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Healthcare Law UPDATE

July 2021

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FEDERAL UPDATE

Secretary of DHHS Renews Public Health Emergency

On July 19, 2021, the Secretary of the U.S. Department of Health & Human Services published an announcement stating that, as a result of the continued consequences of the COVID-19 pandemic, the Secretary is extending the public health emergency. The Secretary's determination is revisited every 90 days. As with the prior extensions, COVID-19 related Section 1135 Waivers also are extended.

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

CMS Issues Proposed Rule for Home Health Agencies

On June 28, 2021, Centers for Medicare & Medicaid Services (CMS) issued a proposed rule (CMS-1747-P) for home health agencies (HHA) for calendar year (CY) 2022. Among other things, CMS:

- Proposes routine, statutorily required updates to home health payment rates for CY 2022. CMS estimates that Medicare payments to HHAs in CY 2022 would increase in the aggregate by 1.7 percent or $310 million;
- Proposes monitoring and analysis of the Patient-Driven Groupings Model (PDGM);
- Solicits comments on a methodology for determining the difference between assumed versus actual behavior change on estimated aggregate expenditures for home health payments as a result of the change in the unit of payment to 30 days and the implementation of the PDGM case-mix adjustment methodology;
- Proposes to utilize the physical therapy low utilization payment adjustment (LUPA) add-on factor to establish the occupational therapy add-on factor for the LUPA add-on payment amounts;
- Proposes to make permanent selected regulatory blanket waivers related to home health aide supervision that were issued to Medicare-participating home health agencies during the COVID–19 public health emergency;

- Proposes to expand the Home Health Value-Based Purchasing Model, beginning January 1, 2022, to the 50 states, U.S. territories, and the District of Columbia; and
- Proposes to establish survey and enforcement requirements for hospice programs as set forth in Division CC, section 407 of the CAA 2021.

Comments to the rule proposal are due no later than 5 p.m. on August 27, 2021, and may be submitted by regular or overnight mail or electronically, with reference to file code CMS-1747-P.

For more information, contact:

Lani M. Dornfeld, CHPC | 973.403.3136 | ldornfeld@bracheichler.com
Joseph M. Gorrell | 973.403.3112 | jgorrell@bracheichler.com
Cynthia J. Liba | 973.403.3106 | cliba@bracheichler.com

No Surprise – HHS Issues First of Several Regulations Prohibiting Surprise Medical Bills

On July 1, 2021, the U.S. Department of Health & Human Services issued the first interim final rule with comment period (Interim Final Rule) in furtherance of the No Surprises

Act, which was enacted as part of the Consolidated Appropriations Act of 2021 (Act). The No Surprises Act protects consumers from incurring excessive out-of-pocket costs due to surprise medical bills and balance billing in certain instances. The Interim Final Rule, among other things:

- Bans excessive billing for emergency services. Emergency services, regardless of where they are provided, must be treated on an in-network basis without requirements for prior authorization;
- Bans high out-of-network cost-sharing for emergency and non-emergency services. Patient cost-sharing, such as co-insurance or a deductible, cannot be higher than if such services were provided by an in-network provider, and any coinsurance or deductible must be based on in-network rates;
- Bans out-of-network charges for ancillary care (such as an anesthesiologist, pathologist, radiologist, or assistant surgeon) at an in-network facility in all circumstances;
- Bans other out-of-network charges without advance notice. In order to bill at a higher out-of-network rate, a healthcare provider must provide the patient with prior notice, generally 72 hours in advance, explaining in plain language that the patient's consent is required to receive care on an out-of-network basis; and
- Bans air ambulance services from sending a patient a surprise medical bill for more than the in-network cost-sharing amount.

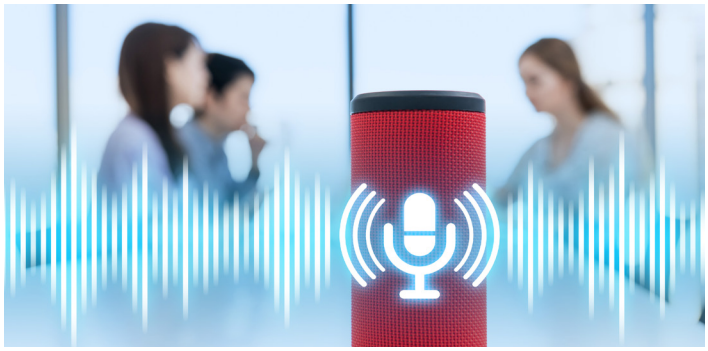
Future regulations will address other aspects of the Act, including the "baseball-type" binding arbitration process for payment disputes between healthcare providers and third-party payors.

New Jersey healthcare providers and insurers are already subject to the Out-of-Network Consumer Protection, Transparency, Cost Containment, and Accountability Act (New Jersey Act), which was signed into law by Governor Murphy in 2018, and is similar in several significant aspects to the No Surprises Act. Among other things, the New Jersey Act prohibits out-of-network providers and healthcare facilities in New Jersey from balance billing patients for (i) emergency or urgent medically necessary services, and for (ii) inadvertent out-of-network services in excess of the patient's deductible, copayment, or coinsurance amount applicable to in-network services. At this point, it is unclear whether the No Surprises Act will supersede, either in whole or in part, the New Jersey Act or the extent of the interplay between the federal and state law. We are hopeful guidance will be issued before the end of the year.

The Interim Final Rule will undergo 60 days of public comment and will take effect on January 1, 2022.

For more information, contact:

John D. Fanburg | 973.403.3107 | jfanburg@bracheichler.com
Keith J. Roberts | 973.364.5201 | kroberts@bracheichler.com
Edward J. Yun | 973.364.5229 | eyun@bracheichler.com



Healthcare Workers File Complaint Against Amazon Alleging the Alexa Device Listens to Protected Information

On June 30, 2021, a group of healthcare workers filed suit against Amazon.com, Inc., alleging that Amazon's Alexa device listens to and stores audio recordings – encompassing those that may contain highly sensitive information, including protected health information under HIPAA. The class-action lawsuit, filed in the state of Washington, alleges that Amazon violates state and federal wiretap laws along with state consumer protection statutes. Among other things, the plaintiffs seek certification as a class, an order declaring that the acts and practices of Amazon violate various state and federal laws including those relating to wiretapping and consumer protection, as well as injunctive relief, and damages.

Amazon notes that Alexa is triggered by a specific "wake word" and, once spoken, the device is triggered to listen to users and respond to user commands. This is how the corporation advertised the device for many years. The suit alleges that the device then initiates a process to record the audio and permanently store the information. In addition, the device incorrectly identifies a "wake word" and records a user when the user is not intending or knowing the user is being recorded. When the device incorrectly identifies a "wake word" it records the audio, stores it, and sends it to human analysts and sometimes third parties to review the recording. The plaintiffs, all healthcare workers in some capacity, allege that Alexa may have captured HIPAA-protected information without the plaintiffs' intent or knowledge. Additionally, it is alleged that Amazon did not disclose that actual humans listen in on these recordings until 2020 – after the plaintiffs purchased their devices. The plaintiffs allege that the only way to stop Amazon from making these recordings is to either mute the device's microphone or unplug it, thereby defeating the device's functionality.

The case should serve as a cautionary tale for healthcare workers to be cognizant of Alexa and similar devices in work and other areas where discussions with or about patients may take place.

For more information, contact:

Lani M. Dornfeld, CHPC | 973.403.3136 | ldornfeld@bracheichler.com
Riza I. Dagli | 973.403.3103 | rdagli@bracheichler.com
Keith J. Roberts | 973.364.5201 | kroberts@bracheichler.com

Department of Justice Steps Up Enforcement Efforts to Combat COVID-19 Related Fraud

The U.S. Department of Justice (DOJ), in coordinated law enforcement actions with other federal agencies, has increased efforts to clamp down on COVID-19 healthcare related fraud. Criminal charges were recently brought against 14 defendants, and the Center for Medicare and Medicaid Services (CMS) took adverse administrative actions against more than 50 medical providers, all in connection with COVID-19 fraudulent schemes. These enforcement actions follow the recent announcement by the DOJ regarding a newly formed COVID-19 Fraud Enforcement Task Force, established to coordinate resources across all federal agencies to bring criminal, civil, and administrative actions in connection with pandemic-related fraud.

The criminal charges filed involve a variety of healthcare fraudulent schemes, including the third criminal action in the nation for misappropriation of Provider Relief Fund monies distributed under the Coronavirus Aid, Relief, and Economic Security (CARES) Act, and for submitting false loan applications and false loan agreements to the Economic Injury Disaster Loan Program. Also, in the first of its kind criminal case, the owners of a laboratory testing company and a consulting company were charged with a kickback scheme for exploiting temporary waivers of telehealth restrictions enacted during the pandemic. The defendants are charged with offering telehealth medical providers access to Medicare beneficiaries for whom they could bill consultations for encounters that did not occur. In exchange, these providers allegedly agreed to refer beneficiaries to the laboratories for expensive and medically unnecessary cancer and cardiovascular genetic testing.

In several other criminal schemes, defendants were charged with offering COVID-19 tests to Medicare beneficiaries at senior living facilities, drive-through COVID-19 testing sites, and medical offices to induce the beneficiaries to provide their personal identifying information and a saliva or blood sample. The defendants are accused of then misusing the information and samples to submit claims to Medicare for unrelated, medically unnecessary, and far more expensive laboratory tests. In many cases, it is alleged that the COVID-19 test results were not provided in a timely fashion or were not reliable, the other laboratory tests ordered were medically unnecessary, and results were often not provided to the patients or their actual primary care doctors.

For more information, contact:

Riza I. Dagli | 973.403.3103 | rdagli@bracheichler.com
Joseph M. Gorrell | 973.403.3112 | jgorrell@bracheichler.com
Susan E. Frankel | 973.364.5209 | sfrankel@bracheichler.com

CMS Proposes Rule Addressing 2022 Medicare PFS and Targeting Improvement in Health Equity and Patient Access

On July 13, 2021, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule announcing policy changes for Medicare payments under the Physician Fee Schedule (PFS) and other Medicare Part B issues for calendar year (CY) 2022. As indicated by CMS, the measures set forth in the proposed rule are reflective of the Biden-Harris Administration's strategy "to create a health care system that results in better accessibility, quality, affordability, empowerment, and innovation."

Following is a summary of the key updates CMS has included in the proposed rule:

- CY 2022 PFS conversion factor of $33.58, a decrease of $1.31 from the CY 2021 PFS conversion factor of $34.89. The reduction comes from the expiration of the 3.75% payment increase provided for CY 2021 by the Consolidated Appropriations Act of 2021 enacted to provide relief during the COVID-19 public health emergency (PHE);
- In terms of telehealth, CMS is proposing to allow certain services that were added to the Medicare telehealth list during the COVID-19 PHE to remain on the list until the end of December 31, 2023, so there is a "glide path" to determine what services should be permanently added to that list following the COVID-19 PHE. It also proposes allowing payment to eligible practitioners when they provide certain mental and behavioral health services to patients via audio-only telephone calls from their homes when certain conditions are met;
- The proposed rule contains several measures aimed at increasing the ability of Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) to provide services, including allowing Medicare, for the first time, to pay for mental health visits provided by an RHC or FQHC through interactive telecommunications technology;
- CMS is introducing a Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs) as the "next evolution" of CMS' Quality Payment Program (QPP). The rule also proposes the first set of proposed MVP clinical areas - subsets of connected and complementary measures and activities used to meet MIPS reporting requirements;
- Significant changes to the Medicare Diabetes Prevention Program (MDPP) are proposed to make it easier for local MDPP suppliers to participate in the program in order to increase beneficiary participation and community outreach; and
- CMS is proposing to authorize direct Medicare payments to Physician Assistants (PA) for professional services they furnish under Part B. Beginning January 1, 2022, for the first time, PAs would be able to bill Medicare directly.

Comments to the proposed rule are due by September 13, 2021.

For more information, contact:

John D. Fanburg | 973.403.3107 | jfanburg@bracheichler.com
Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com
Caroline J. Patterson | 973.403.3141 | cpatterson@bracheichler.com

Maker of Invisalign and Investors Reach a Settlement in Class Action Lawsuit Over Company's Patent Expiration Conduct

The investor plaintiffs in a class-action lawsuit against Align Technology, Inc. ("Align"), the manufacturer of the plastic dental aligner Invisalign, have agreed to settle their claims that the company had lied to Align investors about an increase in competition as its product patents began to expire in 2017. From the late 1990s through 2018, Align had very few competitors in the plastic aligner market, as Align had hundreds of patents for its technology and manufacturing processes. Align investors filed the lawsuit after the company's share prices plummeted following the revelation that the company had implemented a secret aggressive discount promotion on product pricing in 2018 to stem competition and sway doctors to stay with Align products. The investors allege that the secret discount promotion had artificially inflated Align's stock price and the news of the deception caused the stock price to drop by $59 per share.

The investors have agreed to a $16 million settlement with Align, which now requires approval from the court. According to the settlement agreement, class members will receive a pro-rata distribution of a net settlement fund and must demonstrate that they purchased or acquired Align stock during the class period and suffered losses to qualify for recovery.

For more information, contact:

Riza I. Dagli | 973.403.3103 | rdagli@bracheichler.com
Joseph M. Gorrell | 973.403.3112 | jgorrell@bracheichler.com
Susan E. Frankel | 973.364.5209 | sfrankel@bracheichler.com

STATE UPDATE

New Law Allows Hospitals to Construct Housing and Provide Wrap-Around Services

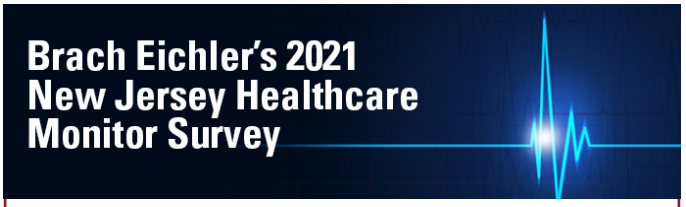
On June 4, 2021, Governor Phil Murphy signed Bill S1676 into law to allow hospitals to construct housing and provide wrap-around services for individuals who are homeless or housing insecure. Specifically, this new Law authorizes general acute care hospitals to adopt, as part of their missions, the goal of addressing issues related to homelessness and housing insecurity. A hospital that chooses to address issues related to homelessness and housing insecurity will be authorized to construct, rehabilitate, or remediate housing and provide wrap-around services for homeless persons and the housing insecure who are treated at the hospital, which wrap-around services may include: (1) referrals to outpatient primary care and behavioral healthcare services; (2) appropriate follow-up care and treatment management assistance; (3) assistance identifying and procuring sources of health benefits coverage, including, but not limited to, coverage under the State Medicaid and NJ FamilyCare programs; and (4) assistance in identifying and accessing appropriate social services, including, but not limited to, food, transportation, housing, employment, and child care assistance.

New Telemedicine Law Awaiting Governor's Signature

On June 30, 2021, the New Jersey Senate passed Bill S2559/A4179, which revises requirements for health insurance providers and Medicaid to cover services provided using telemedicine and telehealth. The New Jersey Assembly had previously passed the Bill on June 24, 2021, and it now awaits Governor Phil Murphy's signature. The Bill requires that reimbursement for telemedicine and telehealth services be equal to the reimbursement rate for the same services when they are provided in person. Current law provides that telemedicine and telehealth services may be reimbursed up to the amount at which the service would be reimbursed if provided in person. This revision is intended to ensure that telemedicine and telehealth services achieve pay parity with in-person services and allows providers to be compensated equally when delivering telemedicine and telehealth services to their patients. Additionally, the Bill prevents health insurance providers from requiring that telemedicine and telehealth services be provided at a certain location to be eligible for reimbursement. Specifically, this means there must be no restriction on the location where a healthcare provider renders services using telemedicine or telehealth or on the location or setting where the patient is located when receiving these services. The Bill also prohibits health insurance providers from restricting the type of platform providers use to interact with their patients so long as the standard of care being provided is the same as if it were in person.

For more information, contact:

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
Ed Hilzenrath | 973.403.3114 | ehilzenrath@bracheichler.com



Attention NJ Physicians: Complete Brach Eichler's 2021 New Jersey Healthcare Monitor Survey and Be Entered to Win!

Brach Eichler's New Jersey Healthcare Monitor has become an important barometer for the practice of medicine in the state. We understand the COVID-19 pandemic and the tumultuous year that followed brought about great concerns around operating your practice, maintaining your staff, and the short and long-term impacts on your patients. Through this brief survey, Brach Eichler seeks to ascertain how your practice has been affected.

Enter for a chance to win a Peloton, Apple Watch, $500 Visa Gift Card, or Apple AirPods!

TAKE THE SURVEY

ATTORNEY SPOTLIGHT

Get to know the faces and stories of the people behind the articles in each issue. This month, we invite you to meet Member Carol Grelecki and Associate James J. Ko.

Carol Grelecki

Carol Grelecki represents the firm's healthcare clients in a wide variety of corporate and transactional matters. Her clients include physicians and physician groups, specialty practice societies, independent practice associations, hospitals, clinical laboratories, utilization managers, billing companies, and other medical professionals. Carol also advises clients with regard to compliance, including matters pertaining to Medicare billing, fraud and abuse, and the Stark and Codey Laws. Additionally, she represents clients in regulatory matters, including healthcare facility licensing issues and the preparation of required policies and procedures.

On the weekends, Carol enjoys hiking and other outdoor activities. She uses various apps to find local trails that are off the beaten track. She also enjoys reading both fiction and nonfiction works, with a particular interest in historical persons and events.

James J. Ko

James Ko focuses his practice on complex healthcare transactional and regulatory matters affecting a wide range of clients in the healthcare industry, including health systems, hospitals, physician groups, provider networks, pharmacies, and clinical laboratories. Specifically, James advises clients on the Anti-Kickback Statute, Stark Law, False Claims Act, HIPAA compliance, state corporate practice of medicine doctrines, state licensure laws, contract drafting, and due diligence. In addition, he has experience helping healthcare providers navigate government audits and investigations.

In his spare time, James enjoys playing basketball and golf, trying new restaurants, and spending time with his wife, two daughters, and his Schichon dog named Tani.

Brach Eichler In The News

On July 28, **John D. Fanburg**, Managing Member and Healthcare Law Chair and **Jay Sabin,** Labor and Employment Counsel, presented at NJAASC's Membership Meeting. John provided a legislative and regulatory update and Jay addressed OSHA's Emergency Healthcare COVID Standard: Coverage and Compliance.

On July 21, **Lani M. Dornfeld** attended the Annual Conference and Trade Show of the Home Care Association of Florida, in which she co-presented on the topic of "Best Practices in Getting Ready for a Transaction Today."

On July 14, Healthcare Law Member **Lani Dornfeld** issued a Healthcare Law Alert entitled "CISA, FBI and OCR Cyber Alerts Concerning Ransomware Attacks and Systems Vulnerabilities."

On July 9, Cannabis Co-Chair **Charles X. Gormally** wrote in the *New Jersey Law Journal* about the effects recreational cannabis will have on the medical cannabis market in an article entitled "Is Recreational Cannabis Good Medicine for Medical Marijuana?"

HIPAA CORNER

OCR Publishes Summer 2021 Cybersecurity Newsletter – On July 14, 2021, the Department of Health & Human Services, Office for Civil Rights (OCR, the HIPAA enforcement agency) published its Summer 2021 Cybersecurity Newsletter, titled *Controlling Access to ePHI: For Whose Eyes Only?* In part, this newsletter focuses on information contained in a recent report of security incidents and data breaches, specifically findings that indicate that 39% of data breaches in the healthcare industry were found to have been perpetrated by insiders (such as employees), not by outside threat actors. The remaining 61% of analyzed data breaches were perpetrated by external threat actors—hackers and other cybercriminals.

The OCR reinforces the importance of various controls to assist in HIPAA Security Rule compliance and overall security of data systems that house protected health information (PHI), including:

- Information Access Management – This includes the implementation of policies and procedures for authorizing access to electronic PHI within an

organization. This may include how access to each information system containing electronic PHI is requested, authorized, and granted, who is responsible for granting access, and what is the criteria for granting access. This should include a consideration of "role-based" access—basing access rights on the parameters of each individual's job functions.

- Access Controls – This includes the implementation of technical controls to ensure only authorized persons are allowed access to electronic systems that house electronic PHI. This includes assigning a unique username and/or number for identifying and tracking user identity, emergency access procedures for obtaining electronic PHI in an emergency, automatic logoff procedures, and encryption and decryption mechanisms.

In the newsletter, the OCR emphasized:

The rise in data breaches due to hacking as well as threats to ePHI by malicious insiders highlights the importance of establishing and implementing appropriate policies and procedures regarding these Security Rule requirements. Ensuring that workforce members are only authorized to access the ePHI necessary and that technical controls are in place to restrict access to ePHI can help limit potential unauthorized access to ePHI for both threats.

This is yet another reminder to healthcare providers and their business associates of the need to implement or update a comprehensive HIPAA compliance program, including ongoing training and monitoring, to protect against both internal and external threat actors.

New StopRansomware.gov Website – On July 15, 2021, the Cybersecurity & Infrastructure Security Agency (CISA) issued an alert about the U.S. government's launch of a new website to help public and private organizations defend against the rise in ransomware cases. Per CISA:

StopRansomware.gov is a whole-of-government approach that gives one central location for ransomware resources and alerts. We encourage organizations to use this new website to understand the threat of ransomware, mitigate risk, and in the event of an attack, know what steps to take next.

The StopRansomware.gov webpage is an interagency resource that provides our partners and stakeholders with ransomware protection, detection, and response guidance that they can use on a single website. This includes ransomware alerts, reports, and resources from CISA, the FBI, and other federal partners.

As of now, the website includes, among other resources, information about ransomware, including what it is, how to detect it, and how to respond if an organization has been the victim of a ransomware attack, as well as how to avoid ransomware in the first place.

For more information or assistance with your privacy and security program or managing a breach incident contact:

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

BRACH EICHLER LLC
Counsellors at Law

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

Colleen Buontempo | 973.364.5210 | cbuontempo@bracheichler.com
Shannon Carroll | 973.403.3126 | scarroll@bracheichler.com
Ed Hilzenrath | 973.403.3114 | ehilzenrath@bracheichler.com
Debra W. Levine | 973.403.3142 | dlevine@bracheichler.com
Caroline J. Patterson | 973.403.3141 | cpatterson@bracheichler.com
Jonathan J. Walzman | 973.403.3120 | jwalzman@bracheichler.com
Edward J. Yun | 973.364.5229 | eyun@bracheichler.com

Associates

Lindsay P. Cambron | 973.364.5232 | lcambron@bracheichler.com
Paul J. DeMartino, Jr. | 973.364.5228 | pdemartino@bracheichler.com
Susan E. Frankel | 973.364.5209 | sfrankel@bracheichler.com
Emily J. Harris | 973.364.5205 | eharris@bracheichler.com
James J. Ko | 973.403.3147 | jko@bracheichler.com
Cynthia J. Liba | 973.403.3106 | cliba@bracheichler.com
Erika R. Marshall | 973.364.5236 | emarshall@bracheichler.com

Roseland, NJ | New York, NY | West Palm Beach, FL | www.bracheichler.com | 973.228.5700