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Health Law UPDATE

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FEDERAL UPDATE

Senate Republican Obamacare Replacement Bill Lacks Support

On July 13, 2017, Senate Republicans unveiled a revised bill to repeal and replace the Affordable Care Act. The revised bill, entitled the "Better Care Reconciliation Act of 2017," updated the replacement bill that Senate Republicans had originally proposed on June 22, 2017. However, due to uniform opposition from Senate Democrats as well as a small number of Republican Senators, it is expected that if it came to a vote, the revised bill would be unsuccessful. Instead, on July 18, 2017, Senate Majority Leader Mitch McConnell suggested that the Senate would next take up a straight repeal of the Affordable Care Act without replacement legislation in place. Repeal legislation had passed the Senate and the House in 2015, but then President Barack Obama had vetoed the legislation.

Some of the key aspects of the proposed revised bill include the following:

- The bill decreases Medicaid funding expansion. In addition, federal funding for Medicaid would be converted to a per capita allotment or a block grant, depending on each state's preference. This will have the effect of reducing federal funding for the Medicaid program, with the potential result that states will reduce Medicaid eligibility.
- The Affordable Care Act requirement that insurers not exclude individuals with pre-existing conditions or charge them higher rates would remain. However, the bill would allow insurance companies to sell cheaper, deregulated insurance plans as long as Affordable Care Act-compliant plans are still sold as well. Critics worry that this could result in split risk pools, one with sick people with pre-existing conditions and the other with healthy young people. Insurance companies would receive subsidies for high-risk individuals with pre-existing conditions.
- The bill provides $45 billion to combat the opioid epidemic.
- The bill would keep the two taxes imposed by the Affordable Care Act on people with high incomes: the 3.8 percent tax on investment income and the 0.9 percent payroll tax. The taxes apply to individuals with income over $200,000 and couples with income over $250,000.
- The Affordable Care Act mandate that individuals purchase insurance or pay a penalty would be eliminated. Instead, there would be a six-month waiting period for individuals who seek insurance after failing to maintain continuous coverage for a certain period of time during the prior year.

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Effective Date for New Home Health COPs Delayed

On July 10, 2017, the Department of Health & Human Services, Centers for Medicare & Medicaid Services (CMS) published a final rule delaying the effective date for the new Conditions of Participation (COPs) for Home Health Agencies (HHAs). CMS delayed the original effective date of July 13, 2017 to January 13, 2018 in response to concerns that HHAs will need a significant amount of time and effort to prepare for the implementation of the new rules, which may require adjustments to resource allocation, to staffing and, potentially, to infrastructure.

In line with the delay in effective date, the final rule also includes two conforming amendments to dates that appear in the regulation text. First, the phase-in date for the requirements at § 484.65(d)—"Standard: Performance improvement projects" is delayed until July 13, 2018. This allows HHAs an additional six months to collect data before implementing data-driven projects. Second, the final rule revises § 484.115(a)—"Standard: Administrator, home health agency." In this provision, all administrators employed by HHAs prior to the effective date of January 2017 were "grandfathered in" meaning that those administrators employed by an HHA prior to July 13, 2017 would not have to meet the new personnel requirements. The final rule replaces the July 13, 2017 effective date with the effective date of January 13, 2018.

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CMS Proposes New MACRA Rules

The Centers for Medicare & Medicaid Services (CMS) recently released a proposed rule relating to the Quality Payment Program (QPP) under the Medicare Access and CHIP Reauthorization Act (MACRA). The proposed rule would set the parameters for Year 2 of the QPP. Calendar year 2017, the first year of the QPP, has been a transition year in which providers could choose to participate in one of two tracks to meet the requirements under the QPP: (1) the Merit-Based Incentive Payment System track; or (2) the Advanced Alternative Payment Model track. The Year 2 proposed rule continues to offer flexibility to clinicians by allowing them to continue using the 2014 edition of Certified Electronic Health Record Technology (CEHRT) into 2018, although CMS will encourage providers to adopt use of 2015 edition CEHRT by providing a bonus to providers who use a 2015 EHR system in 2018.

Also under the proposed rule, CMS would make certain modifications to the QPP to allow more small physician practices to be exempt from complying with some of the MACRA requirements. Under the current rule, physician practices must have less than $30,000 in Medicare Part B allowed charges or fewer than 100 Medicare Part B patients to be exempt. Under the new rule, CMS would expand the exemption threshold to physician practices with less than $90,000 in Medicare Part B allowed charges or fewer than 200 Medicare Part B patients. Additionally, the proposed rule would contain certain other administrative changes that would ease some of the other administrative burdens contained in the original rules. CMS is accepting comments on the proposed rule until August 21, 2017.

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CMS Issues a Proposed Rule to Allow for Pre-Dispute Arbitration Agreements at Long-Term Care Facilities

On June 8, 2017, the Centers for Medicare & Medicaid Services (CMS) published a proposed rule that would remove the ban on pre-dispute arbitration agreements previously instituted in an October 2016 final rule titled "Reform of Requirements for Long-Term Care Facilities." This proposed rule provides that long-term care facilities may enter into pre-dispute arbitration agreements as long as there is transparency in the arbitration process. CMS proposes to remove the provision prohibiting long-term care facilities from entering into pre-dispute arbitration agreements with any resident or his or her representative. CMS also proposes to remove the provision that precludes such facilities from requiring residents to sign an arbitration agreement as a condition of admission to a long-term care facility. CMS, upon reconsideration, believes that the 2016 final rule underestimated the financial burdens placed on providers who are forced to litigate claims in court. Further, CMS believes that arbitration agreements are advantageous to both providers and beneficiaries because they allow for the expeditious resolution of claims without the costs and expense of litigation. The United States District Court for the Northern District of Mississippi has issued a decision granting a preliminary injunction against enforcement of the 2016 final rule that prohibits pre-dispute arbitration agreements.

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OIG Finds Over $700 Million in Inappropriate Meaningful Use Payments

The Department of Health & Human Services, Office of Inspector General (OIG) issued its report on Electronic Health Record Incentive Payments, also known as "meaningful use" dollars, and found that the Centers for Medicaid & Medicare Services (CMS) inappropriately paid $729,424,395 to eligible professionals (EPs) who did not meet the program's requirements. The program was enacted under the Health Information Technology for Economic and Clinical Health Act (HITECH Act) as a means to promote electronic health records (EHR) and improve health care quality, safety, and efficiency. It is estimated that over six billion dollars were paid to EPs under the program from May 2011 to June 2014.

The program requires EPs to attest that they meet program requirements by self-reporting data through CMS's online system. EPs who qualify for both the Medicare and Medicaid programs must elect to receive payments only from one program and may receive payments for up to five years. The audit revealed EPs had insufficient attestation support, inappropriately reported periods, or insufficiently used certified EHR technology. In addition, CMS failed to ensure that EPs who switched programs were placed in the correct payment year. The errors occurred, in part, because CMS conducted minimal documentation reviews of self-attestations, "leaving the EHR program vulnerable to abuse and misuse of Federal funds." The errors discovered totaled approximately $291,222 in inappropriate payments and $2,344,680 in overpayments.

Among its recommendations, the OIG called for "stronger program integrity safeguards" that allow for more consistent verification. The OIG also recommended that CMS recover the inappropriate payments and overpayments revealed by the audit and conduct additional reviews to recover the $729,424,395 in estimated inappropriate payments, as well as any inappropriate payments made after the audit period. CMS indicated it would continue to conduct targeted risk-based audits through 2017.

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STATE UPDATE

BME Proposes Amendments to Screening and Diagnostic Testing Offices

The New Jersey State Board of Medical Examiners has proposed amending N.J.A.C. 13:35-2.6 which regulates screening and diagnostic medical testing offices (SDMTOs). The amendment relaxes the regulation to allow SDMTOs more flexibility and clarifies questions and concerns surrounding SDMTOs.

The proposed changes include clarification that a diagnostic test does not need a specific CPT code or that a fee be charged in order for a practitioner to interpret a test or refer a patient to another practitioner to perform a test. The amendment also makes clear that prior language which prohibited billing for a test which "fails to yield data of sufficient clinical value" was not meant to prohibit billing for a test which simply failed to yield data but rather is meant to prohibit billing for diagnostic tests which are not "recognized in the scientific community as being capable of yielding" sufficient data.

The proposed regulation relaxes who may own SDMTOs to include practitioners or closely allied health professionals (defined as an individual licensed to practice a health care profession in New Jersey) as long as the majority interest is held by practitioners authorized to perform and interpret all of the offered tests.

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DOH Proposed Rule Seeking to Identify and Treat Sepsis

On June 19, 2017, the New Jersey Department of Health (DOH), published a Rule Proposal that would require hospitals to implement and update protocols and training for the early identification and treatment of sepsis and septic shock. The proposed regulations would complement already existing infection prevention programs.

Sepsis, which is a life-threatening complication of infection, is treatable if it is addressed as a medical emergency. Patients diagnosed and treated within an hour following presentation have over an 80% survival rate.

Sepsis is the most expensive condition treated in U.S. hospitals, accounting for $23.7 billion annually. It is also the second most common cause of hospitalization, resulting in approximately 1.3 million stays.

The social impact of sepsis includes the following:

- Sepsis is the largest killer of children, with more than 4,400 children dying annually
- Each year, at least 75,000 maternal deaths worldwide are a result of sepsis
- 258,000 people die from sepsis annually in the U.S., which is more than from prostate cancer, breast cancer and AIDS combined
- More than 38 sepsis cases require amputation each day.

Comments to the rule proposal must be submitted by August 18, 2017 and can be submitted through DOH's website.

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Proposed Amendment to Hospital Licensing Standards Requiring Designation of After-Care Assistance Caregiver

On June 19, 2017, the New Jersey Department of Health (DOH) released proposed amendments and new rules under hospital licensing standards aimed at better defining the content and scope of instructions hospitals must offer non-paid caregivers who agree to perform necessary after-care tasks for hospital patients discharged to their place of residence. In November 2014, Chris Christie approved P.L. 2014, c. 68, which directed the Commissioner of the DOH to promulgate rules addressing this issue with the goal of improving the quality of patient care, reducing hospital readmissions and lowering overall healthcare costs. In response, the DOH met with several interested parties, including the New Jersey Hospital Association, the New Jersey Council of Teaching Hospitals and the American Association of Retired Persons to conduct a comprehensive analysis of caregiver services currently provided in New Jersey, which is reflected in these new proposed amendments and rules.

The proposed amendments and rules include, but are not limited to, establishing new definitions for certain terms such as "discharge plan" and "discharge planning team" and delineating specific actions a hospital must take with regard to a patient's designated caregiver. For example, general acute care hospitals will be required to ask patients who have been deemed able to return to their residence by the hospital's discharge planning team if they would like to designate a caregiver to provide after-care tasks on their behalf. If the patient opts to designate a caregiver, before the patient is discharged, the hospital must offer "after-care assistance" training to the designated caregiver that is either live or recorded at the election of the caregiver. Caregivers would also be able to ask hospital staff questions about the discharge plan and their training.

Written comments on the proposed amendments and rules must be submitted electronically or by regular mail to the DOH by August 18, 2017.

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Legislative Update

Minimum Reimbursement Rate for Private Duty Nursing Services – On July 1, 2017, Senate Bill S3400 was introduced, establishing minimum Medicaid reimbursement rates for private duty nursing services. The bill provides that the minimum Medicaid reimbursement rate for such services is to be no less than $60 per hour when a registered professional nurse provides the services, and no less than $48 per hour when a licensed practical nurse provides the services.

CONs for Certain Inpatient Hospital Beds – On July 3, 2017, Governor Christie signed into law S2844, eliminating the Certificate of Need requirement for inpatient hospital beds for treatment of psychiatric and substance abuse disorder dual diagnosis.

Licensure of NJ Surgical Practices as ASCs – On June 29, 2017, the NJ State Senate passed Senate Bill 278 which would require surgical practices to apply for licensure as ambulatory care facilities. The bill would repeal the requirement that surgical practices be registered by the Department of Health (DOH). Instead, it provides that surgical practices must be licensed by DOH within one year as ambulatory care facilities licensed to provide surgical and related services subject to the same regulatory requirements as the larger ambulatory surgical facilities.

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Brach Eichler In The News

Lani M. Dornfeld spoke at the Home Care & Hospice Association of NJ conference on June 22 in Galloway, NJ, on "Preferred Provider Arrangements: Compliant Partnering to Enhance Quality of Care."

Joseph M. Gorrell recently published an article in *Physicians News Digest* entitled, "The Case for Scrupulous Documentation when Prescribing Opioids." The article may be found here.

John D. Fanburg and **Debra Levine** spoke at the July 18, 2017 meeting of the Medical Society of New Jersey, as part of a policy and strategy panel discussing the corporate practice of medicine.

HIPAA CORNER

Anthem Prepared to Settle Data Breach Lawsuit for Record $115 Million

Anthem has reached a settlement to resolve the multidistrict class action litigation relating to a 2015 cyber attack against the company that exposed the personal information of more than 78 million people. This could be the largest data breach settlement in history if approved by the U.S. District Court for the Northern District of California, San Jose Division, which is scheduled to hear a motion for preliminary approval of the settlement on August 17, 2017.

The settlement does not include any finding of wrongdoing, and Anthem has not admitted to any wrongdoing or that any individuals were harmed as a result of the cyber attack. Regardless, the company has agreed to pay a total of $115 million to resolve the litigation. The settlement will benefit class members in a number of ways. When Anthem discovered the cyber attack in 2015, the company offered two years of credit monitoring and identity protection services to all individuals whose data may have been impacted.

As part of the settlement, $17 million of the funds will be allocated to pay for an additional two years of credit monitoring and identity protection services. Anthem has also agreed that $15 million of the funds will be allocated to pay actual out-of-pocket costs, up to a set amount, that class members claim they incurred due to the cyber attack.

Class members who already have credit services can submit a claim to receive alternative cash compensation instead of receiving the credit services provided by the settlement. The aggregate sum of alternative compensation has been capped at $13 million of the funds with an individual cap of no more than $50.

Finally, Anthem has agreed to implement additional protections over the next three years. These changes include implementing data retention periods, strict access requirements, and mandatory information security training for all associates and annual IT security risk assessments. The settlement further requires Anthem to allocate a certain amount of funds for information security and increase its funding for every additional 5,000 users if Anthem increases its users by more than 10 percent, whether by acquisition or growth.

The Settlement Agreement and Release may be downloaded here.

OCR Offers Free Continuing Education Credits for Completion of HIPAA Access Right Training Module

On July 6, 2017, the Department of Health & Human Services, Office for Civil Rights (OCR) announced the launch of a new video training module for health care providers on patients' right of access under HIPAA. The OCR states that the "module provides helpful suggestions about how health care providers can integrate aspects of the HIPAA access right into medical practice." Providers completing the module may obtain continuing education credits. The module is available via Medscape here or via OCR's Training and Resources webpage here.

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