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# Health Law UPDATE

March 2018

*In This Issue:*



## FEDERAL UPDATE

### 2019 Budget Proposal Adds $7 Billion to Combat Opioid Epidemic

The Trump administration's proposed 2019 budget requests an additional $7 billion for fiscal year 2019 to address the ongoing opioid epidemic. The amount would be in addition to the $3 billion for fiscal year 2018 and $3 billion for fiscal year 2019 already approved by Congress in the recent budget deal passed on February 9. The Department of Health and Human Services' budget summary states the allocated funds shall go toward "improved access to prevention, treatment, and recovery services; more availability and distribution of overdose reversing drugs; better public health data and reporting; research on pain and addiction; and better pain management practices." Experts and lawmakers have called for clarity as to how the funds will be appropriated and are wary that these new funds actually will be used for criminal justice efforts related to opioids rather than health care treatment. Although a good step, advocates say even more funding is critically necessary.

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### February Budget Deal Relaxes Medicare Telemedicine Rules

The Bipartisan Budget Act of 2018, passed on February 9, 2018, expands Medicare's coverage of telemedicine services by expanding the Creating High-Quality Results and Outcomes Necessary to Improve Chronic (CHRONIC) Care Act passed by Congress in 2017. Beginning on January 1, 2019, end-stage renal disease patients may receive monthly clinical assessments via telehealth from a freestanding dialysis facility or their home, rather than telehealth being limited to certain origination sites and geographic areas. Similarly, patients with acute stroke symptoms may receive telehealth services which were previously limited to only patients in rural health areas or areas with provider shortages.

The Act also allows additional types of Accountable Care Organizations (ACOs) to obtain a Next Generation ACO telehealth waiver which will waive geographic restrictions and allow for a patient's home to be the originating site as well as allow tele-dermatology and tele-ophthalmology. The Act also seeks to expand access to telehealth services by Medicare Advantage enrollees beginning in 2020, but leaves the Centers for Medicare and Medicaid Services (CMS) to determine what types of services should be included. CMS should open the public commentary period regarding these services by November 30, 2018.

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### New Report Details Major Gaps in Oversight of Medicaid Assisted Living Facilities Throughout U.S.

The Government Accountability Office (GAO) issued a report to congressional requestors earlier this year noting major gaps in the oversight of Medicaid assisted living facilities in the U.S. GAO found that over half of the states lack adequate reporting to federal authorities, causing significant health and safety issues to be ignored. Twenty-six state Medicaid agencies could not report to GAO the number of critical incidents that occurred in assisted living facilities. Their reasons included (i) the inability to track incidents by provider type, (ii) lack of a system to collect critical incidents, and (iii) lack of a system that could identify Medicaid beneficiaries.

The "critical incidents" that could not be tracked include physical assault, emotional abuse, neglect, sexual assault/abuse, financial exploitation, unexpected/unexplained death, injuries resulting in hospitalization, unauthorized use of restraints, and threat or attempt of suicide, among others.

Further, there were almost 23,000 critical incidents reported by states that did report. This number may be higher, though, because state definitions of reportable incidents differ widely. With many states not reporting, and other states having different standards for reportable incidents, there are significant oversight issues. Although Medicaid is federally funded and helps in the funding of various assisted living facilities, the states are responsible for overseeing the facilities. They are supposed to apprise the federal government annually on any deficiencies regarding the health of their beneficiaries; the report, however, demonstrates that this job clearly has been neglected.

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### Regulations Proposed to Expand Availability of Limited-Duration Insurance

The federal Departments of the Treasury, Labor, and Health and Human Services have proposed regulations to promote the sale of short-term, limited-duration insurance. The proposed regulations are intended to implement an October 2017 Executive Order instructing federal regulators to consider ways to allow more participants to form and join Association Health Plans, purchase short-term insurance, and make better use of health reimbursement arrangements in order to reform the United States healthcare system and expand choices and alternatives to Affordable Care Act (ACA) plans. Short-term policies were originally marketed as a stopgap solution for individuals who were between policies. These policies are regulated by the states and not subject to much federal regulation, and are therefore not subject to the individual market reforms under the ACA.

Short-term policies have increasingly become attractive substitutes to consumers who can pass medical underwriting and are willing to accept lesser coverage in exchange for avoiding the higher-cost, ACA-compliant individual market. The previous administration attempted to reverse this trend by limiting the term of short-term policies to three months from the former twelve. The current administration is proposing to reverse that decision, allowing states to determine whether these policies should be offered as a cheaper alternative to policies that healthy individuals can purchase in an ACA marketplace, or whether these should be banned or limited in order to avoid rate increases for coverage available in the ACA marketplace.

Federal regulators estimate that between 100,000 and 200,000 individuals, most of them young, healthy, and ineligible for premium subsidies, would abandon ACA-compliant individual market policies, and instead switch to short-term coverage. The resulting loss to the ACA marketplace risk pool would raise 2019 premiums by $2 to $4 per member per month, and cost the federal government between $96 to $168 million annually in increased premium subsidies. Comments on the proposed rule are due by April 23, 2018.

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### Health IT Vendor Faces Class Action After Ransomware Attack

Electronic health record software giant Allscripts Healthcare Solutions Inc. has been named in a putative class action in Illinois federal court, alleging that a ransomware attack on the company disrupted service to tens of thousands of doctors and hospitals, and put patients' lives at risk.

Allscripts' data centers in Raleigh and Charlotte, North Carolina, were hit with a strain of ransomware known as "SamSam" on January 18, 2018, which attacked those data centers and, subsequently, shut down access to electronic health records for health care providers nationwide.

The complaint, brought by Palm Beach, Florida-area health care provider Surfside Non-Surgical Orthopedics, alleges that restoring access to patient medical records is not the only damage control that Allscripts must do. Surfside alleged that it and other medical providers could not access patients' records or electronically prescribe medications, forcing Surfside and other class members to cancel appointments.

Surfside alleged Allscripts should have known to protect itself and, by extension, its many clients and their patients, as ransomware attacks are a known threat. Surfside's complaint further pointed out that Allscripts itself had acknowledged in its 2016 annual report that it was a candidate for a security breach or other cyberattack. Surfside demands certification of a nationwide class and asks the court to force Allscripts to change its policies and practices to prevent another such attack. The complaint also demands restitution and disgorgement of the revenues wrongfully retained as a result of Allscripts' wrongful conduct and asks for actual and compensatory damages.

The action should serve as a warning and reminder to HIPAA covered entities and their business associates of the importance of performing periodic risk analyses as required under the HIPAA Security Rule. Such risk analyses are intended to identify security risks, threats, and vulnerabilities which must be addressed through the development and implementation of a risk management plan.

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## State Update

### Florida Eye Doctor Sentenced to 17 Years in Prison in Medicare Fraud Scheme

On February 22, 2018, the Department of Justice, U.S. Attorney's Office for the Southern District of Florida announced that Florida ophthalmologist Dr. Salomon Melgen was sentenced that day to 17 years in prison after being found guilty on 67 counts of health care fraud and related charges. The prison term is to be followed by three years of supervised release.

In sentencing, U.S. District Judge Kenneth A. Marra found that the intended fraud loss was over $72 million and the actual fraud loss to Medicare was $42 million. Dr. Melgen was also ordered to make full restitution to Medicare of $42.6 million. Evidence at trial showed that Dr. Melgen performed medically unnecessary procedures, including eye injections and laser treatments. Dr. Adam Berger, a prosecution witness, testified that Dr. Melgen's tests and treatments were "reckless" and that his infection rate of one in 13 injected patients is "astronomically high." A normal infection rate would be one in 3,300 injected patients.

A key issue at sentencing was the doctor's use of the drug Lucentis, which is injected in tiny doses. It comes in single-use vials that contain four times the necessary dosage amount. The manufacturer's instructions advise discarding the excess medication. Medicare reimburses doctors their wholesale cost of $1,900 per vial plus $114. Dr. Melgen used each vial for three or four injections, charging Medicare $2,014 each time. Prosecutors say the two or three extra injections were Medicare theft. Dr. Melgen's attorneys argue that he did not cost the Medicare program any extra money by avoiding what he would have spent buying more vials.

The doctor also administered the drug to patients who had diabetic-related sight loss even though the drug was not approved for the treatment at that time. Dr. Melgen's lawyer suggested that the doctor gave a false diagnosis to Medicare to be reimbursed for a treatment he knew was effective and benefiting the Medicare recipients. Lucentis is now approved for diabetic-related sight loss.

In a separate federal case, Dr. Melgen was accused of bribing Senator Robert Menendez in exchange for favors, including visas for his foreign mistresses, and the Senator's intercession with Medicare officials.

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## New Jersey Legislative Update

***Governor Murphy Issues Executive Order Regarding Medical Marijuana***—On January 23, 2018, Governor Phil Murphy issued an executive order mandating the Department of Health and the State Board of Medical Examiners to review all aspects of the New Jersey medical marijuana program to remove any potential obstructions. The review includes: (i) an evaluation of the current rules regulating the operations and siting of dispensaries and cultivation facilities, particularly focusing on whether the rules should be revised to remove unwarranted obstructions to expansion; (ii) a review of the current process for obtaining a license to operate a medical marijuana dispensary, including recommendations to expedite that process; (iii) an examination of conditions for participating physicians in the program to ensure that any such requirements are not needlessly onerous; (iv) an analysis of the current list of debilitating medical conditions for which medical marijuana may be authorized pursuant to N.J.S.A. 24:61-3, and a recommendation as to whether doctors should be given flexibility to make these determinations on their own; (v) an assessment of the methods through which patients or their primary caregivers are obtaining medical marijuana and a recommendation of whether rules should be amended to approve additional methods that could facilitate patient access; and (vi) a review of regulations that govern the forms in which medical marijuana can be ingested, taking into consideration the needs for different methods for different patients.

***Proposed Legislation to Remove Limits on Dispensing Medical Marijuana***—On February 15, 2018, bill A3421, entitled "Jake Honig's Law," was introduced in the New Jersey Assembly. The bill was subsequently introduced in the New Jersey Senate. The bill removes limits on the amount of medical marijuana that may be dispensed at one time and expands access to edible forms, including oils. Specifically, the bill provides that alternative treatment centers may make medical marijuana available to patients in oil form, removes a restriction that made edible forms of medical marijuana available only to qualifying patients who are minors, and removes the current two-ounce limit on the quantity of medical marijuana that may be dispensed in a 30-day supply.

***Proposed Legislation to Establish Office of Health Transformation***—On February 8, 2018, bill S1028 was introduced in the New Jersey Senate to establish the Office of Health Transformation to coordinate certain strategic planning for State health care programs. The bill had previously been introduced in the New Jersey Assembly in January 2018. The purpose of the Office of Health Transformation would be to establish a single, comprehensive strategic plan for the coordinated, efficient administration of public healthcare policy and spending, including, but not limited to, the Medicaid and NJ FamilyCare Programs; and the examination of policies and expenditures across departments, divisions, agencies, and programs to determine ways to improve performance and leverage purchasing power.

***Proposed Legislation to Establish Fetal and Infant Mortality Review Commission***—On February 8, 2018, bill A3036 was introduced to establish the Fetal and Infant Mortality Review Commission in the Department of Health. The purpose of the Commission would be to review and report on fetal and infant death rates in the State, identify factors, issues, and the causes associated with fetal and infant death; identify and address health, social, economic, cultural, racial, and ethnic disparities that contribute to fetal and infant death; reduce the adverse complications related to, or associated with, pregnancy and childbirth; and make recommendations to improve the health and well-being of women, infants, and families.

***Proposed Legislation to Establish Health Insurance Reinsurance Plan***—On February 12, 2018, bill A3379, entitled the "New Jersey Health Insurance Premium Security Act," was introduced in the New Jersey Assembly. The bill was subsequently introduced in the New Jersey Senate. The bill would direct the Commissioner of Banking and Insurance to apply for a federal waiver of certain provisions of the Affordable Care Act to support a reinsurance program to help stabilize premiums in the New Jersey individual health insurance market. If the waiver is granted, the bill would create a reinsurance plan known as the Health Insurance Premium Security Plan.

***Proposed Legislation to Institute Individual Mandate in New Jersey***—On February 12, 2018, bill A3380, entitled the "New Jersey Health Insurance Market Preservation Act," was introduced in the New Jersey Assembly. The bill was subsequently introduced in the New Jersey Senate. The bill would restore the recently repealed shared responsibility tax provided under the Affordable Care Act, which requires most individuals, other than those who qualify for certain exemptions, to obtain health insurance or pay a penalty. The bill is intended to ensure that health insurance markets in New Jersey remain robust and affordable by ensuring that individuals who can afford to purchase insurance participate in the market.

***Proposed Amendments to Prescription Monitoring Regulations***—On March 5, 2018, the New Jersey Division of Consumer Affairs proposed amendments to the rules for the New Jersey Prescription Monitoring Program (PMP). The PMP is a tool utilized by prescribers and pharmacists, who must register with the Division to gain access to the system. Its purpose is to combat prescription drug abuse and diversion, and to help practitioners to make the most informed choices about treatment for their patients. The proposed amendments expand access to the electronic database to include licensed mental health practitioners (State-licensed clinical social workers, marriage and family therapists, clinical alcohol and drug counselors, professional counselors, psychologists, or psychoanalysts) who provide treatment for substance abuse to patients at a residential or outpatient substance abuse treatment center licensed by the Department of Health. The proposed amendments also establish the standards for access to the prescription monitoring information by licensed mental health practitioners. In addition, the proposed amendments set forth the provisions for the Director to review the prescription monitoring information to identify and report to practitioners and pharmacies about suspected misuse, abuse, or diversion of a controlled dangerous substance. Comments on the proposed amendments must be submitted by May 4, 2018.

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## Brach Eichler In The News

**John D. Fanburg** presented a legal and regulatory update to the Radiological Society of New Jersey on March 3 and to the New Jersey State Society of Anesthesiologists on March 10. John also addressed the Rutgers EMBA Health Care Symposium on "Innovations in the Future of Healthcare" on March 15.

**Mark Manigan** commented in *The Record* and northjersey.com on ASC regulation on March 14.

**Joseph M. Gorrell** presented on New Jersey opioid legislation at Rutgers RWJ Medical School on March 10.

**Lani M. Dornfeld** will speak at the New Jersey Medical Group Management Association Spring Seminar on April 6 and April 20 on "Curiosity Killed the Cat and Other Common HIPAA Pitfalls." For information visit, www.njmgma.com/calendar-of-events.

To view a full listing of recent news items and to read the articles mentioned above, please visit *http://bit.ly/2tYYFba*.

## HIPAA CORNER

### HIPAA Obligations Don't End When a Business Closes its Doors

A receiver appointed to liquidate the assets of Filefax, Inc., an entity located in Northbrook, Illinois that advertised itself as providing for the storage, maintenance, and delivery of medical records for covered entities, has agreed to pay $100,000 to the U.S. Department of Health and Human Services, Office for Civil Rights (OCR) in order to settle potential violations of the HIPAA Privacy Rule.

On February 10, 2015, the OCR received an anonymous complaint alleging that an individual associated with Filefax was selling medical records. An investigation was opened, and it was confirmed that between January 28 and February 14, 2015, Filefax impermissibly disclosed the Protected Health Information (PHI) of 2,150 individuals by leaving the PHI in an unlocked truck in the Filefax parking lot, or by granting permission to an unauthorized person to remove the PHI from Filefax, and leaving the PHI unsecured outside the Filefax facility.

In addition to the $100,000 monetary settlement, the receiver has agreed, on behalf of Filefax, to properly store and dispose of the remaining medical records found at Filefax's facility in compliance with HIPAA.

The case demonstrates that HIPAA obligations may extend even after a business closes its doors, and that fines and penalties may extend to receivers liquidating assets of defunct businesses.

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