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HEALTH LAW DISPATCH

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Health Information Technology

Cybersecurity Risks in Medical Devices

By Meghan V. Hoppe, Esq.

Every medical device carries with it a certain level of risk and benefit. Medical devices are increasingly connected to the Internet and hospital networks to increase the ability of health care providers to treat and monitor patients. These same attributes also increase the risk of potential cybersecurity threats. Like all computer systems, medical devices can be susceptible to ransomware and security breaches, which may impact patient safety and the effectiveness of the device. Specifically, cybersecurity researchers have raised concerns about vulnerabilities in implantable medical devices, such as pacemakers and insulin pumps, that hackers could exploit to injure or even kill patients.

Notably, the wireless functionality of former Vice President Dick Cheney's heart implant was disabled due to fears it might be hacked in an assassination attempt. More recently, the U.S. Department of Homeland Security warned of issues with Medtronic cardio defibrillators that could potentially allow attackers to monitor and take full control of the devices after they are implanted without the patient knowing. In its advisory notice, the U.S. Department of Homeland Security's Cybersecurity and Infrastructure Security Agency said that hackers with "adjacent short-range access" can potentially "interfere with, generate, modify, or intercept" the radio frequency of the devices and allow access to sensitive data.

Several initiatives are underway to preemptively identify cybersecurity risks in medical devices and deploy strategies to combat the threats. In October 2018, the U.S. Food and Drug Administration and the U.S. Department of Homeland Security announced a memorandum of agreement to implement a new framework for greater coordination and cooperation between the two agencies for addressing cybersecurity in medical devices. Concurrently, the U.S. Food and Drug Administration published draft guidance for management of cybersecurity in medical devices that recommends incorporating the NIST Cybersecurity Framework (NIST-CSF), which includes a combination of both technical and procedural interventions into the design and support of devices. Earlier this year, a government-backed coalition of hospitals and medical device manufacturers released a Joint Security Plan outlining protections that manufacturers should implement and that hospitals should request to ensure the security of medical devices.

Medical device manufacturers should take note of the Joint Security Plan and consider implementing some of the voluntary protections to be one step of ahead of potential vulnerabilities. Hospitals must be vigilant in ensuring that appropriate safeguards are in place for any medical devices purchased and used.

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Pharmaceuticals & Life Sciences

CMS Issues Final Rule Requiring Disclosure of Drug Prices in TV Ads

By Daniel O. Carroll, Esq.

On May 10, 2019, the Centers for Medicare & Medicaid ("CMS") published its final rule requiring direct-to-consumer television advertisements for prescription drugs and biological products for which payment is available under Medicare or Medicaid to include the list price of that drug or product. The new CMS rule applies to drugs or biological products with a list price of $35 or more per month or the usual course of therapy. While the rule is intended to improve pricing transparency and incentivize lower list

prices, there is some concern that this information will be misleading and cause confusion with the public. Such confusion could result in patients making poor healthcare decisions. Confusion could arise because most people do not pay list price for their drugs or biological product. The final rule attempts to address this concern by requiring the following sentence to be included in the advertisement: "If you have health insurance that covers drugs, your cost may be different."

The Pharmaceutical Research and Manufacturers of America ("PhRMA") has been critical of the new rule, but maintains that it supports the idea of providing patients with more transparency about the costs of medicine. In October 2018, PhRMA member companies voluntarily began directing patients to links with comprehensive cost information in their direct-to-consumer television ads. On May 8, 2019, PhRMA announced the launch of its Medicine Assistance Tool, a platform to link patients and healthcare providers to more information about the cost of medicine and help patients find medicine-specific financial assistance programs. PhRMA also asserted that the new rule has operational challenges and "raises First Amendment and statutory concerns."

The rule will become effective on July 9, 2019. It remains to be seen if the new rule will achieve its intended effect or if there will be any challenges made against the new rule.

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State Law

New State Law Mandates Parity for Mental Health Conditions and Substance Use Disorders

By Divya Srivastav-Seth, Esq.

Just in time for Mental Health Month in May, Governor Murphy signed a new law, P.L. 2019, Chapter 58, which requires carriers and group health plans that provide hospital or medical expense benefits in New Jersey to provide coverage for mental health conditions and substance use disorders under the same terms and conditions as they provide for any other sickness or physical health issues and to meet the requirements of the federal law known as the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act ("New Law"). The New Law closes certain of the loopholes existing under the federal law and also requires the New Jersey Department of Banking and Industry ("NJDOBI") to enforce parity by comparison of market conditions for medical/surgical benefits with mental health/substance use disorders.

The New Law applies to health service corporations, commercial insurers, health maintenance organizations, health benefits plans issued pursuant to the New Jersey Individual Health Coverage and Small Employer Health Benefits Programs, the State Health Benefits Program, and the School Employees' Health Benefits Program. It requires mental health and substance use disorder benefits to be offered under the same terms and conditions as medical/surgical benefits. As such, a carrier or plan cannot apply more restrictive non-quantitative limitations ("NQTL") or more quantitative limitations such as copayments, deductibles, aggregate or annual limits or benefit limits to mental health condition and substance use disorder benefits than those applied to substantially all other medical or surgical benefits. NQTLs include but are not limited to decisions involving medical necessity, utilization review, reimbursement rates and provider participation terms.

The New Law delegates to NJDOBI the responsibilities of monitoring and ensuring that carriers and plans maintain the required parity. Each carrier or plan offering hospital or medical expenses will have to submit an annual report to NJDOBI that contains information that will enable NJDOBI to verify that the mental health benefits are not subject to more stringent limitations and restrictions than medical/surgical benefits. The New Law also requires NJDOBI to analyze these industry reports and conduct its own internal agency assessments and market conduct examinations regarding parity compliance. NJDOBI must report its findings annually to the New Jersey Legislature. The New Law is effective as of June 10, 2019.

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Healthcare Litigation

Can An Employer Be Held Vicariously Liable For Punitive Damages Based Solely Upon An Employee's Action

By Terrence J. Hull, Esq.

The requirements for a successful punitive damages claim are well-defined under New Jersey case law. Similarly, vicarious liability under the doctrine of *respondeat superior* is equally well-defined. An interesting issue arises when these two areas of law intersect. The question becomes when, if ever, can an entity be held vicariously liable for punitive damages based solely upon an employee's actions? The case law and reasoning below offers strategy when faced with such a scenario.

When a defendant is named on a vicarious liability basis, punitive damages are only applicable when there has been "actual participation by upper management or willful indifference." Cavuoti v. N.J. Transit Corp., 161 N.J. 107, 117 (1999) (quoting Lehmann v. Toys 'R' Us, Inc., 132 N.J. 587, 625 (1993)). Defining "upper management" is a fact-sensitive inquiry. Typically, upper management is comprised of executive officers, the governing body of the company and those who formulate policies relating to day-to-day operations.

"Concerning punitive damages... a greater threshold than mere negligence should be applied to measure" vicarious liability. Lehmann, supra, 132 N.J. at 624. Moreover, punitive damages may not be recovered against an entity or employer for the wrongful act of an individual, unless the act was specifically authorized, participated in, or ratified by the master. Winkler v. Hartford Acci. & Indem. Co., 66 N.J. Super. 22, 29 (App. Div. 1961).

It is clear then, that when an employer is named in a lawsuit on a vicarious liability basis, punitive damages can only be successfully established and pursued by proof of willful indifference or actual participation by upper management, whether that be by corporate authorization, ratification or participation. Specifically, in the healthcare context, hospitals and medical facilities should remain aware of physicians' and administrators' roles in establishing policies and the extent of their participation in all procedures. Given the foregoing, it may be prudent to advise clients of the active participation requirement in relation to vicarious liability claims for punitive damages, in addition to reviewing policies governing day-to-day activity and how participation in the ratification of employee action is undertaken

For a more in-depth review and discussion of the above, please read the full article available on our website.

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