BRACH | EICHLER LLC

Health Law UPDATE

November 2018

In This Issue:

FEDERAL UPDATE

OCR Initiates Public Awareness Campaign Aimed at Promoting the Civil Rights of Individuals Faced with Opioid-Use Disorders

On October 25, 2018, the Department of Health & Human Services, Office for Civil Rights (OCR) announced in a press release that it launched a public education campaign aimed at improving access to evidence-based, opioid-use disorder treatment and recovery services by discouraging barriers to such treatment and services due to unlawful discrimination, bias, and stereotypical beliefs about those suffering from opioid addiction. To aid in these efforts, the OCR also launched a website for consumers and health care professionals to obtain more information about nondiscrimination laws, federal disability rights, and HIPAA protections for those suffering from opioid-use disorders.

According to an OCR fact sheet on nondiscrimination and opioid-use disorders, the OCR recommends best practices to be observed by certain covered entities, including health care providers, who receive federal financial assistance from HHS. Topics include examining program eligibility and admission criteria to identify and eliminate discriminatory barriers to programs, ensuring non-English speaking individuals have meaningful access to critical programs, and ensuring services are accessible to persons with physical or mobility impairments.

Additionally, the OCR provided a fact sheet outlining the federal disability rights laws in connection with drug addiction.

Finally, the OCR provided guidance on how HIPAA allows health care professionals to respond to the opioid crisis, which explains, among other things, that:

- Providers can share information with a patient's loved ones in certain emergency or dangerous situations, such as when the patient is in a crisis and incapacitated, or is facing a serious and imminent threat of harm.
- Patients with decision-making capacity retain their right to decide when and whether their information will be shared, unless there is a serious and imminent threat of harm.
- Patients' personal representatives, who have authority under state law to make health care decisions for patients, may request and obtain information on behalf of patients.

For more information, contact:

Lani M. Dornfeld | 973.403.3136 | ldornfeld@bracheichler.com
Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com
Andrew J.D. Russo | 973.403.3135 | arusso@bracheichler.com

Proposed Regulations Released by IRS, DOL, and HHS Expand Health Reimbursement Arrangements

The Internal Revenue Service (IRS), the U.S. Department of Labor (DOL), and the U.S. Department of Health & Human Services (HHS) released proposed regulations on October 29, 2018, expanding the use of health reimbursement arrangements (HRAs) to large and small employers. The regulations are in response to President Trump's Executive Order 13183 "Promoting Healthcare Choice and Competition Across the United States."

An HRA is a type of group health plan, funded solely by employer contributions, that reimburses an employee for medical care expenses (as defined under section 213(d) of the Internal Revenue Code) incurred by the employee, or the employee's spouse, dependents, and children up to a maximum dollar amount for a coverage period. The reimbursements are excluded from the employee's income and wages for federal income tax and employment tax purposes. Some HRAs permit unused account balances to be carried over to subsequent years.

HRAs are subject to the Affordable Care Act (ACA) but fail to comply with certain ACA mandates, such as prohibition on lifetime or annual limits on the dollar value of "essential health benefits." Group health plans have been able to get around this prohibition due to rules allowing integration of the HRA into the group health plan. Such integration, however, had not been permitted with individual health insurance coverage. The proposed regulations seek to change that. The proposed rules would now permit HRAs to be integrated with individual health insurance coverage. The regulations would also allow employers to offer HRAs to employees as a stand-alone plan, non-integrated with other group plans.

Thus, effective with plan years beginning on or after January 1, 2020, (1) large and small employers who do not offer health coverage to all or certain employee classes may use a new type of HRA to reimburse those employees for individual health insurance coverage premiums, subject to certain conditions; and (2) employers who offer traditional group coverage may also offer an HRA up to $1,800 (indexed) annually to reimburse employees for certain qualified medical expenses (other than premiums). The regulations clarify that even if premiums for individual health insurance coverage are reimbursed from an HRA, the HRA is not itself an ERISA welfare benefit plan, provided certain conditions are met. In addition, employees are not permitted to take the federal premium tax credit if they accept the HRA or opt out of it and the HRA/individual health insurance coverage is affordable. The proposed regulations will also allow a special enrollment period for the individual insurance market

for those employees whose employers offer an HRA at a time that does not coincide with existing open enrollment periods.

For more information, contact:

Debra C. Lienhardt | 973.364.5203 | dlienhardt@bracheichler.com
Keith J. Roberts | 973.364.5201 | kroberts@bracheichler.com
Susan E. Frankel | 973.364.5209 | sfrankel@bracheichler.com

CMS Finalizes 2019 OPPS Rule

Centers for Medicare & Medicaid Services (CMS) recently published the calendar year (CY) 2019 Outpatient Prospective Payment System (OPPS) final rule. Under the rule, CMS is increasing OPPS rates overall by 1.35 percent for CY 2019, which includes a positive market basket update of 2.9 percent and certain negative updates related to cuts made under the Affordable Care Act. One of the stated goals of the new rule is to remove unnecessary, inefficient payment differences between different provider and supplier types to provide patients with more affordable options for care.

CMS is reducing the payment rate for hospital outpatient clinic visits provided at off-campus, provider-based departments by 60 percent. Currently, hospital outpatient clinics are reimbursed at a higher rate than independent outpatient facilities. Under the new rule, off-campus hospital clinic rates will be reduced to the same level as non-hospital facilities, with the reduction phased in over a two-year period. CMS estimated that this change will save Medicare an estimated $380 million in CY 2019 alone.

CMS is also expanding reductions under the Section 340B drug policy that allows certain participating providers to purchase certain prescription drugs at discounted rates. For CY 2018, CMS paid hospitals 22.5 percent less than the average price for drugs purchased through the Section 340B program, after previously paying for these drugs at a rate of average sales price plus 6 percent. For CY 2019, CMS will extend the 22.5 percent less-than-average price payment rate to certain other types of facilities, including certain off-campus, provider-based departments.

CMS is also reducing the number of measures that providers are required to report under the Quality Reporting Program (QRP). The reduction includes one less reportable measure beginning with CY 2020 and removing seven additional reportable measures for CY 2021. CMS hopes that removing these measures will enable providers to focus on tracking the measures that are most impactful on patient care and on improved patient outcomes.

For more information, contact:

Joseph M. Gorrell | 973.403.3112 | jgorrell@bracheichler.com
Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com
Jonathan J. Walzman | 973.403.3120 | jwalzman@bracheichler.com

OIG Advisory Opinion Regarding Proposed Medigap Discounted Inpatient Deductibles in Exchange for Policyholder Incentive to Use Preferred Hospital Network

On October 29, 2018, the U.S. Department of Health & Human Services, Office of Inspector General (OIG) issued Advisory Opinion 18-12 regarding the use of a "preferred hospital" network as part of Medicare Supplemental Health Insurance (Medigap) policies. Under the proposed arrangement addressed in the Advisory Opinion, an insurance company would contract indirectly with hospitals for discounts on the otherwise-applicable Medicare inpatient deductibles for its policyholders, and in turn, would provide a premium credit of $100 off the next renewal premium to policyholders who use a network hospital for an inpatient stay. OIG determined that the proposed arrangement would not be subject to sanctions under the anti-kickback statute.

The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a federal health care program. (Section 1128B(b) of the Social Security Act.) Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a federal health care program, the anti-kickback statute is violated. HHS has promulgated certain safe harbor regulations that set forth practices that are not subject to the anti-kickback statute because those practices would be unlikely to result in fraud or abuse.

Although OIG did not find any safe harbor applicable to the proposed arrangement, OIG nonetheless determined that despite the lack of safe harbor protection, the proposed arrangement would present a sufficiently low risk of fraud or abuse under the anti-kickback statute. Therefore, the requestor would not be subject to sanctions because, under the proposed arrangement, (1) neither the discounts nor the premium credits would increase or affect per-service Medicare payments; (2) utilization is unlikely to increase; (3) competition among hospitals is unlikely to be unfairly affected; (4) professional medical judgment of policyholders' physicians and surgeons who would receive no remuneration would not likely be affected; and (5) there would be transparency in operation of the arrangement.

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 Final Rule Seeks to Modernize Home Health Care

Centers for Medicare & Medicaid Services (CMS) recently issued a final rule that seeks to focus on patient needs, promote innovation, and reduce administrative burdens in the provision of home health care.

Specifically, the rule allows home health agencies (HHAs) to bill for remote patient monitoring costs. CMS anticipates that this will encourage more HHAs to adopt the emerging technology. Remote monitoring allows patients to share live-time data with their providers and caregivers, which can lead to more tailored care and better health outcomes. The hope is that remote technology will give patients greater independence and empowerment.

New policies are aimed at reducing administrative burdens. For example, certifying physicians no longer need to estimate how much longer home health services are needed when recertifying continued care. CMS will also stop using the number of therapy visits to determine HHAs' reimbursement in 2020. Instead, CMS will implement a case-mix method, which reimburses HHAs based on patient characteristics rather than volume. The change supports CMS's focus on value over volume, acknowledging that some complex conditions do not involve a lot of therapy. The rule also removes seven Home Health Quality Reporting Program measures to streamline reporting and further reduce administrative burdens.

CMS is providing temporary reimbursement for certain in-home infusion services for 2019 and 2020. The rule implements health and

safety standards for home infusion therapy, an accreditation process for qualified home infusion therapy suppliers and an approval and oversight process for the organizations that accredit home infusion therapy suppliers.

For more information, contact:

Debra C. Lienhardt | 973.364.5203 | dlienhardt@bracheichler.com
Mark Manigan | 973.403.3132 | mmanigan@bracheichler.com
Shannon Carroll | 973.403.3126 | scarroll@bracheichler.com

JAMA Study: Patient Access to Medical Records at U.S. Hospitals

A study published in The Journal of the American Medical Association evaluated the current state of the medical records request process of U.S. hospitals by assessing compliance with federal and state regulations and ease of patient access. In accordance with HIPAA, medical requests must be fulfilled within 30 days of receipt in the format requested by the patient if the records are readily available in that format. Additionally, hospitals are permitted to charge a reasonable cost-based fee for the release of medical records.

The study assessed the medical records request process in 83 top-ranked U.S. hospitals. The researchers collected medical records release authorization forms from each hospital and telephoned each hospital's medical records department to collect data on formats of release, costs, and processing times using a script to minimize variation and biases across telephone calls. Data obtained from authorization forms was compared with data obtained from telephone calls.

The study revealed inconsistencies in information provided by medical records authorization forms and by medical records departments in select U.S. hospitals, as well as unaffordable costs and processing times not compliant with HIPAA. As a result, the study concludes there is a need for stricter enforcement of policies relating to patients' access to their protected health information.

For more information, contact:

Lani M. Dornfeld | 973.403.3136 | ldornfeld@bracheichler.com
John D. Fanburg | 973.403.3107 | jfanburg@bracheichler.com
Cynthia J. Liba | 973.403.3106 | cliba@bracheichler.com

STATE UPDATE

New Jersey Legislative Update

Bill Introduced to Prohibit Pre-Approvals—On October 18, 2018, Bill A4613 was introduced in the New Jersey Assembly to prohibit pre-approval or precertification of medical tests, procedures, and prescription drugs covered under health benefits or prescription drug benefits plans. The purpose of the Bill is to ensure that patients who are ill are not burdened with technical requirements by health benefits providers which employ utilization management review systems that slow down medical care. The Bill's sponsor, Assemblyman Jon M. Bramnick, has been concerned that complaints from people who need medical treatment are on the rise, and feels that it is time to end the "nightmare" of the insurance company bureaucracy that is frustrating patients who need care and medicine. It is the sponsor's goal that insurance companies pay for what the doctor orders. In response, a representative from the New Jersey Association of Health Plans stated that "prior authorization serves an important patient-safety role and can protect patients from things like harmful drug interactions since doctors don't always know what other drugs a patient may be taking. It also protects against diversion, fraud, waste, and abuse."

Department of Health Circulates OON Forms—On October 23, 2018, the New Jersey Department of Health (DOH) circulated a memo with draft out-of-network disclosure forms to be used by health care facilities, such as hospitals and ambulatory surgery centers, in order to fulfill their obligations under the recently enacted Out-Of-Network Consumer Protection, Transparency, Cost Containment, and Accountability Act (the Act). The DOH is required by the Act to promulgate rules and disclosure forms to be distributed to insured patients. The memo and the draft disclosure forms are intended to assist general acute care hospitals, satellite emergency departments, hospital-based ambulatory surgery centers, and freestanding ambulatory surgery centers in understanding and meeting their obligations under the Act until the rules and disclosure forms can be adopted through rulemaking.

Bill Introduced Requiring Licensing of Embryo Storage Facilities—On October 18, 2018, Bill A4605 was introduced in the New Jersey Assembly requiring the New Jersey Department of Health (DOH) to regulate and license embryo storage facilities. An identical bill was introduced in the New Jersey Senate on October 15, 2018. The Bill stipulates that a person cannot conduct, maintain, or operate an embryo storage facility in New Jersey unless licensed by the DOH pursuant to the provisions of the Bill. The DOH would be required to promulgate regulations governing the storage and care of human eggs, pre-embryos, and embryos by an embryo storage facility. The regulations would promote safety and best practices among embryo storage facilities and, at a minimum, prescribe standards governing the operation, maintenance, and administration of embryo storage facilities.

Bill Introduced Requiring End-of-Life Training—On October 29, 2018, Bill A4683 was introduced in the New Jersey Assembly requiring certain medical facilities to undertake end-of-life planning and training as a condition of licensure. An identical bill was introduced in the New Jersey Senate on October 18, 2018. Under the Bill, assisted living facilities, dementia care facilities, hospitals, and long-term care facilities are to: (1) require annual education on advance care planning, end-of-life care, and Practitioner Orders for Life-Sustaining Treatment (POLST) forms for administrative and professional medical staff; (2) provide patients and their families, as appropriate, educational materials on POLST forms, advance directives, and hospice and palliative care; and (3) implement policies to identify and address end-of-life issues upon patients' admission to a facility. The Department of Health may suspend the license of a facility that fails to comply with the Bill's provisions.

Dietitian/Nutritionist Licensing Bill Currently Being Evaluated—Committees within the New Jersey Senate and New Jersey Assembly are currently evaluating Bill S2625/A1582 (the "Dietitian/Nutritionist Licensing Act") which would provide for the licensure of dietitians and nutritionists in New Jersey. Applicants for licensure would need to be registered as "Registered Dietitians" by the Commission on Dietetic Registration and meet certain other educational and training requirements. The Bill would prohibit any person from practicing dietetics/nutrition in New Jersey unless that person holds a valid license, subject to a number of exceptions. Critics of the Bill are concerned that it would hamper the practice of any nutrition professional who is not a Registered Dietitian.

For more information, contact:

John D. Fanburg | 973.403.3107 | jfanburg@bracheichler.com
Mark Manigan | 973.403.3132 | mmanigan@bracheichler.com
Ed Hilzenrath | 973.403.3114 | ehilzenrath@bracheichler.com

Brach Eichler In The News

On November 1, **Brach Eichler** was named a Best Law Firm in New Jersey by *Best Lawyers in America*® and ranked in Tier 1 in health care law as well as corporate law, real estate, litigation – real estate, trusts and estates, and personal injury.

John D. Fanburg spoke to the semi-annual meeting of the New Jersey Obstetrical and Gynecological Society on November 2 on liability risk and how prior authorization affects the quality of health care.

On November 7, **John D. Fanburg** addressed the current state of New Jersey's health care industry at Sax LLP's Annual Healthcare Industry Update. **Lani M. Dornfeld** also attended the event.

Lani M. Dornfeld presented a webinar titled "Revisions to Medicare Home Health Moratoria Access Waiver Demonstration," hosted by the Home Care Association of Florida (HCAF), November 7.

Lani M. Dornfeld attended the HCAF Palm Beach Gardens District Meeting on November 28.

To view a full listing of recent news items and to read the articles mentioned above, please visit http://bit.ly/2tYYFha.

HIPAA CORNER

October was Cybersecurity Awareness Month

On October 31, 2018, the Department of Health & Human Services, Office for Civil Rights (OCR) published a newsletter regarding National Cybersecurity Awareness Month.

In the newsletter, the OCR took the opportunity to remind HIPAA-covered entities and business associates of the many basic cybersecurity safeguards they can deploy to reduce the impact of attempted cyberattacks, including:

- **Encryption** – Convert electronic data into unreadable or code format without the use of a decryption key. Encryption can prevent unauthorized users from viewing encrypted data. As part of the HIPAA Security Rule requirements, covered entities and business associates must assess whether encryption is a reasonable and appropriate safeguard to protect electronic protected health information (ePHI) at rest (e.g., stored on a computer) and in motion (e.g., when sent by email).
- **Social Engineering** – Reduce phishing attacks through proper workforce training. The HIPAA Security Rule requires covered entities and business associates to implement security training for all workforce members, including management.
- **Audit Logs** – Record and monitor system activity for early detection and prevention of suspicious activities. The HIPAA Security Rule requires implementation of audit controls to records and examination of activity on information systems containing ePHI.
- **Secure Configurations** – Reduce the attack surface for bad actors and improve your organization's cybersecurity defenses through proper configuration of network devices and software. "The configuration of firewalls, workstations, routers, servers, and other components all play an important role in minimizing the chance of security incidents."

If you would like more information or assistance with developing, updating or implementing your HIPAA compliance program, contact:

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

BRACH | EICHLER LLC
bracheichler.com | Counsellors at Law

Health Care Practice Group | 101 Eisenhower Parkway, Roseland, NJ 07068 | 973.228.5700

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
Debra C. Lienhardt | 973.364.5203 | dlienhardt@bracheichler.com
Mark Manigan | 973.403.3132 | mmanigan@bracheichler.com
Keith J. Roberts | 973.364.5201 | kroberts@bracheichler.com

Counsel

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
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
Shannon Carroll | 973.403.3126 | scarroll@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
Andrew J.D. Russo | 973.403.3135 | arusso@bracheichler.com
Jonathan J. Walzman | 973.403.3120 | jwalzman@bracheichler.com

Stay Connected!

*Follow us on **LinkedIn**: www.linkedin.com/company/brach-eichler-llc and **Twitter**: http://twitter.com/BrachEichler*

You have the option of receiving your **Health Law Updates** *via e-mail if you prefer, or you may continue to receive them in hard copy. If you would like to receive them electronically, please provide your e-mail address to akatz@bracheichler.com. Thank you.*