

Healthcare Law UPDATE

FEDERAL UPDATE

President Trump Issues Executive Order on Advancing American Kidney Health

On July 10, 2019, President Trump [issued](#) an executive order to advance American kidney health, in which the President noted his Administration's dedication to the cause. In the executive order, President Trump asserted that "[t]he state of care for patients with chronic kidney disease and end-stage renal disease (ESRD) is unacceptable." Kidney disease was the ninth-leading cause of death in the United States in 2017. The executive order seeks to promote U.S. policies to prevent kidney failure, increase patient choice, and increase access to kidney transplants. The executive order includes initiatives to educate patients and promote kidney disease awareness and encourages the development of new innovations such as the development of artificial kidneys, as there are not enough kidneys donated to meet the current demand for transplants.

Another main component of the executive order is the inclusion of directives to the Secretary of Health and Human Services (HHS) to select payment models aimed at improving the care of individuals with chronic kidney disease and ESRD. The first directive to the Secretary is to select a payment model to identify and treat at-risk populations earlier in disease development. The payment model selected should test innovations in compensation for providers of kidney services based on kidney patient cost and quality outcomes. The second payment model the Secretary is directed to select should increase home dialysis and kidney transplants by adjusting payments based on the percentage of a participating provider's attributed patients who are on home dialysis or have a kidney transplant. Currently, the use of home dialysis in the United States is drastically [below](#) that of other developed nations.

For more information, contact:

Joseph M. Gorrell | 973.403.3112 | jgorrell@bracheichler.com
Keith J. Roberts | 973.364.5201 | kroberts@bracheichler.com
Cynthia J. Liba | 973.403.3106 | cliba@bracheichler.com

MedPAC Makes Recommendations About "Incident To" Rules in Report to Congress

The Medicare Payment Advisory Commission (MedPAC) is an independent congressional agency established to advise the U.S. Congress on issues affecting the Medicare Program. In its June 2019 [Report to Congress](#) on Medicare and the Health Care Delivery System, among other topics covered, MedPAC addressed the "prevalence" of "incident to" billing for Nurse Practitioners (NPs) and Physician Assistants (PAs), and recommended eliminating "incident to" billing for Advance Practice Registered Nurses (APRNs) and PAs.

In relevant part, MedPAC concluded that: "The rapidly expanding number of APRNs and PAs and states' decisions to increase their authority and independence means that Medicare's "incident to" rules increasingly

In This Issue:

Judge Grants Temporary Restraining Order Halting Enforcement of the NJ Assisted Suicide Law

Rite Aid Announces Launch of In-Store Telehealth Kiosks

Brach Eichler in the News

HIPAA Corner

obscure policymakers' knowledge of who provides care to Medicare beneficiaries. Eliminating this type of billing for APRNs and PAs and requiring these clinicians to bill under their own NPIs would change Medicare's billing policies so that claims better reflect which clinicians deliver care, thus enhancing transparency and improving program integrity."

Topics covered in the report include:

- Beneficiary enrollment in Medicare: Eligibility notification, enrollment process, and Part B late enrollment penalties
- Restructuring Medicare Part D for the era of specialty drugs
- Medicare payment strategies to improve price competition and value for Part B drugs
- Mandated report on clinician payment in Medicare
- Issues in Medicare beneficiaries' access to primary care
- Assessing the Medicare Shared Savings Program's effect on Medicare spending
- Ensuring the accuracy and completeness of Medicare Advantage encounter data
- Redesigning the Medicare Advantage quality bonus program
- Payment issues in post-acute care
- Mandated report: Changes in post-acute and hospice care after implementation of the long-term care hospital dual payment-rate structure
- Options for slowing the growth of Medicare fee-for-service spending for emergency department services
- Promoting integration in dual-eligible special needs plans.

For more information, contact:

Lani M. Dornfeld, CHPC | 973.403.3136 | ldornfeld@bracheichler.com
John D. Fanburg | 973.403.3107 | jfanburg@bracheichler.com
Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com

Rite Aid Announces Launch of In-Store Telehealth Kiosks

Rite Aid Corporation has issued a [press release](#) announcing "RediClinic Express," in partnership with telehealth company InTouch Health. According to the press release, "Rite Aid will leverage InTouch Health's virtual care software platform, Solo™ by InTouch, to power the virtual health program to connect patients to clinicians via RediClinic Express kiosks located in Rite Aid stores. Patients will be able to speak with RediClinic clinicians directly via a secure, two-way high-definition audio/video connection."

Further, "[p]atients will have the ability to schedule appointments online, utilize a self-service touchscreen for check-in, or speak with the kiosk's clinical assistant upon arrival for an appointment. Following check-in, patients are escorted to a private kiosk where their vital signs are taken by the clinical assistant and they are asked to fill out a medical questionnaire. Once those steps are completed, the patient is matched with a clinician

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who will review their intake form and medical history from their remote location and then initiate the virtual care visit.”

For more information, contact:

John D. Fanburg | 973.403.3107 | jfanburg@bracheichler.com

Joseph M. Gorrell | 973.403.3112 | jgorrell@bracheichler.com

Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com

FCC's Advanced Methods to Target and Eliminate Unlawful Robocalls Negatively Impacts Providers

“Do not answer.” This is the consumer default in a world where robocalls, spoofs, and spam are a pervasive and intrusive part of everyday life, and the Federal Communications Commission (FCC) is taking action. According to a [May 2019 FCC Fact Sheet](#), “Stopping illegal robocalls to consumers is the Commission’s top consumer protection priority.” These calls are historically problematic, as they are a vehicle for consumer fraud and identity theft as well as a risk to public safety since the calls interfere with emergency services.

In June 2019, the FCC issued a [declaratory ruling](#) and [proposed rules](#) as part of its strategy to curb illegal robocalls. The declaratory ruling clarifies that providers may: (1) “as a default, block calls based on call analytics that target unwanted calls” so long as consumers are informed and may opt-out; and (2) offer consumers “the option to block calls from any number that does not appear on [their] ‘white list’ or contacts list, on an opt-in basis.” Alternatively, the proposed rules increase protection for emergency/official calls and allow providers to block calls that were not caught during the initial authentication process.

While consumers have long awaited the protections offered by the FCC, the Commission’s actions may have unintended consequences for some healthcare providers. A [letter from the American Dental Association](#) (ADA), dated June 28, 2019, petitions the FCC to affirm its commitment to protecting legitimate calls, specifically, the automated calls utilized by healthcare providers as appointment reminders. To protect these calls from being blocked, the ADA proposed dental offices be included on provider white lists. The FCC declined to respond but acknowledged that the ADA’s concern is shared by others.

For more information, contact:

Riza I. Dagli | 973.403.3103 | rdagli@bracheichler.com

Keith J. Roberts | 973.364.5201 | kroberts@bracheichler.com

Lani M. Dornfeld, CHPC | 973.403.3136 | ldornfeld@bracheichler.com

FCC Proposes Pilot Program to Connect Low-Income Consumers to Telehealth

On July 10, 2019, the Federal Communications Commission (FCC) adopted a [Notice of Proposed Rulemaking](#) proposing a three-year pilot program to help bring telehealth services to low-income patients and veterans. The \$100 million Connected Care Pilot program would provide an 85% discount to eligible healthcare providers to defray the costs of providing telehealth services to medically underserved patient populations.

Healthcare providers often purchase broadband internet access service that enables telehealth connected care either through a broadband carrier or a connected care company. The healthcare provider then provides a connected care service, including the broadband internet access service underlying that connected care service, to the patient directly. The Pilot program seeks to incentivize more providers to provide telehealth services directly to those consumers who cannot afford or otherwise lack their own reliable internet connectivity necessary for connecting to a telehealth service directly from their home or mobile device. The Pilot program seeks

to facilitate effective treatment of a wide range of health challenges, particularly chronic conditions including diabetes management, opioid dependency, high-risk pregnancies, pediatric heart disease, mental health conditions, and cancer.

The FCC seeks public comment on issues concerning: (1) funding of the program as a new budgeted program under the USF; (2) determining eligibility to participate in the program, including the types of health care providers and broadband service providers; (3) limiting the program to health care providers in areas with a shortage of health care professionals or with lower-income patients; (4) targeting the program to tribal lands, rural areas, and veteran populations; and (5) targeting the program for those health conditions that have risen to crisis levels.

For more information, contact:

John D. Fanburg | 973.403.3107 | jfanburg@bracheichler.com

Lani M. Dornfeld, CHPC | 973.403.3136 | ldornfeld@bracheichler.com

Susan E. Frankel | 973.364.5209 | sfrankel@bracheichler.com

OIG's Top Recommendations to Reduce FWA

In July 2019, the Department of Health and Human Services (HHS) issued its annual publication, [Solutions to Reduce Fraud, Waste, and Abuse in HHS Programs: OIG's Top Recommendations](#), which is a list of unimplemented HHS programs the Office of the Inspector General (OIG) believes would “most positively affect HHS programs in terms of cost savings, program effectiveness and efficiency, and public health and safety if implemented.”

Besides general recommendations HHS could implement at large, the recommendations span a wide range of different operating divisions including the Centers for Medicare & Medicaid Services, Administration for Children and Families, Food and Drug Administration, Indian Health Service, and National Institutes of Health.

The recommendations vary in specificity from broad (e.g., “CMS should ensure that national Medicaid data are complete, accurate, and timely”), to more precise (e.g., “CMS should implement the statutory mandate requiring surety bonds for home health agencies that enroll in Medicare and consider implementing the requirement for other providers”), with some requiring legislative action. Alongside each recommendation are key findings from the OIG, the status/progress in implementing the recommendation, and relevant reports. Multiple recommendations have been implemented following the release of the 2018 top 25 recommendations.

For more information, contact:

Riza I. Dagli | 973.403.3103 | rdagli@bracheichler.com

Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com

Keith J. Roberts | 973.364.5201 | kroberts@bracheichler.com

Justice Department Announces \$1.4 Billion Resolution in Opioid Case

The U.S. Department of Justice (DOJ) has [announced](#) its “largest ever” recovery in its case against consumer goods conglomerate Reckitt Benckiser Group plc (RB Group). In the DOJ’s press release, the agency stated that RB Group “has agreed to pay \$1.4 billion to resolve its potential criminal and civil liability related to a federal investigation of the marketing of the opioid addiction treatment drug Suboxone. The resolution – the largest recovery by the United States in a case concerning an opioid drug – includes the forfeiture of proceeds totaling \$647 million, civil settlements with the federal government and the states totaling \$700 million, and an administrative resolution with the Federal Trade Commission for \$50 million.”

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The criminal investigation included allegations that RB Group's wholly-owned subsidiary, Indivior Inc., engaged in "an illicit nationwide scheme to increase prescriptions of Suboxone," a drug approved for use by recovering opioid addicts to avoid withdrawal symptoms while they undergo treatment. The civil settlement addressed, among other issues, allegations that RB Group directly or indirectly promoted the sale and use of Suboxone to physicians who were writing prescriptions without counseling or psychosocial support and for purposes that were unsafe, ineffective, and medically unnecessary.

For more information, contact:

Riza I. Dagli | 973.403.3103 | rdagli@bracheichler.com

Lani M. Dornfeld, CHPC | 973.403.3136 | ldornfeld@bracheichler.com

Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com

CMS Updates The Home Health Prospective Payment Systems

Since July 3, 2000, the Centers for Medicare & Medicaid Services (CMS) has adhered to the home health prospective payment system (HHPPS) for payment of home health services. Currently, home health agencies (HHAs) receive payment for their services from Medicare using a predetermined base payment system, and payments are adjusted according to a beneficiary's health condition and needs, clinical characteristics, and the geographic location of where services are being provided. These adjustments are referred to as "case-mix adjustments." The HHPPS has payment periods of 60 days for a beneficiary and there are no limits to the number of home health services periods a beneficiary may receive.

On July 11, 2019, CMS released a proposed rule to modify the HHPPS. The [proposed rule](#) would update the payment rates HHAs receive from Medicare, resulting in an anticipated 1.3 percent increase (\$250 million) in payments made to HHAs in 2020. Rather than using the number of therapy visits provided to determine home health payments, CMS will implement the Patient-Driven Groupings Model, or PDGM. Under the PDGM, agencies will be reimbursed based on patient characteristics rather than the volume of therapy visits. The proposed rule will also allow for physical therapy assistants to furnish maintenance therapy instead of physical therapy alone. In response to the opioid addiction epidemic, CMS has removed the rule requiring HHAs to report on Improvement in Pain Interfering with Activity Measure. CMS is also adding two new measures which coincide with the agency's push for open communication and access to information: "Transfer of Health Information to Provider-Post-Acute Care and Transfer of Health Information to Patient-Post-Acute Care." If approved, the proposed 2019 Rule would be effective for calendar year 2020.

Comments to the proposed rule are due by September 9, 2019.

For more information, contact:

Riza I. Dagli | 973.403.3103 | rdagli@bracheichler.com

Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com

Keith J. Roberts | 973.364.5201 | kroberts@bracheichler.com

STATE UPDATE

Judge Grants Temporary Restraining Order Halting Enforcement of NJ Assisted Suicide Law

On August 14, 2019, just two days shy of the effective date of the New Jersey Medical Aid in Dying for the Terminally Ill Act, a Mercer County Chancery Division judge issued an order temporarily enjoining and restraining the Attorney General of the State of New Jersey from enforcing the law. In the Verified Complaint filed in the action, the plaintiff, Joseph Glassman, M.D., alleged that the law is unconstitutional because, among

other reasons, it violates the fundamental right to defend life and the rights of physicians to freely practice their religions in which human life is sacred and must not be taken; it violates the canon of common law that it is a crime to kill oneself and to aid and abet the death of another; it violates a physician's right to practice medicine by compelling unwilling physicians "to be involved in the machinery of death, by forcing them to transfer patients' records into the hands of those who would facilitate and enable deadly harm to those patients;" and it abrogates the duty to warn.

The hearing in the matter is scheduled for October 23, 2019, at which time the plaintiff is seeking an order permanently enjoining and restraining the New Jersey Attorney General from enforcing the law.

For more information, contact:

Lani M. Dornfeld, CHPC | 973.403.3136 | ldornfeld@bracheichler.com

Keith J. Roberts | 973.364.5201 | kroberts@bracheichler.com

Ed Hilzenrath | 973.403.3114 | ehilzenrath@bracheichler.com

New Jersey Legislative Update

Public-Private HHA Law Passed – On July 19, 2019, Governor Phil Murphy signed into law [Bill S1373](#), which permits a government-owned home health agency (HHA) to contract with a non-governmental entity that is licensed as a HHA to provide direct, administration, and financial services. Prior to the new law's enactment, licensed HHAs were generally required to provide nursing services through their own staff. An agency could only retain nursing services by contract either temporarily because all available employees had achieved maximum caseloads or to provide specialized care not within the expertise or scope of practice of existing staff. The new law permits governmental HHAs to contract with non-governmental HHAs to deliver services on a longer-term basis. Any such contractual arrangement would be subject to approval by the Department of Health.

New Jersey Joins Enhanced Multi-State Nurse Licensure Compact – On July 19, 2019, Governor Phil Murphy signed into law [Bill S954](#) entering New Jersey into the enhanced Multi-State Nurse Licensure Compact (eNLC). The eNLC provides for mutual recognition of nurse licensure, for registered professional nurses and licensed practical nurses, where 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. While a nurse may be licensed in any state or states that are not parties to the compact, a nurse may only be licensed in one state that is a party to the compact. 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.

New Law Revises Access to Medical Cannabis – On July 2, 2019, Governor Phil Murphy signed into law [Bill A20](#), which revises requirements to authorize and access medical cannabis. The new law makes various revisions to the "Compassionate Use Medical Marijuana Act," including renaming the act the "Jake Honig Compassionate Use Medical Cannabis Act," establishing a new Cannabis Regulatory Commission to oversee the medical cannabis program, revising the requirements necessary to authorize a patient for medical cannabis; revising the permit and operational requirements for alternative treatment centers; establishing discrete cultivator, manufacturer, and dispensary permits; creating a new clinical registrant permit; authorizing delivery of medical cannabis; and establishing additional protections for registry cardholders.

For more information, contact:

Riza I. Dagli | 973.403.3103 | rdagli@bracheichler.com

John D. Fanburg | 973.403.3107 | jfanburg@bracheichler.com

Ed Hilzenrath | 973.403.3114 | ehilzenrath@bracheichler.com

Brach Eichler In The News

Fifteen Brach Eichler lawyers were named to The Best Lawyers in America® 2020. They include Managing Member and Healthcare Law Chair John D. Fanburg and Healthcare Law Members Lani M. Dornfeld, Joseph M. Gorrell, and Carol Grelecki.

John D. Fanburg provided a legal update to members of the Radiological Society of New Jersey on August 6.

On July 30, Keith J. Roberts and John D. Fanburg addressed physicians at Hudson Regional Hospital on navigating PIP regulations for spine surgery.

It's almost here! Join Brach Eichler's healthcare law attorneys and an outstanding group of speakers, including keynote speaker Barry H, Ostrowsky, for our tenth annual New Jersey Healthcare Market Review (NJHMR). The conference will be held September 18 – 19 at the Borgata in Atlantic City. Register today! Visit www.njhmr.com for more information.

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

HIPAA CORNER

Health System Security Breach in Phishing Attack

According to the Wise County Messenger, Wise Health System (WHS) in Decatur, Texas reported to the Department of Health & Human Services (HHS) and notified 35,899 patients that their personal information may have been disclosed after a phishing attack compromised employee e-mail accounts (See HHS February 2018 Newsletter regarding phishing).

On March 14, 2019, a phishing attack was launched against WHS's system. Several employees fell for the phish and provided their login credentials, giving the intruders access to the Employee Kiosk. Although WHS believes the purpose of the attack was to divert payroll direct deposits rather than to obtain patient information, the access obtained may have compromised patient information such as medical record numbers, diagnostic and treatment information, and insurance information.

WHS acted promptly by forcing a system-wide password change, hiring two forensic firms and engaging the FBI. In addition, WHS hired an information security company to do an analysis of the entire system to make sure security is as tight as possible, including training for all employees to help spot phishing e-mails. WHS reported it has not received any reports of patient identity theft since the date of the phishing incident.

This incident should serve as a reminder of the importance of organization-wide HIPAA training on a regular and frequent basis, in order to reduce breach risk.

Every breach or suspected breach incident requires swift action, including assembling an investigative team, performing an investigation, taking mitigating actions, and performing the required Security Rule risk assessment to determine necessary breach reporting (See HHS Cyber-Attack Checklist and Quick Response).

If you need assistance in developing or updating your HIPAA compliance program, in providing staff training, in managing a breach incident, or in fulfilling any required reporting, please contact:

Lani M. Dornfeld, CHPC | 973.403.3136 | ldornfeld@bracheichler.com

Healthcare Law Practice | 101 Eisenhower Parkway, Roseland, NJ 07068

Members

Riza I. Dagli | 973.403.3103 | rdagli@bracheichler.com
Lani M. Dornfeld, HLU Editor | 973.403.3136 | ldornfeld@bracheichler.com
John D. Fanburg, Chair | 973.403.3107 | jfanburg@bracheichler.com

Joseph M. Gorrell | 973.403.3112 | jgorrell@bracheichler.com
Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com
Keith J. Roberts | 973.364.5201 | kroberts@bracheichler.com

Counsel

Shannon Carroll | 973.403.3126 | scarroll@bracheichler.com
Lauren D. Goldberg | 973.364.5228 | lgoldberg@bracheichler.com
Debra W. Levine | 973.403.3142 | dlevine@bracheichler.com
Randall H. Lee | 973.364.5205 | rlee@bracheichler.com

Richard B. Robins | 973.403.3147 | rrobins@bracheichler.com
Jonathan J. Walzman | 973.403.3120 | jwalzman@bracheichler.com
Edward J. Yun | 973.364.5229 | eyun@bracheichler.com

Associates

Colleen Buontempo | 973.364.5210 | cbuontempo@bracheichler.com
Lindsay P. Cambron | 973.364.5232 | lcambron@bracheichler.com
Jocelyn Ezratty | 973.364.5211 | jezratty@bracheichler.com
Susan E. Frankel | 973.364.5209 | sfrankel@bracheichler.com

Ed Hilzenrath | 973.403.3114 | ehilzenrath@bracheichler.com
Cynthia J. Liba | 973.403.3106 | cliba@bracheichler.com
Erika Marshall | 973.364.5236 | emarshall@bracheichler.com