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Health Law UPDATE

February 2019

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FEDERAL UPDATE

2020 Proposed Changes to Affordable Care Act

CMS released on January 17, 2019, the proposed 2020 ACA payment parameters and notice benefits. The intent of the proposal is to lower customer costs and incentivize the public to either obtain health care coverage or continue coverage. This intent aligns with the presidential goal of improving access to health care by providing a better customer experience while simultaneously lowering costs. January's notice provides multiple proposals which impact qualified health plans already on the Exchange, plans in large and small market groups, self-funded groups, as well as the customer. The proposals include lowering the user rate which would result in lower premiums to the customer; changes to prescription drug benefits when generic options are available; allowing issuers to make changes mid-year regarding formulary changes to encourage customers to use generic drug options; revising how risk adjustments are calculated; and incorporating EDGE enrollee data with MarketScan® data, making access easier for customers; adding plans which offer non-Hyde abortion services and plans that do not cover these services; and creating an easier process for individual's to claim hardship by using their tax returns. CMS is seeking comment regarding the proposals for 2020, as well as comments for future proposals by February 19, 2019. The notice also invites the public to comment on other topics. There is a fact sheet available with the highlights.

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Rules Proposed to Improve Access to Electronic Health Information

The U.S. Department of Health & Human Services (HHS) and the Office of the National Coordinator for Health Information Technology (ONC) proposed a new rule to implement provisions of the 21st Century Cures Act (the Cures Act). The proposed rule strives to support the access, exchange, and use of electronic health information (EHI) and address information blocking. The proposed rule promotes the adoption of standardized application programming interfaces (APIs) to support the exchange of health information between providers and patients. The hope is that the health care industry will be able to use this API infrastructure to share EHI in a secure manner with patients through smartphone applications, at no cost. The rule also proposes seven exceptions to the information blocking definition and defines certain activities that would not constitute information blocking, including but not limited to, practices that are reasonable and necessary to prevent harm, protecting the privacy of an individual's EHI, and promoting the security of EHI.

A second rule, proposed by the Centers for Medicare & Medicaid Services (CMS) and HHS, seeks to expand health data exchange among patients and doctors. The rule seeks to allow health information technology to be a resource that makes it faster and easier for providers to deliver high quality care by accessing all available data regarding their patients. For example, when patients receive care from a new provider, a complete record of their health information should be readily available to the new provider regardless of who provided care previously. The proposed rule supports the MyHealthData initiative which aims to break down barriers that prevent patients from gaining access to their health information from the device or application of their choice.

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New Digital Medicine Drug Program that Loans Smartphones to Patients Passes Muster

The Department of Health & Human Services, Office of Inspector General (OIG) recently issued an advisory opinion about whether a drug manufacturer may offer its low-income patients loaner smartphones.

The drug is for the treatment of psychotic disorders and was recently approved by the FDA. This digital medicine drug has multiple components. The patient would ingest a sensor that detects and tracks patient activity levels through a wearable patch. Next, using an application only compatible with iPhones and some Android phones, the patient could also track his or her mood and quality of rest. All this information would be available to the patient's medical providers and caregivers via a website. The problem that the drug manufacturer is seeking to resolve is making the interactive app component of this digital medicine available to low-income patients who do not own a smartphone. By offering a loaner smartphone, low-income patients would gain the ability to collect and track even more data in real time, making the drug more effective.

By way of background, both the Civil Monetary Penalty (CMP) Rule and Anti-Kickback Statute seek to prevent the risk of over-utilization of health care products and services by placing limits on various forms of compensation—in this case, the loaner smartphone.

After analyzing both the CMP Rule and Anti-Kickback restrictions, the OIG decided that this drug program was permissible under the law. Specifically, the OIG decided that the drug program met the "Promotes Access to Care Exception" applicable to both laws. The OIG reasoned that the loaner phone would improve the patient's ability to access his or her full scope of benefits, pose a low risk of harm to patient safety and

quality of care, is unlikely to interfere with clinical decision-making, and is unlikely to result in increased costs to the government payors.

Although this drug may be more expensive than similar alternatives, the OIG gave added value to the additional benefit of its ability to collect and track more data. Along those lines, the drug manufacturer certified to the OIG that the digital medicine drug, along with the app usage, would lower costs to the government payors through increased likelihood of successful treatments from increased patient adherence. This would, in turn, decrease health care utilization costs.

Finally, the OIG made a point to note that the offering would not be advertised to patients, the phone would not have functionality aside from the drug's own application and domestic calling, and patients would not be allowed to keep the loaner phone for more than two 12-week periods. These facts combined were considered sufficient to safeguard against increased patient requests for the drug, and in the OIG's opinion, against risk of fraud and abuse. This OIG opinion may pave the way for drug manufacturers to increase their offerings and presence, at least for interactive digital medicines.

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Texas Prosecution of Multi-Million-Dollar Medicare Fraud Schemes

The Southern District of Texas sentenced two Houston doctors and their co-conspirators to prison terms for their role in defrauding Medicare as a result of the investigative collaboration of the FBI, HHS-OIG, and the Texas Attorney General's Medicare Fraud Strike Force.

In *U.S. v. Ramirez*, (U.S. v. Ramirez, Docket No. 16-cr-00258 S.D.Tex.), the defendants worked together to defraud Medicare for a period of approximately four years by selling false medical orders and other medical documents through the co-defendants "purported" medical clinic. The co-defendants would sell Dr. Ramirez's false medical orders regarding patients' medical conditions and needs to home health agencies in the Houston area. The co-conspirators at the agencies would use the purchased false orders to bill and receive payments from Medicare for services which were not necessary and, in some cases, never provided.

The defendants' actions caused Medicare to pay almost $17 million in false claims. Dr. Ramirez was sentenced to 25 years in prison and an additional three years of supervised release. In addition to a prison sentence, Dr. Ramirez was ordered to pay more than $26.7 million in restitution. One co-defendant was sentenced to 30 years in prison and ordered to pay restitution of more than $20 million and forfeit $250,000. The remaining co-defendant is to be sentenced this April.

In the second case before the Southern District of Texas, *U.S. v. Do*, (U.S. v. Do, Docket No.17-cr-00417, S.D. Tex.), Dr. Do pleaded guilty to conspiracy to commit health care fraud. Dr. Do was ordered to serve three years in prison and then three years of supervised release. In addition to a prison sentence, Dr. Do was ordered to pay more than $1.8 million in restitution and forfeit almost $275,000.

Dr. Do pleaded guilty to conspiracy to commit health care fraud and in pleading "admitted to fraudulently signing Plans of Care and other medical documents that falsely and fraudulently certified and re-certified patients for home health services" when these services were not needed or not provided. In addition to falsely certifying patients' "need" for home health services, Dr. Do and his co-conspirators also fraudulently billed Medicare for diagnostic tests that patients either did not need or were never administered. Medicare paid out an estimated $2 million for fraudulent diagnostic tests and another $10 million for fraudulent home health services.

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EHR Vendor to Pay $57.25 Million Settlement for False Claims Act Allegations

The Department of Justice (DOJ) announced on February 6, 2019 that electronic health records (EHR) vendor Greenway Health LLC has agreed to pay $57.25 million to settle allegations that it caused users of its product, Prime Suite, to submit false claims to the government for incentive payments by misrepresenting the capabilities of the software. The settlement also covers allegations that Greenway violated the Anti-Kickback Statute by paying customers to recommend the product to others. Greenway has not admitted wrongdoing.

The American Recovery and Reinvestment Act of 2009 established the Medicare and Medicaid EHR Incentive Program for health care providers to show "meaningful use" of EHR technology. The incentive payments were available to providers who adopted certified EHR technology. To be a certified EHR product, companies that developed EHR programs were required to satisfy certification standards established by the U.S. Department of Health & Human Services (HHS). The DOJ alleged that Greenway falsely obtained certification for its Prime Suite product by concealing aspects of the program that did not meet HHS standards. The DOJ further alleged that the program was set up to provide inaccurate data to providers, causing Prime Suite users to falsely attest to the government that they were eligible for EHR incentive payments when, in fact, they had not met all the necessary requirements.

As part of the settlement, Greenway entered into a five-year Corporate Integrity Agreement (CIA) with the HHS Office of Inspector General requiring, among other things, that customers of Prime Suite be permitted to obtain the latest versions of the software at no charge, and the opportunity to migrate their data from Prime Suite to another Greenway product at no charge or to another EHR vendor without penalties or fees.

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OIG Proposes Modifications to Protect Discounts from AKS Safe Harbor Scrutiny

The Office of Inspector General (OIG) of the Department of Health & Human Services (DHHS) has proposed a new regulation with the goal of creating incentives to lower list prices and reduce out-of-pocket spending on prescription drugs. If adopted, the proposed regulation would expressly be excluding from safe harbor protection under the Anti-Kickback Statute (AKS) rebates on prescription drugs paid by manufacturers to pharmacy benefit managers (PBMs), Part D plans, and Medicaid managed care organizations. The new regulation would also create a new safe harbor under the AKS that would protect discounts offered to patients at the pharmacy counter from AKS scrutiny. The proposed regulation would create new safe harbor protection for fixed fee services arrangements between manufacturers and PBMs.

According to the OIG, under the current system, rebates offered by drug manufacturers to PBMs, which are typically in the form of a percentage of list price, encourage higher drug prices. However, these rebates are typically not used to reduce patients' out-of-pocket costs. In addition, the current rebate system discourages the use of lower-priced generics and biosimilars by rewarding PBMs for encouraging the use of more expensive brand name pharmaceuticals.

By amending the AKS safe harbors to protect upfront discounts, the new regulation would counteract the incentives behind rising list prices because drug companies would no longer be able to cite their rebate contracts as an excuse to keep raising list prices. In addition, amending the safe harbor regulations to protect reductions in price that are reflected at the point of sale, drug manufacturers would be encouraged to offer discounts that will directly benefit patients by lowering their out-of-pocket costs at the pharmacy counter. Finally, by minimizing the rebates that drug manufacturers can offer PBMs and Part D plan sponsors, the new regulation would eliminate incentives that tend to discourage the use of generic drugs and biosimilars and cause patients to pay more out of pocket. The DHHS fact sheet can be found here.

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STATE UPDATE

New Jersey Legislative Update

Multistate Nurse Licensure Compact Legislation Makes Progress in NJ Senate – On February 7, 2019, the Senate Budget and Appropriations Committee reported favorably on a substitute for S954, with amendments, which would enter New Jersey in the enhanced multistate Nurse Licensure Compact (eNLC), which was implemented on January 19, 2018. The eNLC provides for a mutual recognition model of nurse licensure (for registered professional nurses and licensed practical nurses), in which a nurse only needs to obtain one license from the nurse's state of residence in order to be permitted to practice nursing in any other state that is a party to the compact, as long as the nurse complies with the state practice laws of the state in which the patient is located at the time that care is rendered. Currently, a nurse is required to be licensed in, and by, each state in which the nurse chooses to practice. The eNLC is intended to address the expanded mobility of nurses and the use of advanced communication technologies (telemedicine) by nurses, which requires greater coordination and cooperation among states in the areas of nurse licensure and regulation. The eNLC also establishes a coordinated licensure information system that will include a database on the licensure and disciplinary history of all nurses licensed in the party states. The party states will be required to report to the coordinated system all adverse actions against nurses, including actions against multistate licensure privileges, any current significant investigative information yet to result in an adverse action, and denials of applications and the reasons for the denials.

Legislation Introduced Regarding Maternity Care Protocols – On January 17, 2019, Bill A4930 was introduced in the New Jersey Assembly to establish training protocols and treatment guidelines for general hospitals providing maternity care. The New Jersey Senate introduced a similar bill on January 24, 2019. Under the Bill, each general hospital providing maternity care would be required to follow protocols and guidelines in the following areas as a condition of licensure to ensure the safety of female patients in maternity care:(1) maternal depression and anxiety; (2) maternal venous thromboembolism; (3) obstetric care for women with opioid use disorder; (4) obstetric hemorrhaging; (5) postpartum care basics for maternal safety from birth through postpartum stage; (6) prevention of retained vaginal sponges following birth; (7) reduction of peripartum, racial, and ethnic disparities; (8) safe reduction of primary cesarean birth; (9) severe hypertension during pregnancy; (10) multidisciplinary support following a severe maternal event; and (11) postpartum care basics for maternal safety from maternity to well-woman care.

Legislation Introduced Regarding Alternative Drugs List – On January 17, 2019, Bill A4915 was introduced in the New Jersey Assembly to require health insurance carriers to provide a list of alternative drugs to health care professionals and covered persons under certain circumstances. The New Jersey Senate introduced the identical Bill on February 7, 2019. The Bill requires a carrier that offers a health benefits plan in New Jersey which provides coverage for pharmacy services, prescription drugs, or for participation in a prescription drug plan, to provide to a prescribing health care professional and to a covered person, in a situation where the carrier denies a covered person's coverage for a drug prescribed by the health care professional, a written list of all alternative drugs that are covered by the health benefits plan and that are interchangeable with, and therapeutically equivalent to, the drug for which coverage was denied. The carrier would be required to provide the list of alternative drugs along with the explanation of benefits or other notice of the denial of coverage.

Legislation Introduced to Exempt Certain Surgical Technologists from General Educational and Training Requirements - On January 17, 2019, Bill S3334 was introduced in the New Jersey Senate to exempt certain surgical technologists from general educational and training requirements. An identical Bill was introduced in the New Jersey Assembly on January 28, 2019. The Bill provides that the training and certification requirements for surgical technologists set forth under current law do not apply to surgical technologists who were employed at a surgical practice on January 16, 2018, which was the effective date of a New Jersey law requiring that surgical practices be licensed by the NJ Department of Health as ambulatory care facilities. Formerly, surgical technologists employed at a surgery practice (one OR), were not required to meet certain training and certification requirements that apply to surgical technologists employed at licensed health care facilities, as surgical practices were not licensed by the Department of Health. As a consequence of the enactment of the law requiring licensure, surgical practices now constitute licensed health care facilities, and surgical technologists employed at the existing surgical practices are now required to demonstrate that they either: completed an accredited surgical technologist educational program; hold and maintain a certified surgical technologist credential; completed a military-based or United States Public Health Service Commissioned Corps surgical technologist training program; are in the service of the federal government; or were employed to practice surgical technology in a licensed health care facility on January 16, 2018. If the new Bill becomes law, surgical technologists who were employed at a surgical practice on January 16, 2018 will be exempt from the foregoing training and certification requirements.

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Brach Eichler In The News

Brach Eichler's perspective on multi-state cannabis operators is covered in a February 22 article in *Forbes*.

Lani M. Dornfeld has become Certified in Health care Privacy Compliance by the Compliance Certification Board. Details are contained in the insert to this month's *Health Law Update.*

John Fanburg imparts advice in "3 tips for ASCs in 2019 from a health law attorney" appearing in the February 22 edition of *Becker's ASC Review.*

Keith Roberts commented in *Law360* on February 1 regarding a recent appellate victory involving a doctor's refusal to testify.

Have you registered yet? Our tenth annual **NJ Health care Market Review (NJHMR),** will be held on June 19 - June 20 at the Borgata in Atlantic City, NJ. For more information, click here.

To view a full listing of recent news items and to read the articles mentioned above, please click here.

HIPAA CORNER

OCR Marks 2018 as a Record-Breaking Year for HIPAA Enforcement

The Department of Health & Human Services, Office for Civil Rights (OCR) announced on February 7th a $3 million settlement with Cottage Health for potential HIPAA violations affecting over 62,500 individuals in relation to two data breaches in December 2013 and December 2015. In addition to the settlement, Cottage Health will undertake a robust corrective action plan to comply with HIPAA rules.

By way of background, the first breach arose when unsecured electronic protected health information (ePHI) on a Cottage Health server was accessible via internet without requiring a username and password, due to an issue with the Windows security configuration settings. As a result, certain patient information was available to anyone with access to the server. The second breach occurred when a server was misconfigured following an IT response to a troubleshooting ticket, exposing unsecured ePHI via internet. The same type of ePHI was exposed in this second breach.

OCR's investigation revealed that Cottage Health failed to:

- conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of ePHI;
- implement security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level;
- perform periodic technical and non-technical evaluations in response to environmental or operational changes affecting the security of ePHI; and
- obtain a written business associate agreement with a contractor that maintained ePHI on its behalf.

According to OCR Director, Roger Severino, this "record year underscores the need for covered entities to be proactive about data security if they want to avoid being on the wrong end of an enforcement action. The Cottage settlement reminds us that information security is a dynamic process and the risks to ePHI may arise before, during, and after implementation covered entity makes system changes."

In 2018, OCR settled 10 cases and was granted summary judgment in a case before an Administrative Law Judge for a total of $28.7 million for enforcement actions (surpassing 2016's record of $23.5 million by 22 percent). OCR also achieved the single largest individual HIPAA settlement in history with a $16 million judgment against Anthem, Inc. (surpassing 2016's record of $5.5 million by almost 300 percent).

If you need assistance in managing a breach incident or making any required reporting, or in implementing a HIPAA privacy and security program, please contact::

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BRACH EICHLER LLC

HEALTH LAW **ALERT**

LANI M. DORNFELD
CERTIFIED IN HEALTHCARE PRIVACY COMPLIANCE

Health Law Member Lani M. Dornfeld has recently been given the CHPC® designation (Certified in Healthcare Privacy Compliance) by the Compliance Certification Board (CCB®), an organization that has developed criteria to determine competence in the practice of compliance and ethics across various industries and specialty areas. The CCB® recognizes individuals meeting these criteria through its compliance certification programs and rigorous testing.

This designation adds additional heft to Lani's already robust knowledge of data privacy in the health care industry as well as her ability to assist healthcare providers and business associates with:

- Legal obligations under:
  - HIPAA
  - 42 CFR Part 2 (for substance use disorder treatment records)
  - State identity theft and breach notification laws
- Privacy and security:
  - Policies and procedures
  - Training
  - Breach incident response, investigation and reporting
- Response to government audits and investigations
- Business associate requirements and agreements
- Everyday questions and guidance

According to the CCB®, an individual Certified in Healthcare Privacy Compliance (CHPC®) is "someone with knowledge of relevant regulations and expertise in compliance processes sufficient to assist the healthcare industry in understanding and addressing legal obligations, and promote organizational integrity through the operation of effective compliance programs."*

If you need assistance with developing, updating, or implementing your information privacy and security compliance program, or in responding to a breach incident or government inquiry or investigation, contact Lani at 973-403-3136 or ldornfeld@bracheichler.com.

*www.compliancecertification.org

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