

Health Law UPDATE

FEDERAL UPDATE

Facing Defeat, ACA Repeal/Replace Bill Pulled from House Vote

On March 24, 2017, House Speaker Paul Ryan removed the American Health Care Act (AHCA) from consideration due to an anticipated failed floor vote in the House of Representatives. The AHCA was intended to repeal and replace major parts of the Affordable Care Act (ACA), also known as Obamacare. Even though Republicans hold a sizable majority in the House, control the Presidency and have strongly supported repealing the ACA since its passage in March 2010, the AHCA met surprising resistance within the party. Members of the House “Freedom Caucus” argued that the AHCA did not go far enough to address all of their concerns with the ACA while moderate Republicans had reservations about the bill after the House Rules Committee adopted changes to the AHCA that would eliminate minimum requirements for insurance plans to cover ten “essential health benefits,” including maternity care, emergency room trips and prescription drugs. This coupled with no support across the aisle from Democrats, forced Speaker Ryan, with the consent of President Trump, to withdraw the AHCA just minutes before the scheduled vote.

Some Republican Senators are now promoting their own health care reform ideas while Democrats have urged cooperation once repeal has been taken off the table. In the meantime, the ACA will remain in place for the foreseeable future as President Trump attempts to focus on other agenda items, including tax reform. Shortly after withdrawing the bill, Speaker Ryan stated that “Obamacare is the law of the land. It is going to remain the law of the land.” Speaker Ryan further added, “We’re going to be living with Obamacare for the foreseeable future. I don’t know how long it’s going to take us to replace this law.”

We will continue to monitor the ACA and any repeal and replace plans that are introduced in the upcoming months.

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HHS Unable to Reduce Backlog in Medicare Appeals

The U.S. Department of Health & Human Services (HHS) has reported that it is unable to comply with a federal court order to eliminate pending Medicare billing appeals by the court-ordered 2021 deadline. In fact, HHS reports that there are currently 667,326 pending Medicare billing appeals, and the number is expected to rise to 687,382 by the end of 2017. In addition, the number is expected to reach over one million pending appeals by the end of 2021.

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The current 2021 deadline is still in effect. However, despite taking initiatives addressing the problem, HHS advises that elimination of the pending appeals backlog is unrealistic. According to the agency, the Office of Medicare Hearings and Appeals can only address and estimated 92,000 claims annually with current staffing. Further complicating matters, the number of pending appeals is greater than originally anticipated.

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OIG Allows Free Meals and Lodging Under Affordable Care Act “Exception”

On March 3, 2017, the United States Office of the Inspector General (OIG) issued a favorable advisory opinion regarding a hospital’s proposal to provide free or reduced-cost lodging and meals to certain financially needy patients. The opinion specifically addressed whether the program would violate the federal Anti-Kickback Statute (AKS). The OIG concluded that the proposal would not violate the AKS, because it meets an exception recently established by the Affordable Care Act that allows the financial benefit to be provided if it improves a beneficiary’s ability to obtain services payable under Medicare or Medicaid, and poses a low risk of fraud and abuse.

In the specific case reviewed by OIG, the system hospital operates a Level 1 trauma center and provides state-of-the-art treatment to patients who reside in rural and medically underserved areas. The program would be limited to modest hotels and hospital cafeteria meals. To qualify for the program, the patient must reside 90 miles or more from the hospital and in a medically underserved or a health professional shortage area, as defined under the Public Health Service Act; the patient’s household income could not exceed 500% of the federal poverty level; and the patient’s treatment must warrant the hotel stay. Based on those facts, the OIG found that the exception applied. The decision suggests that other medical providers may now have flexibility in designing similar programs to promote access to care.

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Department of Justice Publishes Guidance for Corporate Compliance Plan Assessment

In February, the United States Department of Justice (DOJ) published guidance titled “Evaluation of Corporate Compliance Programs.” The effectiveness of an existing corporate compliance program is one of the factors the DOJ considers when deciding whether to bring fraud charges against a company. The guidance includes questions that federal prosecutors may ask during a fraud investigation when evaluating a corporation’s compliance efforts. The guidance covers a broad range of topics, including internal investigations, compliance program design and merger and acquisition concerns. The guidance suggests that companies should have proactive compliance protocols in place and conduct rigorous internal investigations when they suspect fraud may have occurred. Companies should also know how to properly and timely respond to agency search warrants and subpoenas.

The guidance is applicable to criminal investigations only. However, the points it addresses also provide guidance in handling civil investigations. The fact that the DOJ published the guidance indicates that the DOJ will continue to vigorously pursue health care fraud, including monetary recovery from parties committing fraud. The guidance may be found at the following link: <https://www.justice.gov/criminal-fraud/page/file/937501/download>.

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CMS Delays Implementation of New CoPs for Home Health Agencies

On April 3, 2017, the Centers for Medicare & Medicaid Services (CMS) published a proposed rule delaying the implementation of the new home health Conditions of Participation (CoPs). The original date of implementation, July 13, 2017, has been postponed by six months to January 13, 2018. The CoPs final rule, published on January 13, 2017, revised the COPs that home health agencies must meet in order to participate in Medicare and Medicaid programs. The changes were part of CMS’ overall effort to achieve measurable improvements in the quality of care furnished through the programs while also eliminating unnecessary regulatory and procedural burdens on providers.

According to CMS, the delay is in response to several comments received from the industry expressing a need for a significant period of time to prepare for implementation of the new rules, noting that home health agencies would likely need to adjust resource allocation, staffing and potentially infrastructure. CMS will be accepting comments on this proposed rule until June 2, 2017.

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House Passes Tort Reform Measures

The United State House of Representatives recently passed several “tort reform” bills. The Fairness in Class Action Litigation Act would narrow

the scope of parties who can be certified as a “class” in a class action suit. The Act would also limit recovery of attorneys’ fees by successful parties. The Innocent Party Act would make it harder to include additional parties in certain suits, thereby decreasing the chance that suits will be moved from federal courts to state courts, which are viewed as more sympathetic to plaintiffs. The Lawsuit Abuse Reduction Act would require judges to sanction attorneys who were found to have brought frivolous lawsuits. A fourth bill, which did not pass in the House, would have capped non-economic damages in medical malpractice actions at \$250,000.

The bills were promoted by physician and business groups who argued that courts have become overly tolerant of baseless lawsuits. Civil rights and consumer groups opposed the bills, arguing that they would limit the ability to pursue legal remedies against wealthier or more powerful parties.

Despite passing the House, many experts believe it unlikely that any of these bills will pass the Senate.

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STATE UPDATE

NJ Appeals Court Explains Hospital Self-Critical Analysis Privilege and Reporting Duties

A New Jersey appeals court ruled on February 6, 2017 that a hospital defending a medical malpractice case was not required to give the patient an internal hospital memo reviewing the event. The court found that the memo was privileged since it was made as part of the hospital’s “self-critical analysis” in developing and implementing a patient safety plan, as provided in the Patient Safety Act (PSA). The privilege applied even if the hospital did not report the event to the New Jersey Department of Health or the patient. The case is *Brugaletta v. Garcia*, 448 N.J. Super. 404 (App Div. 2017).

The court also ruled that the hospital did not violate its obligation under the PSA to report a “serious preventable adverse event.” No “preventable” event was proven, because the patient did not show that the event could have been anticipated and prepared for in advance.

The case demonstrates that while the PSA places many safety requirements on hospitals, it also provides hospitals with substantial protections, when they engage in self-critical analysis to promote patient care.

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NJ Adopts Emergency Rules on Opioid Prescribing

On February 15, 2017, an emergency new rule was adopted establishing limitations on the prescribing of opioids and other Schedule II controlled dangerous substances, for both acute and chronic pain, by physicians, podiatrists, dentists, advanced practice nurses, physician assistants and certified nurse midwives. The emergency rule was authorized

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by Governor Chris Christie on March 1, 2017 and is set to expire on April 30, 2017. Concurrently with the issuance of the emergency rule, an identical proposed rule to be adopted by the New Jersey State Legislature was filed.

The emergency rule establishes new requirements to be followed by providers when writing initial and follow-up prescriptions for certain medications. The new guidelines include:

- A new or initial prescription for these medications may only be written for 5 days or less at the lowest effective dose of an immediate-releasing medication;
- A new or initial prescription shall mean a prescription for someone who has never been issued a prescription for the medication or its pharmaceutical equivalent or has not been issued such a prescription in over a year;
- Following the initial 5 day prescription, a provider may write an additional prescription not to exceed 30 days;
- The provider must undertake a thorough examination of the patient, review the patient's medical history which reflects the nature, frequency and severity of any pain, and access and consider relevant PMP information;
- A discussion must take place which includes reviewing the risks of addiction, physical or psychological dependence, overdose associated with opioid medications, the danger of taking opioid medications with alcohol, the requirements for proper storage and disposal of opioid medications and non-opioid/non-pharmaceutical management of pain; and
- When issuing a 3rd prescription for such opioid medication, the provider and patient must enter into a pain management agreement regarding each parties responsibilities in providing and utilizing these medications.

Due to the emergency adoption of this rule, the provisions therein are immediately effective. Failure to adhere to the standards set forth in this emergency rule may subject a health care provider to penalties, including license suspension or revocation.

The Division of Consumer Affairs will make guidance materials available on its website that may be used by providers to help facilitate the required discussions noted above.

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NJ DOH Adopts Interim Rules For Dementia Care Homes

The New Jersey Department of Health (DOH) adopted interim rules to regulate the licensure and operation of dementia care homes, effective February 7, 2017. The rules establish standards to ensure that dementia care homes function in a manner to protect the health, safety and welfare of residents, while promoting a home-like atmosphere. The rules specifically address the following areas: (i) licensing standards; (ii) resident rights; (iii) admission and retention of residents; (iv) personal

care services; (v) pharmacy services; (vi) physical plant; (vii) resident records; and (viii) dietary standards.

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Legislative Update

HHA Partnering — On March 20, 2017, Assembly Bill A4731 was introduced that would expand the option of government home health care agency to partner with non-government provider to deliver health care services, such as direct services, administration and financial services.

CON for Special Care Nursing Facilities — On March 20, 2017, Assembly Bill A4720 was introduced that would eliminate certificate of need requirements for certain special care nursing facilities.

Prescription Monitoring — On March 20, 2017, Assembly Bill 4741 was introduced which requires practitioners to check prescription monitoring information before issuing certain prescriptions to emergency department patients.

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Brach Eichler In The News

Fourteen members of Brach Eichler have been named by New Jersey Super Lawyers magazine among the top attorneys in New Jersey for 2017, double the number of members that were named to the prestigious ranking in 2016. Each year, no more than five percent of the lawyers in the state are selected by the research team at Super Lawyers to receive this honor. In addition, five Brach Eichler attorneys were named to the Rising Stars list for 2017, which recognizes the top up-and-coming attorneys age 40 or under or who are in practice for 10 years or less. Each year, no more than 2.5 percent of the lawyers in the state are selected by the research team at Super Lawyers to receive this honor.

Those named by New Jersey Super Lawyers in 2017 are **Edward Capozzi, Matthew Collins, Susan Dromsky-Reed, John Fanburg, Jay Freireich, Stuart Gladstone, Joseph Gorrell, Alan Hammer, Mark Manigan, Allen Popowitz, Anthony Rainone, Keith Roberts, Carl Soranno and Rose Suriano.**

In addition, those named to the Rising Stars list for 2017 are **Shannon Carroll, Mark Fantin, Lauren Goldberg, Thomas Kamvosoulis and Jonathan Walzman.**

Congratulations to **Lauren D. Goldberg** in her promotion to the position of Counsel.

Lani M. Dornfeld is speaking at the Home Care Association of New Jersey on April 20th, on the topic "Advance Planning for Buying or Selling a Home Care or Hospice Business." For more details or to register, visit the following link: http://www.homecarenj.org/index.php?option=com_events&task=icalrepeat.detail&evid=86&Itemid=158&year=2017&month=04&day=20&title=advance-planning-for-buying-or-selling-a-home-care-or-hospice-business&uid=8d7ae8320252cc4a289c3a807b84ba72.

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Brach Eichler is hosting the NJASC and Health Care Market Review at Harrah's Atlantic City on May 4-5, 2017. Once again, **Mark Manigan** is Program Chair and **Debra Lienhardt** is Event Coordinator. To register or for additional details, visit: <http://www.njbmr.com/>

HIPAA CORNER

OCR Provides Insight on Enforcement Initiatives and Upcoming Guidances

In March, the Health Care Compliance Association held its annual Compliance Institute. During the event on March 27, Iliana Peters, Senior Advisor for HIPAA Compliance and Enforcement at the Department of Health & Human Services (HHS) Office for Civil Rights, made a presentation wherein she discussed current trends the agency has seen in enforcement and upcoming guidances to be issued.

In her presentation, Ms. Peters detailed several guidances that would be published in the future. Specifically, OCR will release guidance materials related to social media, text messaging and the "minimum necessary" standard. The agency also plans to provide an update of existing FAQs to account for Omnibus and other recent developments. In addition, Ms. Peters discussed continued enforcement issues faced by OCR. According to the presentation, individual and entities still often conduct an incomplete or inaccurate risk analysis in cases where a breach has occurred and many entities continue to lack transmission security by not properly encrypting transmission data.

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