BRACH | EICHLER LLC

Health Law UPDATE

February 2017

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FEDERAL UPDATE

Congress Fast-Tracks Partial "Repeal" of the Affordable Care Act

The House and Senate passed a budget resolution on January 13, 2017, to begin the process to repeal significant portions of the Affordable Care Act (ACA). The resolution limits debate to 20 hours, effectively preventing Democrats from blocking the legislation by filibuster.

The next step in the process calls for House and Senate committees to draft a reconciliation bill that would defund the ACA by at least $1 billion dollars over the next 10 years. The bill likely would eliminate tax penalties for uninsured persons and employers who do not offer coverage for employees; eliminate billions of dollars provided to states for Medicaid programs; and repeal subsidies for private health insurance obtained on a health exchange. President Trump and House Speaker Paul Ryan have pledged that the ACA repeal and a replacement plan will take place simultaneously to avoid chaos and disruption in the health system. Mr. Ryan set forth a timeline for Congress to vote on the bill this April. While there has yet to be a specific replacement plan identified, both President Trump and Speaker Ryan indicated recently that one could be presented in March.

The reconciliation bill would only need to pass Senate vote by a simple majority regarding fiscal matters, such as tax credits. Other provisions of the ACA, such as the allowance for children to remain on their parents' health insurance until age 26, cannot be repealed by the reconciliation process and would need a 60 vote "super majority" in the Senate to be repealed.

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President Orders "One-In, Two-Out" Regulatory Scheme

On January 30, 2017, President Trump issued an Executive Order adopting a "one-in, two-out" regulatory scheme in an effort to reign in costs associated with regulations and decrease onerous burdens on businesses. The Presidential mandate requires that if an executive department or agency proposes for notice and comment or promulgates a new regulation, it must identify at least two existing regulations to be repealed and eliminated. Heads of the various agencies and departments are directed to not increase the incremental costs of regulations greater than zero for the fiscal year of 2017, unless required by law or with written advice by the Director of the Office of Management and Budget (OMB). Further, for the fiscal year of 2018 and every fiscal year thereafter, the heads of each agency or department must identify in its annual regulatory cost submissions to the OMB each regulation that increases incremental costs, the offsetting existing regulations that were eliminated, and provide the agency's best approximation of the total costs or saving associated with. Toward this end, the Director of the OMB must provide the heads of the agencies and with detailed guidance on how to implement the President's directives.

This controversial new policy has already been met with opposition. One February 8, 2017, the Natural Resources Defense Council, the Communications Workers of America and Public Citizen filed suit in the U.S. District Court for the District of Columbia to block the Executive Order. Plaintiffs argue the order exceeds the President's authority and jeopardizes important health, safety and environmental protections while failing to consider the benefits of the regulations.

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CMS Addresses Backlog in Medicare Appeals

The Department of Health & Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) issued a final rule effective March 20, 2017, changing the Medicare appeals procedures followed by HHS. The CMS rule attempts to decrease the backlog that has forced providers to wait over 900 days, on average, for an administrative law judge hearing. The new rules allow precedential decision-making at the Department Appeals Board level to increase consistency in decisions, and attorneys to hear appeals instead of administrative law judges.

HHS will publish all designated precedents on a website and these precedents will bind all lower-level decision-makers. HHS believes the number of appeals will decrease as providers are able to decide what claim denials or decisions should be appealed, based on review of the prior decisions.

As part of the effort to reduce the backlog in claims, HHS is also:

- Asking for additional resources for all appeal levels to boost adjudication capacity.
- Implementing administrative changes to decrease the number of pending appeals.
- Introducing legislative reforms, such as more funding for new authorities to manage the volume of appeals.

Currently, however, the future of the regulation is uncertain due to the President's recently issued "Freeze Memo" which raises doubts about the

implementation dates of all pending regulations. See our Health Law Alert published with this Health Law Update for further information.

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CMS Releases Final Rule Amending Home Health CoPs

On January 9, 2017, the Department of Health & Human Services, Centers for Medicare & Medicaid Services (CMS) released final rules setting forth amended conditions of participation for home health agencies. These are the minimum health and safety standards that home health agencies (HHAs) must adhere to in order to qualify to participate in Medicare and Medicaid. Highlights of the rule include:

- A patient rights condition of participation and the steps that must be taken to assure those rights.
- An expanded patient assessment requirement.
- A requirement that patients and caregivers have written information about upcoming visits, medication instructions, treatments administered, instructions for care, and the contact information of a HHA clinical manager.
- A requirement for an integrated communication system that ensures that patient needs are identified and addressed and care is coordinated among all disciplines.
- A requirement for a data-driven, agency-wide quality assessment and performance improvement program.
- A new infection prevention and control requirement.
- A skilled professional services requirement that focuses on appropriate patient care activities and supervision.
- A coordination requirement that makes a licensed clinician responsible for all patient care services.
- Revisions to simplify the organizational structure of home health agencies.
- New personnel qualifications for HHA administrators and clinical managers.

Although the rule is slated to become effective on July 14, 2017, the President's Freeze Memo has called into question whether the effective date will remain in place and, in fact, whether the regulations will go into effect at all. See our Health Law Alert published with this Health Law Update.

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Final Rule on 340B Program Sets Price Ceilings for Covered Drugs and Subjects Drug Companies to Fines for Overcharges

The Department of Health & Human Services (HHS) established the 340B drug discount program in the 1990s. The program allows safety-net health care organizations known as "covered entities" to enter into a pharmaceutical pricing agreement (PPA) with drug manufacturers to access lower-priced medicines. When a drug manufacturer signs a PPA and joins the Program, it agrees that the prices charged for covered outpatient drugs to covered entities will not exceed defined ceiling prices.

On January 5, 2017, HHS published a final rule to set the calculation of 340B ceiling prices and application of civil monetary penalties (CMPs) for charging above the ceiling price. This rule, effective March 6, 2017, establishes the basic ceiling price as the average manufacturer price, minus the unit rebate amount. With regard to new drugs where sufficient information to establish a 340B ceiling price is not yet available, the estimated 340B price is equal to the drug's wholesale acquisition cost minus the statutory Medicaid Drug Rebate Program rebate applicable to the drug. The new rule requires manufacturers to offer refunds for overcharges on new drugs.

The rule provides that CMPs are not to exceed $5,000 for each instance where a drug manufacturer "knowingly and intentionally" overcharges a covered entity for a covered outpatient drug. The HHS Office of Inspector General will have authority to bring 340B CMP actions. However, the future of the final rule is uncertain as it is subject to the President's Freeze Memo. See our Health Law Alert published with this Health Law Update.

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DHHS Expands Exclusion Authority Relating to Federal Health Care Programs

The U.S. Department of Health & Human Services, Office of Inspector General (OIG) issued a Final Rule, effective February 13, 2017, enacting new policies for excluding individuals and entities from participation in federal health care programs such as Medicare and Medicaid. The rule makes many notable changes to current exclusion regulations, including the following:

- Setting a time limit of ten years in which the OIG can look back for acts which may be the basis of exclusion.
- Establishing an early reinstatement process for providers that were excluded after losing their health care license for reasons such as lapses in professional competence, professional performance or financial integrity.
- Increasing the amount that federal healthcare programs would have to lose in order for the loss to be considered an aggravating factor in determining how long the exclusion should last.
- Permitting the OIG to exclude individuals who hold ownership or control interests in excluded entities.
- Permitting banning providers from Medicare and Medicaid for illegally prescribing or distributing controlled substances, or for obstruction of investigations and audits.

The rule may be subject to repeal as part of the Trump Administration's threatened repeal of the Affordable Care Act. Additionally, since the rule was not yet in effect at the time of the issuance of the President's Freeze Memo, the current implementation date is likely to be postponed. See our Health Law Alert published with this Health Law Update.

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Medicare Moratoria Extended on Ambulance and HHA Providers and Suppliers

On January 9, 2017, the Department of Health & Human Services, Centers for Medicare & Medicaid Services (CMS) extended the statewide "temporary" moratoria on the enrollment of new Medicare Part B non-emergency ground ambulance providers and suppliers in New Jersey, Pennsylvania and Texas, and the enrollment of new Medicare home health agencies, subunits and branch locations in Florida, Illinois, Michigan and Texas. According to CMS, the need for the moratoria stems from a review of factors suggesting a high risk of fraud, abuse and waste in the geographical areas affected.

The extended ban is for a six-month term and went into effect on January 29, 2017. CMS will re-evaluate the ban, and, if deemed necessary, will extend the ban in six-month increments.

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STATE UPDATE

Governor Christie Signs Executive Order Declaring Opioid Addiction a Public Health Crisis

On January 17, 2017, Governor Chris Christie signed Executive Order No. 219, declaring the abuse of and addiction to opioid drugs a New Jersey public health crisis. Governor Christie created the "Governor's Task Force on Drug Abuse and Control" (Task Force), to consist of eight members including the Attorney General, the Commissioners of the Departments of Health, Human Services, Correction, Education, Children and Families, and Banking and Insurance, and a Chairperson to be appointed by the Governor.

The Task Force is charged with developing a comprehensive strategy to combat the epidemic. The Attorney General is further authorized to take all necessary steps to limit initial prescriptions of opioids to patients, and must establish standards to ensure that additional quantities are only prescribed under limited conditions. The Commissioner of the Department of Children and Families must take action to ensure that residential substance use disorder treatment facilities are able to use their spaces effectively. The Commissioner of the Department of Education is tasked with developing a comprehensive curriculum to educate children about the dangers of substance abuse.

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New Jersey Supreme Court to Rule on Insurance Fraud Statute

On January 4, 2017, the New Jersey Supreme Court (NJSC) heard oral argument in a case addressing the scope of the New Jersey Insurance Fraud Prevention Act (IFPA). AllState Insurance Company sued a New York lawyer, Borsody, and a California chiropractor, Dahan, who helped a New Jersey chiropractor, Neuner, set up a multidisciplinary medical practice.

Neuner attended a seminar led by Borsody and Dahan that discussed setting up a multidisciplinary medical practice. As the seminar suggested, Neuner set up a management company and a professional corporation. The corporation was owned on paper by physicians licensed in New Jersey, but Neuner had actual control over the practice including hiring and firing physicians.

The trial court ruled that Neuner's actions violated New Jersey regulations which prohibit a chiropractor's clinical oversight of a physician. As a result, it ruled that any insurance claims submitted by the practice violated the IFPA. The jury awarded $1.3 million in damages to AllState, which were tripled to $3.9 million under the IFPA. The appeals court then overturned the trial court and ruled that the IFPA was not violated, because Dahan and Borsody were never informed by any New Jersey agency that their model violated New Jersey law. In addition, the model was permissible in other jurisdictions. The NJSC granted AllState's request to appeal and recently heard oral argument. More to follow.

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Legislative Update

Governor Christie Takes Legislative Steps in War on Opioid Addiction – On February 6, 2017, Governor Christie signed into law legislation (S2156) which significantly impacts the current consent procedures for health care professionals who prescribe opioid drugs to patients under the age of 18. The law requires prescribers to provide additional warnings to the parents or guardians of unemanicipated minor patients about the risks of developing an addiction to opioid drugs. The prescriber is also required to obtain written acknowledgement that the conversation occurred and place the acknowledgement in the patient's record.

Behavioral Health Care Coverage – On January 19, 2017, the New Jersey Senate introduced a bill (S2919) that would expand health insurance coverage for behavioral health care services and enhances enforcement and oversight of mental health parity laws.

Medicaid Funding of Substance Use Disorder Programs – On January 23, 2017, New Jersey Assembly Concurrent Resolution 223 (NJ ACR223) was introduced requesting President Trump and Congress to take action to permit federal Medicaid funding for certain substance use disorder programs.

Shared Space for PC and BH Services – On January 23, 2017, the New Jersey Assembly introduced a bill (NJ A4523) which would require the New Jersey Department of Health to permit certain health care facilities to use shared clinical space when providing primary health care and behavioral health care for mild to moderate behavioral health conditions.

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Brach Eichler In The News

Serving as president of Mountain Ridge Country Club in West Caldwell from 2012 to 2016, **John D. Fanburg** was recently named by BoardRoom magazine as one of the Top 22 Private Club Presidents for 2016. For more info, see *https://www.tapinto.net/towns/livingston/articles/livingston-resident-named-to-top-22-private-count*

Richard B. Robins presented a lecture on Current Legal Issues in Dentistry to the Young Dentist Study Club on February 6, 2017.

HIPAA CORNER

Illinois Health Care Network to Pay $475K for Untimely Breach Notifications

The Department of Health & Human Services (HHS), Office for Civil Rights (OCR) recently entered into a resolution agreement with Presence Health Network (Presence) stemming from delayed breach notification to affected individuals, the media and the OCR. In late 2013, a hospital in the Presence network discovered that paper-based operating room schedules, containing the PHI of 836 individuals, went missing from the hospital's surgery center. In the report to the OCR, Presence noted that, due to a miscommunication between its workforce members, there was a delay in its provision of breach notifications. In particular, notifications, which are required to be made as soon as possible but within 60 days, were made after 104 days to the affected individuals, 106 days to the media and 101 days to the OCR. In the course of investigating this breach, the OCR also reviewed other breach notifications made by Presence that had been untimely made.

Presence will pay HHS $475,000 in resolution of the allegations, and has entered into a "Corrective Action Plan" with OCR under which Presence must, among other things, revise its existing policies and procedures relating to the HIPAA Breach Notification Rule. The resolution agreement should serve as a warning and reminder to covered entities of the importance of having in place a current and effective breach notification policy, of investigating suspected and alleged breaches in a timely manner and for ensuring that all required notifications are made within required timeframes.

For more information or assistance in reviewing, preparing or updating your breach notification policy or managing a breach investigation, contact:

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HEALTH LAW ALERT

FEBRUARY 2017

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NEW ADMINISTRATION MAKING ITS MARK ON REGULATIONS: THE FREEZE MEMO

On January 20, 2017, Reince Preibus, White House Chief of Staff and Assistant to the President, issued a Memorandum on behalf of President Trump to the Heads of Executive Departments and Agencies (Freeze Memo). The purpose of the Freeze Memo was to communicate the Administration's plan for managing the federal regulatory process at the outset of the President's term and ensure that all appointees and new leadership have the opportunity to review any new or pending regulations.

Subject to certain exceptions (as discussed below), the President laid out steps to be taken for new and pending regulations that fall into the following categories: (i) regulations yet to be sent to the Office of the Federal Register (OFR); (ii) regulations sent to the OFR but not yet published; and (iii) regulations that have been published but not yet implemented.

Specifically, the Memorandum mandates that no further regulations be sent to the OFR until a department or agency head appointed or designated by the President has reviewed the regulation. Additionally, all regulations that have already been forwarded to OFR but not yet published must be withdrawn consistent with OFR procedures. Finally, for those regulations that have been published but not yet implemented or taken effect, agencies are directed to postpone their effective dates for 60 days from the date of the Freeze Memo pending a review of the regulations for any possible questions of law, policy or fact. If, upon review, no substantial questions of law, policy or fact arise, no further action needs to be taken. However, if the regulations do raise substantial questions of policy, law or fact, agencies must notify the Office of Management and Budget (OMB) to take further appropriate action. According to the President, agencies should consider proposing for notice and comment a rule to delay the effective date beyond the 60 day period and where questions of fact, law and policy have been raised, consider further notice and comment rulemaking.

Exceptions to the Freeze Memo

There are two exceptions to the Freeze Memo. Regulations that are subject to statutory or judicial deadlines are excluded along with emergency situations relating to health, safety, financial or national security matters. In the event a regulation qualifies as fitting within one of these exceptions, the applicable governmental agency must notify the OMB Director who will review whether the exception is appropriate under the circumstances.

Certain Health Care Regulations Affected

Two pending regulatory actions relevant to the health care industry are among those affected.

On January 13, 2017, HHS, Centers for Medicare & Medicaid Services (CMS) published a rule amending

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the conditions of participation (CoPs) that home health agencies must meet in order to participate in the Medicare and Medicaid programs. The effective date of the final rule was set for July 13, 2017.

Separately, on January 18, 2017, HHS, Substance Abuse and Mental Health Services Administration (SAMHSA) published a final rule updating regulations governing the confidentiality of substance use disorder program patient records (amendments to 42 C.F.R. Part 2). This rule was to become effective on February 17, 2017.

On February 15, 2017, SAMHSA published a notice in the Federal Register, stating the new effective date of the final rule is March 21, 2017. At the same time, however, SAMHSA made the following statement, calling into question whether there may be a further delay or other action prior to the new effective date: "The 60-day delay in effective date is necessary to give Department officials the opportunity for further review and consideration of new regulations, consistent with the Assistant to the President's memorandum of January 20, 2017" (i.e., the Freeze Memo).

Our office reached out to the agencies regarding the status of the pending regulations. CMS indicated that the agency does not know when or if the new CoPs rule will become effective; the agency is awaiting direction once new leadership is in place. On February 15, 2017, SAMHSA indicated that the final rule is likely to become effective on March 21, but this could change depending on certain actions by new agency leadership.

These are just two of the many pending regulations that are now on hold and subject to further evaluation once new leadership is in place. A few of the other regulations affected by the Freeze Memo are discussed our February 2017 Health Law Update.

At this early stage of the new Administration, it remains unclear which direction the various agencies will take on the pending regulations. Our office will continue to monitor the status of these regulations and the effects of the Freeze Memo.

If you have any questions about how the regulatory freeze affects your organization, feel free to contact a member of our health law team below.

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