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Proposed Legislation Regarding Hospital Charitable Assets—On March 5, 2018, bill S2247 was introduced in the New Jersey Senate to allow charitable assets set aside from the sale of a nonprofit hospital to a for-profit entity to be allocated to a successor nonprofit charitable entity that is establishing and operating an equivalent nonprofit hospital. The bill was subsequently introduced in the New Jersey Assembly on March 12, 2018. Under the “Community Health Care Assets Protection Act,” the New Jersey Attorney General must determine an amount of assets to be set aside as a charitable obligation when a for-profit corporation or out-of-state nonprofit corporation acquires a nonprofit hospital, based on the full and fair market value of the hospital at the time of the acquisition. The reversion of assets to a nonprofit charitable entity would occur upon the determination by the New Jersey Superior Court that the allocation of the assets to the acquiring nonprofit charitable entity would be more consistent with the original nonprofit hospital’s purpose.

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Brach Eichler In The News

Lani M. Dornfeld addressed the NJ Medical Group Management Association April 6 on “Curiosity Killed the Cat & Other Common HIPAA Pitfalls.”

Joseph M. Gorrell and **Debra W. Levine** spoke at a NJ Institute for Continuing Legal Education session on “2018 Health Law Fundamentals,” April 12.

Mark Manigan presented “Business Trends in Orthopaedics and New Jersey Regulatory Update” to the New Jersey Orthopaedic Society on April 14.

John D. Fanburg commented on the implications of the new “out-of-network” bill in *NJBIZ*.

To view a full listing of recent news items and to read the articles mentioned above, please visit <http://bit.ly/2tYYFba>.

HIPAA CORNER

ONC Issues Resource Guide Regarding Access to Health Records

The Office of the National Coordinator for Health Information Technology (ONC) recently published a patient and caregiver resource titled, [“The Guide to Getting & Using Your Health Records.”](#) Publication of the guide continues ONC’s focus on educating the public on individuals’ rights to access their health information, including electronically. This continued focus should serve as a reminder that patients and caregivers have become well aware of individual rights under HIPAA, and that health care providers must ensure their staff members are well trained to ensure providers do not violate HIPAA’s requirements.

NJ AG Settles Alleged HIPAA Violations: Reminder for Covered Entities to Vet Third-Party Vendors

Early last month, the State of New Jersey, Office of the Attorney General (AG) and the New Jersey Division of Consumer Affairs (DCA) announced an agreement with Virtua Medical Group, P.A. (VMG) to [settle](#) allegations that VMG “failed to properly protect the privacy of more than 1,650 patients whose medical records were made viewable on the internet as a result of a server misconfiguration by a private vendor.” [View final consent judgement.](#)

According to the AG/DCA announcement, VMG had engaged a medical transcription vendor (a HIPAA business associate) to transcribe dictations of medical notes, letters, and reports by VMG physicians at three of its offices. The vendor updated software on a password-protected File Transfer Protocol website (FTP site) where the transcriptions were stored and, during the update, the vendor unintentionally misconfigured the web server. The FTP site then became accessible without a password. The outcome was that Google searches using search terms containing anything that was in the dictation information resulted in the searcher obtaining medical information, including the documents located on the FTP site. Even after the vendor corrected the server misconfiguration and removed the transcribed documents from the FTP site, “Google retained cached indexes of the files which remained publicly accessible on the internet.” VMG became aware of the issue when a patient called stating that her daughter found portions of her medical records from a VMG office on Google.

“Although it was a third-party vendor that caused this data breach, VMG is being held accountable because it was their patient data and it was their responsibility to protect it,” said Sharon M. Joyce, Acting Director of the Division of Consumer Affairs. “This enforcement action sends a message to medical practices that having a good handle on your own cybersecurity is not enough. You must fully vet your vendors for their security as well.”

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Despite the fact that some items were beyond the direct observation or control of VMG, DCA alleged VMG engaged in additional violations of the HIPAA Security Rule, including:

- Failing to implement a workforce and management security awareness and training program
- Being delayed in identifying and responding to the security incident, mitigating harmful effects of the incident, and documenting the incident and outcome
- Failing to establish and implement procedures to create and maintain retrievable exact copies of ePHI maintained on the FTP site
- Improperly disclosing patient-protected health information
- Failing to maintain a written or electronic log of the number of times the FTP site was accessed.

The takeaways from this settlement are many, including that:

- In addition to oversight and sanctions by the federal Department of Health and Human Services, Office for Civil Rights, HIPAA covered entities and their business associates may be sanctioned by state Attorneys General and other state oversight agencies.
- HIPAA covered entities must properly vet and engage in due diligence of their business associates to ensure they have in place robust HIPAA Privacy Rule and Security Rule programs, periodic risk and gap analyses, risk management plans, workforce training, and appropriate safeguards to electronic protected health information.

- Covered entities should consider negotiating indemnification clauses into business associate contracts, for indemnification by the business associates for business associate acts and omissions that result in penalties to the covered entities.
- Covered entities must ensure they have in place their own robust HIPAA compliance programs, training, periodic risk and gap assessments, risk management plans, and training
- Covered entities must properly investigate and respond to each and every potential or actual privacy breach, to ensure compliance with the requirements of both the HIPAA Breach Notification Rule and state statutes and regulations governing privacy breaches.

For more information or if you need assistance with business associate vetting or contracts, your HIPAA compliance program, risk analysis or training, or in responding to a privacy or security breach or incident, contact:

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