

Health Law UPDATE

January 2018

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FEDERAL UPDATE

Changes to the Health Care Landscape in the Air: CVS to Purchase Aetna in Major Health Care Deal

CVS Health Corp. (CVS) announced it will be purchasing Aetna in 2018 for \$69 billion, \$77 billion including debt, in a deal that will send ripples throughout the health care world. The transaction is intended to integrate multiple health care professionals, including doctors and pharmacists, in order to build a less expensive, more cohesive, and easier to navigate platform for patients. One of the stated reasons behind the deal is to help lower the rising costs of health care in the United States.

While CVS currently offers consumers over 1,000 walk-in clinics, just under 10,000 of its pharmacies will include space for other health care services, such as vision, hearing, nutrition, wellness, and medical equipment.

Analysts speculate that this deal may cause other larger mergers across the health care spectrum to follow in the steps of CVS and Aetna, creating further changes to the U.S. health care skyline. CVS and Aetna are pushing away from the traditional doctor's office model to a broader model of health care that can reach patients on the internet, over the phone, or in the CVS down the block.

On January 16, 2018, a major Aetna stockholder filed a class action lawsuit against Aetna, on behalf of himself and similarly situated stockholders, alleging the company filed materially incomplete and misleading information with the Securities and Exchange Commission relating to the transaction. No word yet on what impact the suit will have on the deal.

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OIG Work Plan Updates Include Review of Telemedicine and Severe Malnutrition Payments

Starting last June, the Department of Health & Human Services, Office of Inspector General (OIG) has been updating its Work Plan on a monthly basis. Last November, OIG's Office of Audit Services (OAS) added three items, two of which directly impact health care facilities.

With increasing Medicaid telehealth payments, the OIG intends to examine whether Medicaid payments for services delivered via telecommunication systems were allowable in accordance with Medicaid requirements. The OIG cites concern about a significant bump in claims for telemedicine, telehealth, and telemonitoring services that beneficiaries receive through interactive transmissions that include video, audio, and data.

The OIG also will examine how hospitals are billing for severe malnutrition. Hospitals are permitted to bill for treatment of malnutrition based on the severity of the condition—mild, moderate, or severe. When severe malnutrition occurs among Medicare patients, it is classified as a major complication or comorbidity (MCC) and results in higher Medicare reimbursement. The OIG intends to review the accuracy of hospital inpatient claims where patients are classified as an MCC, due to the increased costs associated with such claims.

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OIG Issues Advisory Opinion on Real-Time EMR Interface Program to Reduce Readmissions

In a recent Advisory Opinion (AO 17-07), the Department of Health & Human Services, Office of Inspector General (OIG) determined that a pilot program that could improve the efficacy of medication therapy management (MTM) services among Medicare Advantage (MA) beneficiaries would present minimal risk to federal health care programs and patients. Under the arrangement, a sponsoring pharmaceutical manufacturer would collaborate with an MA Plan, a hospital system, an IT vendor, and a trade association to design and implement a data transmission program that provides electronic discharge and medication information from the hospital system to the MA Plan to determine whether MTM pharmacists' access to real-time discharge information can help decrease re-hospitalizations for certain conditions identified under the Hospital Readmission Reduction Program. The IT vendor would modify the hospital system's existing electronic medical record, then design and implement the interface that allows data transmission for use by the MA Plan pharmacists. The MA Plan would then track and report on metrics such as discharge volume, timing of MTM service delivery, and outcomes. If the program is successful, the trade association would then promote written training materials and a program summary, which would be branded with the pharmaceutical manufacturer's name and include impact findings on the drug class level, but not on the individual drug level.

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OIG Allows Discounts to Nursing Facility Payors

In a recent Advisory Opinion (AO 17-08), the Department of Health & Human Services, Office of Inspector General (OIG) determined that a company's proposal to develop a network of nursing facilities that would provide discounts on the daily rates they charge to private long-term care insurers and their policyholders would present minimal risk to federal health care programs and patients. Under the arrangement, any nursing facility that is located in the particular state, maintains an overall quality rating of three stars or higher, and agrees to provide a discount off its daily private payor rate for a semi-private room is eligible to participate in the company's network. Only private long-term care insurers are permitted to participate in the company's network. Any policyholder would be eligible to receive a discount, but the discount would apply only to participating payor-covered stays, and the discount would not be offered for days of stay covered by a federal health care program.

Other than the discount, the network facilities would provide no benefit to participating payors and their policyholders, and neither the facilities nor the policyholders would pay the network for its services. The discount would be split two-thirds to the payor and one-third to the policyholder. However, a participating payor would be required to pay the network an administrative fee each time the payor received a discount under the program. Policyholders would remain free to choose any nursing facility permitted by the terms of their participating payors' plans, but the discount would be available only for covered stays provided by network facilities. The payors would be required to provide clear written notice to policyholders informing them about the plan and their right to select any facility.

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New FDA Policies Regarding Digital Health Software

The FDA released two drafts and one final policy document on December 7, 2017 that provide guidance regarding the "21st Century Cures Act." The first draft guidance makes clear what types of clinical decision support software (CDSS) are no longer considered medical devices and, therefore, no longer regulated by the FDA. CDSS that allows a provider to independently review the basis of a recommendation by the CDSS is excluded from FDA regulation, while programs that process or analyze information to make treatment recommendations will remain under FDA purview. Similarly, patient decision support software, used by patients and their caregivers, that allows for independent review will also not be subject to FDA regulation.

The second draft guidance clarifies the FDA's interpretation of the types of software that are no longer considered medical devices under FDA regulation. Software that is used (1) as administrative support for a health care facility; (2) to maintain or encourage a healthy lifestyle and is unrelated to diagnosis, cure, mitigation, prevention, or treatment of disease (like a fitness application); (3) to serve as electronic patient records; and (4) to transfer, store, convert, and display data and results would no longer be medical devices subject to FDA regulation.

The finalized guidance establishes common principles for regulators to use when evaluating the safety, effectiveness, and performance of Software as a Medical Device (SaMD).

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STATE UPDATE

New Jersey Legislative Update

Dementia Care Homes Regulations Adopted—The New Jersey Department of Health (DOH) adopted new regulations setting forth licensing standards for dementia care homes. By way of background, licensure authority for such facilities was transferred to the DOH from the Department of Consumer Affairs in 2016. Due to this transfer of authority, the DOH was charged with promulgating regulations for the licensure and oversight of dementia care homes. However, because the process for adopting regulations is lengthy, the DOH adopted interim regulations in February 2017. On November 21, 2017, the final regulations were adopted after being vetted through the DOH's standard rulemaking process.

The regulations cover all aspects of the licensure and operation of dementia care homes, including the following areas: (1) the application process for licensure; (2) resident rights; (3) training and staffing requirements; (4) pharmacy services; (5) physical plant requirements; and (6) the maintenance of resident records. Existing dementia care homes and individuals and entities interested in opening new dementia care homes should carefully review these new regulations for compliance.

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Health Care Professional Reporting Responsibility

Regulations Readopted—Effective November 21, 2017, the New Jersey Division of Consumer Affairs readopted, without amendments, the rules implementing the Health Care Professional Responsibility and Reporting Enhancement Act. Among other requirements, the regulations require health care entities to report a health care professional's conduct relating to impairment, incompetence, or professional misconduct which relates to patient safety if the health care entity has taken action against them.

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Medical Marijuana Regulations Amended

—Effective December 18, 2017, the Compassionate Use Medical Marijuana regulations were amended. The definition of "debilitating medical conditions" was revised to include post-traumatic stress disorder. This permits individuals who suffer from post-traumatic stress disorder to qualify to obtain and use marijuana for medicinal purposes.

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Proposed Legislation Regarding Electronic Health Records and Controlled Dangerous Substances—On November 30, 2017, S3592 was introduced in the New Jersey Senate to require electronic health records systems to meet requirements to accept, process, and transmit prescriptions for Schedule II controlled dangerous substances. Vendors that sell, lease, or license an electronic health records system as of the bill's effective date will be required to satisfy this requirement within one year following the bill's effective date.

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Bill Requiring Health Care Facilities to Provide Information Concerning Palliative Care and Hospice Care Passes Assembly—On December 7, 2017, A542 was passed in the New Jersey Assembly and referred to the New Jersey Senate. The bill establishes the “Palliative Care and Hospice Care Consumer and Professional Information and Education Program” in the New Jersey Department of Health. The purpose of the program will be to ensure that comprehensive and accurate information and education about palliative care and hospice care are available to the public, to health care providers, and to health care facilities.

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Bill Requiring the Provision of Information Concerning Substance Treatment Programs Passes Assembly—On December 7, 2017, A2430 was passed in the New Jersey Assembly and referred to the New Jersey State Senate. The bill requires that a person experiencing a drug overdose who is administered an opioid antidote is provided with information concerning substance abuse treatment programs and resources, including information on the availability of opioid antidotes. If the person is admitted to a health care facility or receives treatment in the emergency department of a health care facility, a staff member designated by the facility, such as a social worker or addiction counselor, will be required to provide the information once treatment for the drug overdose is complete but prior to the person's discharge from the facility.

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Bill Requiring Practitioners to Check Prescription Monitoring Information Passes Assembly—On December 7, 2017, A4741 was passed in the New Jersey Assembly and referred to the New Jersey State Senate. The bill requires prescribers, or their authorized designees, to check a patient's prescription monitoring information when issuing a prescription for a Schedule II controlled dangerous substance to a patient receiving care or treatment in the emergency department of a general hospital. The bill also provides that medical scribes and licensed athletic trainers working in a clinical setting may be authorized by a practitioner to access prescription monitoring information, provided the practitioner is responsible for the use or misuse of the information.

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Bill Entering New Jersey in Multi-State Nurse Licensure Compact Passes Assembly—On December 7, 2017, A3917 was passed in the New Jersey Assembly and referred to the New Jersey State Senate. The bill will enter New Jersey into the Nurse Licensure Compact—a multi-state compact that establishes a mutual recognition system for the licensure of registered professional nurses and licensed practical nurses. Under a mutual recognition system, a nurse only needs to obtain one license from the nurse's state of residence in order to be permitted to practice nursing in any other state that is a party to the compact, provided that the nurse complies with the practice laws of the state in which the patient is located at the time that care is rendered. Currently, a nurse is required to be licensed in, and by, each state in which the nurse chooses to practice.

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Bill Licensing Radiologist Assistants Passes Assembly—On December 18, 2017, S3237 was passed in the New Jersey Senate. The bill had previously passed the New Jersey Assembly on December 7, 2017. The bill amends the Radiologic Technologist Act to provide for the licensure and registration of radiologist assistants by the Radiologic Technology Board of Examiners, in the Department of Environmental Protection. The bill also provides for the approval by the State Board of Medical Examiners of delegated fluoroscopic procedures that a radiologist assistant may perform, and the level of supervision by a licensed radiologist necessary for the radiologist assistant to perform those procedures.

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Bill for Licensure of Ambulatory Care Facilities to Provide Integrated Primary Care Services Including Behavioral Health Care Passes Senate—On December 18, 2017, S1710 was passed in the New Jersey Senate and referred to the New Jersey Assembly. The bill requires the Department of Health (DOH) to establish a single license for facilities providing integrated behavioral and physical health care. It requires the DOH to establish a new integrated health care facility licensing system under which facilities will provide primary care, mental health care, substance use disorder treatment, or a combination of such services under a single license. The DOH would have broad authority to set standards for facilities holding an integrated health care facility license, similar to its authority over other health care facilities.

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Brach Eichler In The News

John D. Fanburg was interviewed by two NJ radio stations, NJ 101.5 <http://bit.ly/2qQYbnb> and WCTC Radio, on Brach Eichler's health law outlook for 2018.

Lani M. Dornfeld spoke at the Home Care Association of Florida Home Care Warmup Meeting on January 17th on the topic, “Home Health Employer Protections: Can You Improve Yours?” For more information, <http://bit.ly/2AMpaIQ>

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On January 31st, **John D. Fanburg** and **Lani M. Dornfeld** will speak at the New Jersey Association of Ambulatory Surgery Centers General Membership Meeting. John will present an update on Legislative and Regulatory Issues and Lani will speak on the topics, “Curiosity Killed the Cat & Other Common HIPAA Pitfalls,” and “HIPAA Business Associates: What’s the Big Deal?” For more information, <http://bit.ly/2CPmH1Z>

John D. Fanburg and **Charles X. Gormally** were quoted in *NJBIZ* about the prospect of legal cannabis in New Jersey. <http://bit.ly/2FFL1O>

HIPAA CORNER

HHS Highlights Office for Civil Rights’ Ongoing Response to the Opioid Crisis, While Implementing the 21st Century Cures Act

The Department of Health & Human Services, Office for Civil Rights (OCR) launched an array of new tools and initiatives in response to the opioid crisis, while implementing the 21st Century Cures Act. The aim of these tools is to ensure families and caregivers can have access to the information needed to prevent and address emergencies, such as opioid overdoses and mental health crises, while also protecting patient privacy.

OCR has launched two new websites — one for patients and their families and another for providers — which cover the ways in which HIPAA applies to mental and behavioral health information. The sites are meant to make existing HIPAA provisions more user-friendly, and to clarify the circumstances under which HIPAA allows covered entities to disclose mental health and substance abuse disorder-related information to family and caregivers.

OCR is also working to create updated HIPAA guidance on research, as specified in the 21st Century Cures Act. It has launched a working group to study and report on the uses and disclosures under HIPAA of protected health information (PHI) for research purposes. The working group will include representatives from relevant federal agencies as well as researchers, patients, health care providers, and experts in health care privacy, security, and technology. The working group will release a report addressing whether uses and disclosures of PHI for research purposes should be modified to facilitate research while protecting individuals’ privacy rights.

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HEALTH LAW ALERT

JANUARY 2018



COMPENSATION FROM PHARMACEUTICAL COMPANIES: **NEW LIMITATIONS AND OBLIGATIONS ON PRESCRIBERS**

On January 16, 2018, new regulations limiting gifts and payments from prescription drug and biologics manufacturers to prescribers became effective in the State of New Jersey. Under the rules, payments received by physicians and other prescribers for non-clinical services rendered to the pharmaceutical industry will be capped at \$10,000 per year. These rules do not apply to arrangements with prescribers entered into on or before January 15, 2018.

Limitations Imposed on Prescribers’ Bona Fide Services

Under the newly revised rules, “prescribers” may not accept more than \$10,000 in aggregate from all pharmaceutical manufacturers in any calendar year for “bona fide services” provided by the prescriber, including promotional speaking activities, participation on advisory boards, and other consulting arrangements. Payments for speaking at education events that are considered “bona fide services” are not subject to the cap, but must be set at fair market value and must be set forth in a written agreement and meet other specific requirements. Payments for research activities, and royalties and licensing fees are not subject to the cap, but other requirements apply. A “prescriber” is defined to mean a New Jersey-licensed physician, podiatrist, physician assistant, advanced practice nurse, dentist, or optometrist. Prescribers speaking at education events or promotional activities must directly disclose to attendees, either orally or in writing at the beginning of the presentation, that the prescriber has accepted payment for bona fide services from the sponsoring pharmaceutical manufacturer within the preceding five years. Prescribers employed by pharmaceutical manufacturers must satisfy other obligations under the rules.

Bona Fide Services

Bona fide services provided by a prescriber to a pharmaceutical manufacturer must be set forth in a written agreement, and include speaking presentations at promotional activities and education events, participation on advisory boards, and consulting arrangements. The written agreement must contain a number of detailed elements, including the specific services to be provided and the specific compensation amount based on the fair market value of the services.

Other Acceptable Items

In addition to the annual cap, prescribers are permitted to receive certain items and reimbursement from pharmaceutical manufacturers, including patient educational items of nominal or no value to the prescriber (e.g., anatomical models for patient education use); pharmaceutical manufacturer subsidized registration fees at education events that are available to all event participants; modest meals provided through event organizers at education events with certain limitations; modest meals provided by a manufacturer to non-faculty prescribers through promotional activities; and reasonable payment or reimbursement of travel, lodging, and other personal expenses associated with the provision of bona fide services, associated with employment recruitment, or in connection with research activities.

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BRACH EICHLER Health Law ALERT

Sample Medications

The rule does not change a prescriber's ability to accept sample medications from pharmaceutical manufacturers, so long as the samples are intended to be used exclusively for the benefit of the prescriber's patients, the prescriber does not charge patients for such samples, and the prescriber satisfies all dispensing standards set forth in the prescriber's licensing board rules.

Prohibited Gifts and Payments

Prescribers and their immediate family members (unless employed by the pharmaceutical manufacturer and part of regular employment benefits) are prohibited from accepting gifts and other payments from pharmaceutical manufacturers, including:

- Financial benefits (e.g., gifts, payments, stock, stock options, grants, scholarships, subsidies, and charitable contributions)
- Entertainment or recreational items (e.g., theater or sporting event tickets or leisure trips)
- Meals with a fair market value in excess of \$15
- With certain exceptions, any item of value that does not advance disease or treatment education, such as:
 - Pens, note pads, clipboards, mugs, or other items with a company or product logo
 - Items intended for the personal benefit of the prescriber or staff (e.g., floral arrangements and artwork)

- Items that may have utility in both the professional and non-professional setting (e.g., electronic devices), unless the item is used by patients and remains in a common area of the prescriber's office
- Any payment in cash or cash equivalent (e.g., gift certificates)
- Any payment or direct subsidy to a non-faculty prescriber to support attendance at, as remuneration for time spent attending, or for the costs of travel, lodging, or personal expenses associated with attending any education event or promotional activity.

Under the rule, "immediate family member" includes the prescriber's spouse, civil union partner, or domestic partner, as well as children and all other relatives who reside in the same household as the prescriber.

How Can We Help?

The rules contain a number of restrictions and nuances for prescribers receiving payments from pharmaceutical manufacturers. Further, the rules require specific items and provisions be set forth in written agreements between the prescriber and manufacturer. Should you need assistance regarding the permissible and restricted activities and payments under the rule, or in preparing or reviewing agreements with pharmaceutical manufacturers, please contact us.

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