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Health Law UPDATE

October 2017

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FEDERAL UPDATE

Sanders Proposes Medicare for All Act of 2017

Senator Bernie Sanders recently proposed *Senate Bill 1804,* which seeks to expand Medicare into a universal health insurance program. The bill would replace America's health care system with a public system funded by higher taxes.

Expected Benefits. Enrolled individuals would be entitled to certain essential health benefits, including hospital services; ambulatory patient services; primary and preventive services; prescription drugs, medical devices, and biological products; mental health and substance abuse treatment services (including inpatient care); laboratory and diagnostic services; comprehensive reproductive, maternity, and newborn care; pediatrics; oral health, audiology, and vision services; and short-term rehabilitative and habilitative services and devices.

Rollout. Children would immediately receive universal Medicare cards. Adults not currently eligible for Medicare would be phased in over four years based on age. In the first year, the plan would cover Americans over 55. By year two, everyone over 45 would be covered. In year three, the plan would cover those over 35, and in year four, all Americans would be covered.

Funding. The bill is projected to require significantly more revenue, but there is no plan for how to fund the bill. Senator Sanders released a number of funding proposals, including a 7.5 percent payroll tax on employers, a 4 percent income tax, and additional taxes on wealthier Americans and corporations. Critics say that even the proposed methods would fall far short of funding the plan.

Support. The bill is backed by at least 16 Democratic senators, which is an unprecedented level of support for this type of proposal. In the House, a single payer bill introduced by Rep. John Conyers has the support of more than 60 percent of Democrats.

Insurance Response. Insurance industry representatives criticize the bill, indicating it will eliminate choice, undermine quality, stymie innovation, and place a heavier burden on taxpayers.

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Chronic Care Management Reimbursement: Changes to Payment Rules Ease Burdens

On June 1, 2015, the Centers for Medicare and Medicaid Services (CMS) implemented a reimbursement program for providers administering chronic care management (CCM) services, allowing doctors to bill under CPT code 99490 for services they might already have been providing to their chronically ill patients. CCM services are management and support services provided by clinical staff, under the direction of a physician or other qualified health professional, to a patient residing at home or in a domiciliary, rest home, or assisted living facility. Services may include establishing, implementing, revising, or monitoring a patient's care plan, coordinating the care of other professionals and agencies, and educating the patient or caregiver about the patient's condition, care, and prognosis.

Medical providers have been hesitant to incorporate formal CCM into their practices, partly because billing CPT code 99490 is not straightforward and the technological and record-keeping requirements proved onerous. In the rule's first iteration, CMS dictated everything from documentation using specific types of electronic health records (EHR), to how many providers could bill for CCM services at the same time, and from patient access to informed consent requirements.

In 2017, the CCM program was further updated, and the certified EHR requirements and need for a signed consent form were removed. New codes were added: CPT Code 99487 for complex CCM of patients who have five or more chronic conditions and who take eight or more medications; CPT code 99489, which is an additional 30-minute code that can only be billed with 99487, allowing physicians to give more time to complex patients; and G code GPP7, which allows physicians to bill for comprehensive assessment and care planning.

CMS continues to revise the CCM program and released a proposed rule for the 2018 physician fee schedule payment policies last month. The proposal contains several major changes that would make it easier for physicians to provide and bill for CCM services. CMS is proposing to pay for new telehealth services, including additional CCM telehealth codes: CPT codes 96160 and 96161 — health risk assessment; and HCPCS code G0506 — care planning for chronic care management. The rule also would establish payment to rural health clinics and federally qualified health clinics for regular and complex CCM services, general behavioral health integration services, and psychiatric collaborative care models.

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OIG Deems Pharmacy Membership Program Low Risk

In Advisory Opinion 17-05 released by the Office of Inspector General (OIG) on September 7, 2017, the OIG concluded that a pharmacy membership program that provides rebates and discounts to participating members would not violate the Social Security Act's prohibition against providing inducements to beneficiaries and would not impose sanctions under the Anti-Kickback Statute, deeming the arrangement low risk.

The requester of the opinion is an owner/operator of retail pharmacies that administers a benefit program to participants who satisfy certain enrollment criteria and pay an annual fee. The benefit program gives participants: (1) discounts on retail prices for specific items, including generic drugs, paid entirely out-of-pocket; (2) discounts on clinical services paid entirely out-of-pocket; and (3) credits toward future retail purchases.

The Social Security Act prohibits, with certain limited exceptions, a provider from offering or transferring remuneration to a Medicare or state health care program beneficiary that could influence beneficiary decisions to utilize that provider. The OIG determined the membership program qualified for the rebate exception to the prohibition because: (1) the rewards consist of coupons, rebates, or other rewards; (2) the rewards are offered on equal terms to the public, regardless of health insurance status; and (3) the offer is not tied to the provision of services under Medicare or other state health care programs. Importantly, participants would remain responsible for any items or services purchased through the program, the discounts/rebates may not be used in conjunction with any form of insurance or health plan, and the pharmacies would not bill for any items or services purchased under the program.

For similar reasons, the OIG also opined that the arrangement poses a low risk under the Anti-Kickback Statute.

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Hurricane Irma Prompts Legislation to Protect Seniors During Natural Disasters

In the wake of 12 resident deaths in a Broward County nursing home that lost power to its air conditioning units during Hurricane Irma, a number of Florida senators have introduced bills at the state and federal level in order to safeguard against such future tragedies and better protect seniors during emergencies such as natural disasters.

At the state level, FL SB284 (18R) was introduced on September 15, 2017 by Florida State Senator Lauren Book (D-Plantation). The bill would require facilities to have power sources and fuel to operate for at least five days during a power outage, and would require state inspections at least once every two years to ensure compliance. The next day, Florida Governor Rick Scott issued emergency rules requiring all assisted living facilities (ALFs) and nursing homes to obtain ample resources, including a generator and the appropriate amount of fuel, to sustain operations and maintain comfortable temperatures for at least 96 hours following a power outage. The emergency rule carries with it a 60-day deadline for implementation.

The emergency action also requires:

- The State Fire Marshal to conduct inspections of generators within 15 days after installation at the facilities;
- Local emergency management officials to either approve or deny the emergency management plans already required to be submitted to them by law from residential healthcare facilities to ensure sufficient protection of life;
- Each local emergency management agency to post all approved facility emergency management plans to their website within ten days after the plan's approval; and
- Facilities to submit proof of compliance with the emergency rules to state agencies AHCA and Elder Affairs within 48 hours after each plan's approval.

While a number of nursing homes have objected to the emergency rules on cost and logistical grounds, Governor Scott remains steadfast in his decision.

At the federal level, Senator Bill Nelson (D-Fla.) introduced a bill on September 19, 2017 to create a national advisory committee to find ways to better prepare and care for the nation's seniors during a disaster. The bill would require the Health & Human Services (HHS) Secretary to establish a National Advisory Committee on Seniors and Disasters. The 15-member panel would be appointed by the HHS Secretary and be comprised of federal and local agency officials, as well as non-federal health care professionals with expertise in disaster response. The panel would be charged with providing guidance to local, state, and federal officials on how to better prepare seniors for an emergency.

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STATE UPDATE

Florida Supreme Court Rules on Home Health Referrals Protection

The Florida Supreme Court recently ruled that referral sources of home health providers can be a protected legitimate business interest under state law governing restrictive covenants. The Court's decision was related to the interpretation of a 2016 Florida statute that set forth requirements for the enforceability of contractual restrictive covenants. Specifically at issue is a requirement in the statute that a person seeking enforcement of a restrictive covenant must prove the existence of "legitimate business interests" justifying the restrictive covenant, and whether a list of examples of what is considered a legitimate business interest set forth in the statute was meant to be exhaustive.

In a unanimous decision that resolved a split among two different Florida appellate courts, the Court ruled that despite the fact that referral sources are not included in the list of legitimate business interests set forth in the statute, the list was not intended to be exhaustive, and was only intended to serve as an example of certain types of legitimate business interests that justify the enforcement of a restrictive covenant. Whether or not

something is a legitimate business interest is dependent upon the facts and circumstances of each case and the particular industry involved. In the context of home health businesses that heavily rely on referrals, it is reasonable to conclude that there is a legitimate business interest in protecting referral sources.

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U.S. Supreme Court Will Not Hear Medical Records Disclosure Case

The U.S. Supreme Court has decided that it will not hear a Florida case regarding the disclosure of medical records, involving Southern Baptist Hospital of Florida, Inc. (Baptist) and a patient injured by alleged negligent care from Baptist. Baptist petitioned the Supreme Court to review and decide on whether a hospital is required to disclose certain medical records during a medical malpractice lawsuit or whether those records may remain undisclosed. The argument for disclosure was made by the patient pursuant to a citizen-initiated 2004 Amendment to the Florida Constitution (Amendment) and Baptist's argument for nondisclosure was made under the federal 2005 Patient Safety Act.

The Patient Safety Act allows hospitals to submit information regarding medical errors to patient safety organizations with the purpose, at least in part, to analyze these errors and learn how to prevent similar errors in the future. Baptist argued that the information submitted is voluntary and, under the Patient Safety Act, there are confidentiality protections.

The Florida Supreme Court ruled against Baptist based on the Amendment, which permits broad access to adverse medical incident records. The court held that the Patient Safety Act did not preempt the Amendment and that, in fact, the two laws worked in harmony.

Baptist petitioned the U.S. Supreme Court, arguing that the Patient Safety Act was undermined by the Amendment, and as such, the Patient Safety Act must take precedence over the Amendment and preempt it in any areas of conflict. However, based on the holding of the Florida Supreme Court, health care providers currently cannot shield documents that are not privileged under Florida state law or the state constitution by virtue of such health care providers' sole and unilateral decision to voluntarily place records under the medical error reporting system created by the Patient Safety Act. The U.S. Supreme Court's refusal to hear this case continues to render this Florida Supreme Court's holding as effective.

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Rules Proposed to Limit Drug Company Influence on Prescribers

On October 2, 2017, the New Jersey Attorney General proposed new rules to prohibit prescribers from accepting lavish meals and uncapped compensation for speaking engagements, consulting work, and other services from drug companies. New Jersey doctors collected $69 million from drug companies and device manufacturers in 2016. Two-thirds of the $69 million received by New Jersey's doctors went to just 300 physicians, with 39 each having received at least $200,000. The objective of the proposed rules is to make sure treatment decisions by prescribers are not being improperly influenced by pharmaceutical manufacturers, particularly with regard to highly addictive opioids.

The proposed rules strengthen and clarify existing limitations for prescribers by providing objective standards to make prescribers accountable for the receipt of "things of value" from pharmaceutical manufacturers by, among other things:

- Delineating prohibited items to include cash, gift cards, entertainment and recreational items, items for prescriber's personal use, payments supporting non-faculty attendance at promotional activities, and continuing education events;
- Setting standards for agreements by which prescribers are paid for "bona fide services," i.e., speaking at promotional activities and continuing education events, participating in advisory bodies and under consulting arrangements;
- Requiring the terms of those agreements to be in writing, with dollar amounts and an articulation of the prescriber's expertise;
- Allowing for and defining the value (not to exceed $15 for each provider) and frequency (4 times each year from each manufacturer) of "modest" meals that can be provided in different settings for learning; and
- Capping the compensation for bona fide services (with the exception of speaking at continuing education events) from all manufacturers at $10,000 every calendar year.

Comments on the proposed rules must be submitted by October 10, 2017 and there is a public hearing scheduled for October 19, 2017.

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New Jersey Legislative Update

Amendments to Elevated Blood Lead Levels Regulations Adopted — Effective September 18, 2017, the NJ Department of Health adopted amendments to the regulations governing childhood elevated blood lead levels. The key change was lowering the childhood blood lead level reference value to initiate treatment and case management intervention to five micrograms per deciliter from ten micrograms per deciliter in order to comport with the recommendations of the Advisory Committee on Childhood Lead Poisoning Prevention to the Federal Centers for Disease Control and Prevention. In addition, throughout the regulations, the term "lead poisoning" was replaced with "elevated blood lead level" in order to incorporate the language.

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Brach Eichler In The News

On November 3, 2017, **John D. Fanburg** will participate in a panel to discuss how healthcare parameters impact the OB/GYN practitioner, at the semi-annual meeting of The Jersey Obstetrical and Gynecological Society. For more information: *http://bit.ly/2wQPEvv*

On November 14, 2017, **John D. Fanburg** will present a legal update at the annual meeting of The Radiological Society of New Jersey. For more information: *http://www.rsnj.org/*

HIPAA CORNER

Ransomware Attacks and Hacking Incidents Have Huge Consequences

On September 12, 2017, Health Data Management (HDM) published "The Biggest Data Breaches in Healthcare in 2017." *http://bit.ly/2wyngyo*

The breaches summarized by HDM fall into the general categories of hacking incidents and ransomware attacks, including hacking of network servers, hacking of desktop computers, hacking and deletion of an appointment information system, hacking of email and hacking of a file-sharing website. In total, more than 2 million patient records were affected.

The Department of Health and Human Services, Office for Civil Rights (OCR), the HIPAA enforcement agency, has published guidance and a number of newsletters to educate HIPAA covered entities and their business associates about security incidents and how to protect against them. See *http://bit.ly/2uJAcjr*. The risks and vulnerabilities associated with such attacks must be included in periodic risk and gap analyses conducted by covered entities and business associates.

The OCR deems ransomware attacks and hacking incidents to be a breach of protected health information, unless the covered entity or business associate is able to prove otherwise. This is accomplished through a detailed investigation, incident response measures, and a multi-factor risk assessment. Penalties associated with failure to perform periodic risk and gap analyses and failure to properly manage a breach incident, investigation, and response can be massive.

If you need additional information and/or assistance with HIPAA policies and procedures, training, or managing and responding to a security breach or other breach incident, do not hesitate to contact:

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