BRACH | EICHLER LLC

Health Law UPDATE

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FEDERAL UPDATE

CMS Proposes to Cancel Mandatory Bundled Payment Models

On August 17, 2017, the Centers for Medicare & Medicaid Services (CMS) proposed a rule to cancel the Episode Payment Models (EPMs) and Cardiac Rehabilitation (CR) incentive payment model as well as to revise aspects of the Comprehensive Care for Joint Replacement (CJR) model. The proposed rule is meant to offer CMS greater flexibility to design and test other episode-based payment models, while still allowing it to test and evaluate the impact of the ongoing CJR model.

The EPMs and CR incentive models were designed as mandatory payment models and implemented to test the effects of bundling cardiac and orthopedic care beginning on January 1, 2018. The CJR payment model was established to test the effects of bundling on orthopedic episodes involving lower extremity joint replacements. The CJR model began on April 16, 2016 and is currently in its second performance year. Under the proposed rule, the CJR model would continue on a mandatory basis for 33 of the 67 original geographic areas, with an exception for low-volume and rural hospitals.

CMS believes that requiring hospitals to participate in additional episode payment models at this time is not in the best interest of the agency or providers. Mandating such episode payment models could deter providers from participating in future voluntary efforts. CMS stated that if, at a later date, it decided to test these models on a voluntary basis, it would expect to implement them by way of soliciting applications and securing participants' agreements, consistent with how CMS implements other voluntary models. Comments on the proposed rule may be submitted to CMS no later than October 16, 2017.

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CMS Releases Hospice Compare Website and Simplifies Notice of Election Submission Process

On August 16, 2017, the Centers for Medicare & Medicaid Services (CMS) released Hospice Compare, a website designed to help consumers choose the best hospice provider.

Hospice Compare Website. The website permits patients and their families to review quality ratings, compare up to three facilities at a time, and bookmark favorite facilities for future reference.

In the "compare" view, consumers can get a snapshot of how the facilities stack up against each other on key quality measures, including how well a facility handles:

- Treatment preferences
- Patient beliefs and values
- Pain screening
- Pain assessment
- Screening for shortness of breath
- Treatment for shortness of breath
- Bowel regimens for patients treated with opioids.

In the "profile" view, consumers can see how a facility measures up to the national average in each category.

Identifying Errors in Hospice Compare Data. Prior to the release of data each quarter, CMS gives providers 30 days to review their quality measures using a Hospice Provider Preview Report. Preview reports should be saved, as they are available only for 60 days.

If a provider believes there is an error in the Preview Report, it must submit a request for review to *HospicePRquestions@cms.hhs.gov* within the 30-day period. The email request must contain the following information:

- Hospice CMS certification number (CCN),
- Hospice agency name and mailing address,
- CEO or CEO-designated representative contact information including, name, email address, telephone number, and physical mailing address, and
- Information supporting the claim that the data contained within the Preview Report is wrong, including quality measures affected and aspects of quality measures affected (denominator or quality metric).

Electronic NOE Submissions. On July 27, 2017, CMS issued a memo announcing that, as of January 1, 2018, hospice notices of election (NOEs) may be submitted via electronic data interchange (EDI). Previously, NOEs had to be submitted via paper claim submissions or direct data entry. According to CMS, the EDI transfer should expedite the process and reduce errors involved in direct data entry.

The change reflects CMS's efforts to move away from paper submissions and toward electronic data exchanges.

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Opioid Crisis: Still Not "Officially" a National Emergency

A few weeks after firmly stating his intention to declare the opioid crisis a national emergency, President Trump has yet to take the steps necessary to do so.

There are currently 28 active national emergencies, none of which are clearly directed at U.S. public health. National emergencies, each of which must be renewed by the President annually, are typically used to freeze the assets of foreign nationals or impose sanctions on another country. While national emergencies can be declared to address public health crises, the most direct way to do so is through the declaration of a public health emergency.

Public health emergencies are distinct from national emergencies declared by the President. Instead, the Secretary of Health and Human Services, Tom Price, could declare a public health emergency on his own. This would unlock a range of expanded powers for the Department of Health and Human Services, permitting the Secretary to issue grants and spend money for this purpose which he otherwise could not do. The Secretary also would be given additional freedom to direct resources and amend regulations.

Only with the swine flu outbreak in 2009 was a recent public health emergency also declared a national health emergency to the entire country. If the President chooses to formally declare the opioid crisis a national emergency, the federal government may look to states that already have implemented public health emergencies to address the opioid crisis, including Maryland, Massachusetts, Alaska, Arizona, Virginia, and Florida. These states provide a model for (1) using public health emergency declarations to implement new prescription guidelines for healthcare professionals; (2) expanding educational programs about addiction; (3) increasing access to treatment including medications for addiction treatment; and (4) broadening availability of emergency tools such as naloxone, a medication used to revive someone who has overdosed. These combined efforts can make a significant impact in saving lives.

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STATE UPDATE

UnitedHealthcare Underpaying Out-of-Network Emergency Medical Providers

Mid-Atlantic Surgical Associates PC (Mid-Atlantic), a cardiac surgery group, filed a class action lawsuit against UnitedHealthcare, alleging that UnitedHealthcare underpaid out-of-network providers for emergency medical services and advised its patients, both verbally and in writing, to ignore bills for services from these providers. Mid-Atlantic asserted that UnitedHealthcare violated state and federal regulations in order to pressure out-of-network providers, including Mid-Atlantic, to become in-network providers with UnitedHealthcare. It is alleged that UnitedHealthcare has offered to defend its members, by paying for their lawyers, if out-of-network providers sue members to collect outstanding balance bills, i.e., the difference between what UnitedHealthcare decides to pay Mid-Atlantic, and its member's copayment, coinsurance, or deductible. It is believed that the class members in this action, out-of-network providers that have been subject to UnitedHealthcare's underpayments, number into the hundreds.

UnitedHealthcare argued that providers must accept payment that UnitedHealthcare deems to be sufficient under FAIR Health usual and customary charge data regardless of Mid-Atlantic and other providers' actual billed charges. Alternatively, Mid-Atlantic contended that there is no agreement between them and UnitedHealthcare, and Mid-Atlantic never agreed to accept payments based on FAIR Health.

Mid-Atlantic is seeking, among other damages including compensatory damages, injunctive relief, and counsel fees, (1) that UnitedHealthcare pay out-of-network emergency medical services in amounts that ensure balance bills are not sent to the patients, and (2) confirmation that out-of-network providers are permitted to bill a UnitedHealthcare member the difference between the payment made by UnitedHealthcare and such member's copayment, coinsurance, or deductible.

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DCA Proposes Amendments to Health Care Service Firm Regulations

The New Jersey Division of Consumer Affairs (DCA) recently published proposed regulations to amend existing rules governing health care service firms. The regulations generally require health care service firms to register with the DCA and provide basic rules for operating health care service firms in New Jersey. The current regulations define a health care service firm as any person who operates a firm that employs individuals to provide health care or personal care services either directly in the home or at a care-giving facility. "Health care services" means any services rendered for the purpose of maintaining or restoring an individual's physical or mental health, or any health-related services for which licensure, registration or certification is required. "Personal care services" are defined to include bathing; toileting; transferring; dressing; grooming; and assistance with ambulation, exercise, or other aspects of personal hygiene.

Under the proposed amendment, a person who operates a firm that employs individuals to provide companion services would be included within the definition of health care service firms that require registration with the DCA. "Companion services" would be defined as non-medical, basic supervision, and socialization services that do not include assistance with activities of daily living and that are provided in an individual's home, and may include household chores. The proposed amendment also would require all new and existing health care service firms to annually submit evidence of accreditation by an accrediting body for homemaker agencies participating in Medicaid; one that is recognized by the New Jersey Department of Human Services. Also under the proposed amendment, a health care service firm would be required to submit an audit to DCA every third year. The audit would be required to be conducted by a certified public accountant and be divided into a compliance component and a financial component. The DCA will be accepting comments regarding the proposed amendment through October 20, 2017.

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BME, BON, and DOBI Propose Amendments to Regulations and a New DOBI Rule

Two New Jersey professional licensing boards, the State Board of Medical Examiners (BME) and the State Board of Nursing (BON), published proposed amendments to regulations in the September 5, 2017 New Jersey Register. In addition, the New Jersey Department of Banking and Insurance (DOBI) proposed amendments to certain regulations and a new regulation.

The BME published a proposed amendment to N.J.A.C. 13:35-7.5, Requirements for the Dispensing of Drugs and Special Limitations Applicable to the Dispensing of Drugs for a Fee. Under New Jersey law, N.J.S.A. 45:9-22, physicians are prohibited from dispensing more than a seven-day supply of drugs or medications. The law provides exemptions to this prohibition, including a statutory amendment adding a new exemption for dispensing a food concentrate, food extract, vitamin, mineral, herb, enzyme, amino acid, tissue or cell salt, glandular extract, neutraceutical, botanical, homeopathic remedy, or other nutritional supplement. The BME proposes to amend its regulations to recognize the new exemption to the seven-day dispensing limitation.

The BON proposes to readopt nursing rules at N.J.A.C. 13:37, with amendment. The proposal includes an amendment to continuing education requirements. In particular, the rule adds an additional manner in which a registered professional nurse or licensed practical nurse may obtain continuing educational hours, as follows: successful completion of continuing education courses or programs related to nursing approved by, or offered by entities accredited by, the American Nurse Credentialing Center. Credits will be awarded one hour for each 60 minutes of attendance. The BON also proposes to delete certain outdated/expired requirements regarding continuing education for organ and tissue donation and certain proofs for certification training.

The DOBI, Office of Life and Health, has proposed amendments to N.J.A.C. 11:24-1.2 and 11:24A-1.2 and 2.3, to reinforce the existing rights of a covered person (a person who receives benefits or health care services under a health benefits plan) to request to receive services from an out-of-network provider, but pay only network-level cost sharing when the network associated with the covered person's plan does not contain a qualified, accessible, and available provider to perform the needed service.

The DOBI also proposes to amend regulations governing prompt payment of health benefit claims, at N.J.A.C. 1:22-1.2, 1.6, 1.9 and 1.10, and proposes a new rule at 11:22-1.5. DOBI proposes to amend the rules governing the prompt payment of claims to increase transparency and accountability related to health benefit plans. The new rule at N.J.A.C. 11:22-1.5 would set forth the minimum requirements for an Explanation of Benefits (EOB), including that every carrier will be required to provide an EOB, electronically or in writing, to a covered person in response to the filing of a claim by a provider or a person covered under a health benefits plan. A carrier or its agent must provide an EOB within 30 days if the claim is filed electronically or 40 days if the claim is submitted in writing. The EOB will be required to include at least: (1) name of the covered person; (2) name of the provider; (3) date of service; (4) clear description of the service; (5) billed charge; (6) allowed charge; (7) non-covered amount; (8) a specific explanation of why a charge is not covered by the health benefits plan, with specific requirements for how denial reasons must be stated; (9) the amount that is the covered person's responsibility due to deductible, coinsurance, and copayment; (10) the accumulation toward the covered person's deductible or family deductible, if applicable; (11) amount paid by plan, with any paid interest shown separately; (12) an explanation of the process to appeal the determination on the claim; and (13) a telephone number for additional information on the processing of the claim, or (14) if review of the claim is still pending upon issuance of the EOB, the EOB shall so state and items (6) through (10) can be omitted.

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Legislative Update

Amendments to Physician Assistant Regulations — On August 21, 2017, the State Board of Medical Examiners, as recommended by the Physician Assistant Advisory Committee, proposed to amend its rules and promulgate new rules to implement P.L. 2015, c. 224, which created an expanded, physician-delegated scope of practice for physician assistants. P.L. 2015, c. 224, which became effective on August 1, 2016, revised the scope of practice for physician assistants, requires all physician assistants in the State to maintain malpractice liability insurance or a letter of credit, and requires physician assistants to have a separate written agreement with each physician who delegates medical services to the physician assistant. Written comments on the proposed rules must be submitted by October 20, 2017.

Prescription Drug Insurance Coverage — On August 24, 2017, Assembly Bill A5144 was introduced to require health insurers to provide coverage for prescription drugs through the entire course of treatment as determined by the prescriber. The time period for the course of treatment would be determined solely by the covered person's prescriber without the imposition of any utilization management requirements.

Health Care Facilities Legislation Passed by Legislature — On July 31, 2017, the New Jersey Assembly passed S2563, which had previously been passed by the Senate on June 22, 2017. The bill clarifies Department of Consumer Affairs rulemaking authority over freestanding residential health care facilities, and prohibits eviction of residents from such facilities, except for good cause. The bill now awaits approval from Governor Christie.

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Brach Eichler In The News

In "Maintaining the Integrity of Physician-Owned Practices (*Law360*)," **John D. Fanburg** writes about two recent cases, Allstate vs. Northfield and Carothers vs. Progressive, and their implications for the purchase and sale of medical practices. *http://bit.ly/2vSj0I7*

Lani M. Dornfeld recently commented in *Law360* about a potential increase in HIPAA/confidentiality-based patient suits as a result of a recent NJ ruling. *http://bit.ly/2vIp5r1*

HIPAA CORNER

Ransomware Attack Puts 33,000 Patients at Risk

St. Mark's Surgical Center in Fort Myers, Florida was the target of a ransomware attack earlier this year that prevented access to patient data, including protected health information (PHI), such as names, dates of birth, and Social Security numbers. A ransomware attack will infiltrate a company's data, encrypt it and only offer the release of the data upon payment of a ransom. It is possible a ransomware attack also could cause the breach of PHI outside the organization.

The Department of Health and Human Services, Office for Civil Rights (OCR), the HIPAA enforcement agency, reports that ransomware attacks are on the rise with over 4,000 daily attacks since early 2016, a 300% increase compared to 2015. HIPAA requires covered entities and business associates to have in place security measures that can help prevent ransomware attacks, including, among other measures, (1) a security management process, which includes a risk analysis to identify threats and vulnerabilities; (2) procedures to guard and detect against malicious software; (3) staff training to educate staff to identify, assist in detecting, and report malicious software; and (4) implementation of access controls to limit access to PHI to only those necessary.

The OCR has issued guidance stating that ransomware attacks are presumed to result in a breach of PHI unless the affected covered entity or business associate can prove, through an investigation and risk assessment, that there is a low probability PHI was compromised. Covered entities have a maximum of 60 days following the discovery of a breach to report the breach to affected individuals and, in certain circumstances, to the OCR and other authorities. In this matter, St. Mark's was assessed a monetary penalty for late notification.

If you need assistance with your organization's HIPAA policies and procedures, risk management plan, or investigating and responding to a breach or suspected breach incident, please contact a member of our Health Care Practice Group.

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