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What 2015 will bring for wearable tech

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Wearable health technology is coming. Expect to check email on your smartwatch by the end of 2015. Your fitness tracking devices will continue to evolve, and you'll be checking more health self-data as it flows through your wrist-based device.

Key legal and regulatory questions regarding these devices are: Does the capture and transmission of health information make your smartwatch, app or fitness tracker a "medical device"? Is the information that flows through such devices subject to HIPAA requirements? When do "business associate agreements" come into play? What state law privacy and security rules apply to wearable health tech? And finally, who owns the data generated from wearables?

Medical Device Advice

To understand federal Food and Drug Administration rules governing wearables, turn to FDA guidance on mobile apps that transmit or store health data. If the intended use of the app is for diagnosis, cure, mitigation or treatment of disease, then the app is a "mobile medical app" subject to FDA medical device regulation. This means the manufacturer must register with the FDA, list the device, follow FDA quality system controls, submit a cybersecurity plan, report adverse events, and comply with other FDA requirements, such as prohibitions against misbranding and adulteration.

The FDA's guidance further clarifies some of the circumstances in which an app is likely considered a mobile medical app (i.e., medical device). These include when: (1) the app is intended to be used as an accessory to a regulated medical device; and (2) the app transforms the mobile platform into a regulated medical device. For example, an app that controls the inflation or deflation of a blood pressure cut-off is an accessory to a regulated medical device; an app that uses an attachment to measure blood glucose levels transforms the mobile platform into a device.

An app that displays, transfers, stores or converts patient-specific medical device data from a connected medical device is probably a mobile medical app. An app that connects to a bedside monitor and transfers the patient's information to a central viewing category might fall within this category.

On the other hand, FDA says that an app is not a mobile medical app when it merely: provides general information about disease; organizes and tracks health information; helps the patient document, show or communication health information; automates simple tasks for providers; or enables patients or providers to interact with an electronic health record. In such cases, compliance with medical device regulation is unnecessary.

By and large, these FDA rules will also apply to wearable health technology. Some wearables will be considered medical devices, as opposed to merely a fitness tracker or storage device.

Year in Review: A look at critical developments in 2014 affecting California practitioners.

Friday, December 19, 2014

Government
Controversial state high court nominee gets sterling rating
A commission that vets judicial nominees has given state Supreme Court nominee Leondra R. Kruger its highest rating of "exceptionally well qualified," a rebuff to critics who complained that the 38-year-old lawyer lacks experience.

Litigation
Potential class action again accuses hedge fund of insider trading in Allergan stock
Investors claiming they lost out in the hostile takeover bid for Allergan Inc. have filed a potential class action against the two companies that made the unusual but failed run at the Irvine maker of Botox.

Intellectual Property
Bizarre petition serves as reminder
Judges have complained for years that patent lawyers don't write in plain English, and the U.S. Supreme Court joined the chorus earlier this month. By **Ben M. Davidson**

Alternative Dispute Resolution
John M. Drath
Drath has been a part-time neutral for years, but continued practicing until recently. He said he realized what a better mood he was in if he woke up knowing he had a mediation ahead, compared to a morning when he had a deposition.

Solo and Small Firms
Preparation Pays
One of the oldest plaintiffs' firms in San Diego, Casey Gerry Schenk Francavilla Blatt & Penfield LLP is best known for its aggressive and relentless stances on litigation.

Litigation
Taxpayers to foot bill to defend civil rights lawsuit against schools
A civil rights lawsuit on behalf of California students allegedly denied a quality education due to disruptive conditions in some high-poverty public schools will get a multimillion-dollar defense by taxpayers.

Ethics/Professional Responsibility

Does HIPAA Apply?

The Health Insurance Portability and Accountability Act, or HIPAA, governs the privacy and security of protected health information - that which is created or received by a health care provider, health plan, employer or health care clearinghouse and "relates to the past, present or future physical or mental health or condition of any individual," among other things.

Compliance is onerous: HIPAA's privacy rule and security rule together impose numerous standards, and implementation specifications for those standards. This means that an organization must do everything from appoint a privacy officer and implement a policy to disclose only minimally necessary protected health information, to implement physical, administrative and technical safeguards to protect against unauthorized breaches of protected health information.

However, HIPAA does not apply universally - rather, it only applies to the transmission of health information in electronic form, in connection with specified transactions (such as submission of health claims to a health insurer). Since data generated by wearables generally is not submitted to insurance electronically - as it often bypasses physicians altogether, and is merely used for health and fitness - HIPAA probably does not apply.

However, even if HIPAA does not apply, state privacy and security laws do. Typically, these state laws prohibit unauthorized disclosure of (1) personal health information, and (2) personally identifiable information, which includes information beyond health-related data. Since many states contain mirror-like HIPAA provisions, it will be prudent for wearable manufacturers of to assess whether they fit the definition of a "business associate" under relevant state law, and are subject to state law compliance concerning either protected health information or personally identifiable information, or both.

As wearable health technology grows more sophisticated, self-data generated by wearables is likely to expand in scope and precision, and to be used in-office (or via telemedicine) as part of understanding the patient's overall health. HIPAA's definition of personal health information is broad, and since HIPAA compliance is a gold standard, it is often prudent to meet HIPAA requirements, even if only state law applies.

Who Owns the Data

HIPAA's privacy rule contains clear rules about the patient's right to review their medical record, make copies and initiate amendments. But in the land of self-data, manufacturers' terms of use control ownership, just as in telemedicine. Companies will draft terms of use and present them as a fait accompli with language that effectively states, "by using our service, you, the user, accept these terms and conditions, including provisions that grant us sole ownership of all the information sent through this website and associated mobile platform or health information technology."

Is privacy dead? Not necessarily. For most, you want your peer group to know that you ran 20 miles this week; or that you ate nothing but carrot juice on Tuesday. You don't want anyone to know that you were diagnosed with Lyme disease or are taking medication to control diabetes.

In other words, health information is shareable; medical information is not. Health sharing is culturally acceptable; medical sharing, prohibited by law. People are willing to boast about their health and wellness, and to share their accomplishments on social media; their diseases and diagnoses, though, are private. They will share everything about their bodies and minds with their friends, except what goes on in the doctor's office. The whole regulatory edifice is built on protecting against inadvertent or inappropriate disclosure of disease information - of information revealed in the officer of a doctor, health plan, employer or health care clearinghouse.

With wearable health technology, we are unsure of the exact divide between wellness and medicine, and wearables blur the distinction. As soon as self-data becomes more widely shared with doctors and part of the patient's medical record, the paradox of extreme protection and extreme self-sharing will manifest more clearly. As will the paradox between legal protections for personal health information and the notion that your telemedicine provider, mobile medical app developer or wearable manufacturer owns your health data.

State laws requiring protection of personally identifiable information and penalizing data breaches will further magnify regulatory conundrums and confuse both consumers and vendors as to who owns what, and why, they must pay if data leaks out.

Tomorrow's Expectations

Long Beach attorney to get 10 years for helping client hide income
Richard C. Brizendine, 59, pleaded guilty to federal financial crimes after structuring shady deals for a marijuana dealer.

Administrative/Regulatory
State chief deputy treasurer to join Manatt
Steve Coony will start in Manatt's Sacramento office on Jan. 1. Coony will serve as a managing director in the firm's government and regulatory practice.

Criminal
Number of executions hits lowest in 20 years
California leads the nation in number of inmates awaiting execution, even as 2014 marks the lowest rate of executions in the U.S. since 1994, according to a report released Thursday.

Personal Injury & Torts
Orange County jury orders FedEx to pay mother $7.5M in wrongful death case
The plaintiff's attorney, Brian J. Panish of Panish Shea & Boyle, said he believes the verdict may be the highest ever awarded in Orange County in a lawsuit by a parent over the wrongful death of a child.

Litigation
Receiver appointed in fight over microgreen company
A judge recently appointed a receiver to run the business operations of a company that grows organic microgreens, finding the current management situation warranted third party oversight until an ownership dispute could be resolved.

Immigration
LA city attorney, bar association team up to fight immigration consulting scams
City Attorney Mike Feuer vows to prosecute scam artists. The cross-jurisdictional partnership will also offer free resources and access to qualified attorneys and consultants.

Litigation
Personal injury attorney slams former employees for denying compensation
Marc I. Willick is aiming for damages from Napoli Bern Ripka Shkolnik LLP over asbestos cases filed in his name without his knowledge.

Criminal
After Supreme Court ruling, prosecutors change tune in Ventura murder case
A week after the Supreme Court ruled a trial judge should have considered arguments for disqualifying a prosecutor in a high-profile Ventura County murder case, the district attorney's office ended its push for the death penalty.

Corporate
Farmer Bros. promotes corporate counsel to GC

For the moment, wearable health tech manufacturers are managing to bypass onerous regulatory burdens, such as compliance with FDA medical device rules, HIPAA and similar state provisions, and any intimation from the consumer protection standpoint that consumers should own their own health data.

As wearable health tech data further enters the medical arena, if only because patients begin sharing the data with their physicians - and data breaches are inevitable - regulatory questions will arise. Companies must know what privacy and security obligations apply, and whether their claim to ownership of patient information goes too far. And policymakers will either conclude that we are under-regulating in an area where companies own all our information - or over-regulating, in an age where nothing is private and everything is shareable.

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Thomas J. Mattei Jr. is the coffee maker and distributor's second general counsel in its 102-year history.

Ethics/Professional Responsibility
San Jose company sanctioned for firm's irrelevant discovery requests
An electronics distributor, represented by the law firm Berliner Cohen, has been slapped with a $4,800 fine for pursuing "wildly irrelevant" discovery requests as it prepares to go to trial over alleged wage and hour violations.

Litigation
Warehouse workers at Port of Los Angeles sue over wage ordinance violations
A group of 500 warehouse workers filed a complaint against their employers, who operate and staff warehouses at the Port of Los Angeles, alleging violations of the city's Living Wage Ordinance.

Bar Associations
Considerations for the State Bar board
On the agenda for the Board of Trustees' regular meeting Friday is a discussion item proposing the appointment of a special commission to evaluate and recommend improvements to the State Bar. By **Teresa J. Schmid**

Ethics/Professional Responsibility
Out-of-state clients: an ethical minefield
With the help of technology, risks once limited to the largest firms now reach virtually every firm. By **J. Randolph Evans, Shari L. Klevens and Suzanne Y. Badawi**

Environmental
Growth pains, little reform for CEQA in 2014
Major California Environmental Quality Act reform continued to be elusive in 2014. By **Nicki Carlsen and Andrew Brady**

2014 saw a wave of environmental law changes
The past year saw several developments in environmental law at both state and federal levels, particularly regarding water supply, water quality and regulation of greenhouse gas emissions. By **Kathryn L. Oehlschlager and David M. Metres**

Perspective
Data breaches and standing: a 38-million-victim question
The number of high profile breaches of personal data seems to be proliferating. Do victims have standing to sue the entity that held the data? By **Erik S. Syverson and Scott M. Lesowitz**

Law Practice
MCLE: Learn the basics of property exempt from money judgments
The object of this article and self-study test is to provide an overview of claims of exemption for judgment debtors. By **Julius O. Abanise**

Judicial Profile
Tracie L. Brown
Superior Court Judge San Francisco County (San Francisco)

Government
Federal prosecutors taking somewhat softer approach toward pot shops
Most U.S. attorney's offices in California do not appear to be pursuing dispenaries as aggressively since an August 2013 memo from Deputy Attorney General James Cole, lawyers say.