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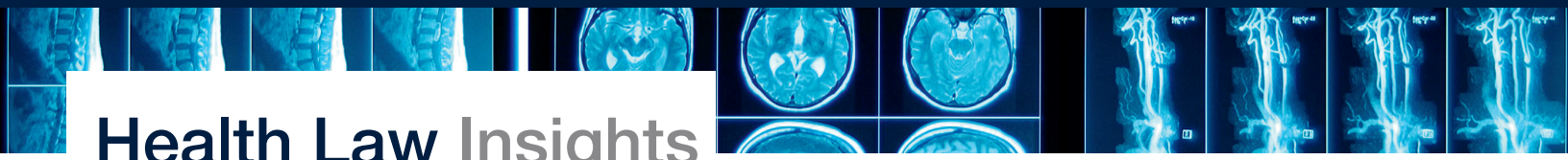

Health Law Insights

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Failure to Update Business Associate Agreement Results in Significant Penalties

A recent settlement between the Department of Health and Human Services, Office for Civil Rights (OCR), and Care New England Health System of Providence, Rhode Island (CNE), demonstrates the importance of maintaining compliant Business Associate Agreements (BAAs), and the potential costs associated with the failure to update BAAs entered into prior to the adoption of expanded BAA content requirements in March 2013. CNE, the parent of a regional health system, provides technical support and information security as a business associate to its member entities. A hospital member of the CNE system disclosed to OCR in November 2012 that protected health information (PHI) for as many as 14,000 patients may have been compromised due to the loss of two unencrypted backup tapes.

In the course of its investigation, OCR discovered that the BAA between CNE and the hospital was dated March 15, 2005. The BAA was not updated until August 28, 2015, in response to OCR's investigation.

OCR determined that hospital PHI transmitted by CNE between September 2014 and August 28, 2015 was disclosed by the hospital to CNE under the auspices of a BAA between the parties that failed to include specifications required by HIPAA's Privacy and Security Rules at 45 C.F.R. §§ 164.502(e), 64.308(a) and 164.532(d). As a result of this and other noncompliant conduct, OCR concluded that the hospital impermissibly disclosed the PHI of over 14,000 patients to CNE without obtaining the necessary assurances through a written BAA from CNE that it would appropriately guard the PHI.

The Massachusetts Attorney General's Office and the hospital agreed to a settlement of $150,000 in connection with the November 2012 loss of unencrypted backup tapes. Additionally, OCR announced on September 23 that it had entered into a settlement agreement mandating a $400,000 monetary payment and implementation of a corrective action plan by CNE to resolve the system's violations of HIPAA Privacy and Security Rules resulting from the hospital's disclosure of PHI to CNE under a noncompliant BAA. OCR also could have sought civil monetary penalties, but declined to do so on account of the state settlement.

The incident is an important reminder of the expensive penalties that may result from a simple oversight and that it is imperative for covered entities to update BAAs that were executed prior to March 2013.

Compliance Concerns Raised Over Proposed Hospital Outpatient Department Rule

In an August 26, 2016 letter to the Centers for Medicare & Medicaid Services (CMS), the American Hospital Association (AHA) expressed serious concern over the portion of the calendar year 2017 hospital outpatient prospective payment system (OPPS) proposed rule that would implement the site-neutral payment provision of the Bipartisan Budget Act of 2015 (Act). Specifically, the AHA is alarmed that the proposed site-neutral policies raise significant compliance risks under the federal physician self-referral law (Stark Law) and the federal Anti-Kickback Statute.

It has been clear since passage of the Act that off-campus hospital outpatient departments (HOPDs) that relocated, changed service lines or began billing under the OPPS on or after

November 2, 2015 would no longer receive facility fees under the OPPS. What was not known prior to the publication of the proposed OPPS rule was how CMS would implement the new payment regime. Pursuant to the proposed rule, sole payment would be rendered under the Medicare Physician Fee Schedule to the physician who performed the service.

Further, the proposed OPPS rule provides that HOPDs that are not excepted from the new site-neutral provision are still considered HOPDs as that term is defined in Medicare regulations. Under the Medicare definition, the financial operations of the HOPD must be fully integrated within the financial system of the hospital. In practice, hospitals routinely cover HOPD overhead expenses, such as costs associated with the building, equipment, nonphysician clinical staff, supplies, patient medical records, etc.

Though hospitals would remain obligated under Medicare regulations to integrate the expenses of affected HOPDs, the proposed rule would end all reimbursement that the hospital previously received from the government for providing such services. At the same time, physicians providing services at off-campus HOPDs would be paid by Medicare to cover expenses as if the physicians themselves owned and operated the facility, even though they did not.

The proposed rule thereby exposes hospitals to compliance risks while providing very little opportunity to rectify arrangements rendered suspect by the rule. To the extent that a hospital continues to pay overhead costs for a non-excepted HOPD, it could be perceived as offering free services and supplies to community physicians who provide services at the HOPD. It is axiomatic under federal fraud and abuse laws that hospitals not provide free goods or services to referring physicians. Assuming there are referrals to the hospital from community physicians who perform services at the HOPD, Stark Law and/or Anti-Kickback Statute prohibitions could be triggered in such cases.

The proposed rule's effective date of January 1, 2017 further exacerbates compliance concerns, forcing hospitals to make extensive changes to existing HOPD clinical care arrangements within an abbreviated time frame. Such abrupt changes to existing agreements may cause the modified agreements to fall outside numerous Stark Law exceptions and Anti-Kickback Statute safe harbors, which require that compensation terms be "set in advance" for the duration of the arrangement between the parties. The "set in advance" condition has been interpreted by CMS to require that the terms of physician compensation remain fixed for at least one year following the consummation of an agreement or amendment thereto.

The concern raised by the AHA may be mitigated if the physicians performing services at the HOPD are employees or independent contractors of the hospital (or an affiliated entity) and assign their Medicare collections to the hospital entity. However, any arrangement in which a physician collects payments directly from Medicare for services performed at an HOPD impacted by the site-neutral payment policy could be viewed as suspect if the arrangement fails to require the physician to reimburse the hospital for HOPD-associated expenses.

AHA is calling on CMS to forgo finalization of the proposed rule because it would require "impacted hospitals to accept significant compliance risk" and to "delay the implementation of the site-neutral policies in the proposed rule by at least one year." AHA claims that "[t]his delay would provide the time necessary for CMS to develop a fair and flexible payment policy under which hospitals would be able to receive direct payment for . . . their non-excepted HOPDs and for non-excepted items and services that they furnish in excepted HOPDs."

McCarter & English will continue to monitor this development for its potential to affect our clients.

Medicare ACOs Improving Care and Generating Savings, According to CMS Report

CMS announced in an August 25 press release that the 2015 quality and cost results for Medicare Accountable Care Organizations (ACOs) demonstrated progress among the country's ACOs with respect to cost and quality, highlighting in particular the progress made by the most advanced ACO iteration, the Pioneer ACO Model. ACOs, which are at the heart of the American health care system's shift from a fee-for-service model to a pay-for-performance model, are groups of doctors, hospitals and other health care providers who come together voluntarily to give coordinated, high-quality care to their Medicare patients. CMS describes the goal of Medicare ACOs, which were created by the Affordable Care Act, on its website, stating, "The goal of coordinated care is to ensure that patients, especially the chronically ill, get the right

care at the right time, while avoiding unnecessary duplication of services and preventing medical errors. When an ACO succeeds both in delivering high-quality care and spending health care dollars more wisely, it will share in the savings it achieves for the Medicare program."

CMS noted in the release that over 400 Medicare ACOs generated more than $466 million in Medicare savings in 2015 and that 125 of those ACOs qualified for shared savings payments by meeting both financial thresholds and quality performance benchmarks.

The Medicare Shared Savings Program (MSSP) was established under section 3022 of the Affordable Care Act with the goal of improving the quality of care for Medicare Fee-for-Service beneficiaries while reducing unnecessary costs. According to the CMS press release, MSSP ACOs generated total savings of $429 million and 119 MSSP ACOs earned shared savings. CMS noted that 83 ACOs maintained health care costs below their benchmark but failed to earn shared savings due to their failure to achieve minimum savings targets.

CMS also reported progress among MSSP ACOs with respect to both financial and quality goals, noting: 31 percent met their minimum savings rate in 2015 (compared with 28 percent in 2014 and 26 percent in 2013); average quality performance improved by over 15 percent for four measures; and over 91 percent of ACOs in their second or third year during 2015 increased their overall performance score in at least one of four quality measures. CMS observed that the MSSP has received continued interest from new applicants and from current participants who are seeking to remain in the program.

The Pioneer ACO Model is made up of a smaller subset of ACOs and is geared toward health care organizations with deeper experience providing care over a variety of settings. The CMS website explains that the Pioneer Model "will allow these provider groups to move more rapidly from a shared savings payment model to a population-based payment model on a track consistent with, but separate from, the Medicare Shared Services Program." Though few in number, the 12 Pioneer ACOs managed to achieve a combined savings of $37 million, with eight generating savings and six earning shared savings. Of the four Pioneer ACOs that failed to achieve savings, only one fell outside the minimum loss rate, rendering it liable to Medicare for payment. From a quality perspective, the average quality score among the Pioneer ACOs rose from 87.2 percent in 2014 to 92.26 percent in 2015, while nine of the 12 ACOs achieved quality scores above 90 percent.

New Regulations Provide Guidance on Permissible Scope of Employee Wellness Programs

Over the past decade, employee wellness programs have been adopted by human resource departments across the United States as a means to encourage employees to engage in healthy lifestyles and to reduce insurance expenditures. Wellness programs, especially prevalent among health care industry employers, provide incentives to employees, often in the form of lower health insurance premiums, to meet personalized wellness goals.

According to a 2013 Rand Research Report, half of United States employers offer some form of wellness program. Of these employers, 72 percent offer programs combining health risk assessments (HRAs), and various biometric data collection or other health screenings. The purpose of the programs is to identify health-related behaviors and risk factors so that early intervention might positively impact the progression of lifestyle-related diseases and potentially decrease health care costs. Based on a concern for the growing percentage of employees suffering from lifestyle-related diseases, the Affordable Care Act (ACA) specifically provided for incentive-based wellness programs as a component of employer-sponsored health care plans. Under the ACA, an employer may provide incentives of up to 30 percent of the total cost of self-only coverage under an employer-sponsored plan to employees who participate in wellness programs and/or penalize employees who choose not to do so in the same amount.

The ACA, however, expressly requires that all wellness programs comply with the requirements of the Americans with Disabilities Act (ADA) and the Genetic Information Non-Discrimination Act (GINA), both of which restrict an employer's right to obtain disability-related information from employees and/or subject employees to medical testing. Accordingly, programs that sought health-related information through HRAs or involved biometric testing were at risk of violating the ADA unless they were considered "voluntary health programs," which the ADA permits.

On May 17, 2016, the Equal Employment Opportunity Commission (EEOC) issued a final rule intended to

align the ADA and GINA with the ACA. The new regulations, which resolve doubts concerning the legality of health data collection practices under the ADA and GINA, expand the permissible use of incentives to wellness programs that are offered outside the parameters of an employer-sponsored plan and govern the use of financial incentives in voluntary wellness programs that require employees to complete questionnaires regarding health-related matters (i.e., HRAs) or utilize medical examinations.

The new regulations provide guidance to employers on the parameters for ADA-compliant "voluntary health programs" by defining two key terms: "voluntary" and "health program." "Health program" is defined as a program "reasonably designed to promote health or prevent disease." Programs will be considered noncompliant if they are overly burdensome with respect to time commitment, involve "unreasonably intrusive" procedures, are a "subterfuge for violating the ADA" or other anti-discrimination laws, or require employees to incur significant costs for medical examinations. Above all else, the purpose of the program must be to benefit the health of employees as opposed to, for example, identifying conditions that increase health care costs.

"Voluntary" is defined as "not required." Employees cannot be denied access to health coverage for failing to participate, and an employer cannot threaten, coerce, intimidate or otherwise retaliate against employees who do not participate. The requirements of the plan must be disclosed to employees prior to participation, and such disclosure must advise employees what information will be obtained, how it will be used and who will receive it. EEOC will be publishing a sample disclosure form on its website for employer use.

The new ADA regulations also set forth the level of incentives that may be provided to employees who elect to participate. Not surprisingly, the maximum level of incentive/penalty mirrors the ACA—30 percent of the self-only coverage selected by the employee.

Additionally, under the new GINA regulations, it is now lawful to permit a spouse of an employee to participate in wellness programs and obtain the same incentives. Prior to the issuance of the new regulations, spouses could not even be offered the opportunity to participate. It remains unlawful, however, for children to be offered the opportunity to participate.

Information regarding the new rules and regulations is available on the EEOC's website, www.eeoc.gov. Before implementing or modifying a wellness program, employers should review the regulations under the ADA, GINA and the ACA or consult counsel.

CMS Issues Final Rule Modifying Nursing Home Regulatory Framework

More than a year after proposing major rule changes impacting the nursing home industry, on September 28, 2016, CMS published the first major changes to the regulatory framework governing nursing homes in a quarter century (the Final Rule). The 700-page Final Rule elicited a mixed reaction from nursing home operators, as some provisions upset long-standing industry precedents, while other changes contained in the proposed rule that had previously been met with strong industry resistance were tabled. The Final Rule will take effect on November 28 of this year.

One controversial provision upends the use of mandatory arbitration clauses. Under the Final Rule, nursing homes will no longer be permitted to require patients, as a precondition to admission to the nursing home, to sign agreements compelling arbitration in the event of a dispute. Despite strong opposition from the nursing home industry, CMS finalized a provision prohibiting the practice, condemning such agreements as unconscionable. CMS also kept in place an expanded definition of "willful infliction of injury," although it reassured nursing home operators that it wouldn't be interpreted in an overly broad fashion.

Nursing home industry interests nevertheless prevailed upon CMS to exclude other disfavored provisions contained in the proposed rule. CMS opted not to finalize regulations requiring patients to be screened by a physician or other health care practitioner before being transferred to hospitals from nursing homes, and regulations pertaining to the provision of outpatient rehabilitation services to non-residents. Nursing home operators are encouraged to consult with health law experts to determine what procedural changes should be implemented in preparation for the effective date of the Final Rule.

Appellate Court Rejects Religious Discrimination Claim by Employee Terminated for Flu Vaccine Noncompliance

In an opinion with potentially far-reaching consequences for hospitals and providers throughout the state, the Superior Court of the State of New Jersey, Appellate Division, held on October 3 that a hospital employee terminated for her refusal to obtain a flu shot could not maintain a religious discrimination claim against the hospital when she failed to provide the hospital with evidence of a sincere religious belief. The unanimous decision of the three-judge appellate panel upheld a lower court ruling in favor of the Hospital.

In *Yvonne Lombardo Brown v. Our Lady of Lourdes Medical Center, Inc.*, the plaintiff, a hospital employee who worked as a community health organizer, requested a medical exemption from a hospital policy at Our Lady of Lourdes Medical Center (Hospital) requiring employees to be vaccinated. The Hospital implemented the vaccination policy in 2012 in the interest of protecting patient and employee health by preventing the spread of the flu. Exemptions to the policy were available to employees with documented medical conditions and to employees who opposed the vaccine based on religious grounds, provided such beliefs were supported by documentation from clergy.

The plaintiff, who alleged a negative reaction to the flu vaccine over a decade earlier, applied for an exemption in October and December 2012 and was rejected both times. After being suspended for one week in January 2013 for noncompliance with the vaccine mandate, she was ultimately terminated in March 2013. Ms. Brown instituted an action in state court, claiming that the Hospital had violated her rights under the New Jersey Law Against Discrimination (LAD) by failing to provide an accommodation for her and by terminating her for the exercise of her rights. Subsequently, the plaintiff filed a motion to amend her complaint to add a claim for religious discrimination. The trial court denied the motion to amend and ultimately granted the Hospital's motion for summary judgment in May 2015 to dismiss the lawsuit. The plaintiff appealed the decision denying the motion to amend.

Citing trial court Judge Anthony Pugliese's opinion, the Appellate Division panel upheld the decision denying the motion to amend, reasoning that "'[b]ecause plaintiff did not allege 'a sincerely held religious belief,' an 'employer has the right to require certain things of the job[,]' and that as 'in the health care field, immunization is a reasonable . . .' requirement, the court found no 'basis for this plaintiff on a case of religious discrimination.'"

The plaintiff's failure to allege a religious objection to the vaccination, or that certain religions were provided exemptions while other religions were not, barred a successful claim under the LAD. In affirming the decision of Judge Pugliese, the Appellate Division panel explained that "[a]bsent any of these allegations, and in light of the LAD's requirement that employers offer reasonable accommodations for their employees' religious beliefs, we conclude that plaintiff could not establish a prima facie case under the LAD . . . ."

Telemedicine Legislation Moves Forward in New Jersey

A New Jersey state legislative panel has unanimously approved proposed legislation that aims to regulate telemedicine, the remote diagnosis and treatment of patients by means of telecommunications technology. On September 26, the New Jersey Senate Health, Human Services and Senior Citizens Committee voted unanimously to refer the bill to the Senate Budget and Appropriations Committee.

Telemedicine is defined by the American Telemedicine Association (ATA) as "the use of medical information exchanged from one site to another via electronic communications to improve a patient's clinical health status." The proposed legislation sets forth a broad definition of telemedicine, but does exclude from that definition the use of audio-only telephone conversation, e-mail, instant messaging, phone texting or fax transmissions.

Among other requirements, the proposed legislation would necessitate the state's Medicaid program and NJ FamilyCare to cover telemedicine services to the same extent that such services would be covered if they were delivered through traditional in-person means or methods, mandate that New Jersey insurers reimburse telemedicine services at the same rate that they reimburse in-person visits, and require the state's Board of Medical Examiners to review the Interstate Telemedicine Licensure Compact that is currently being promoted by the Federation of State Medical Boards, which would establish a universal system of reciprocal licensing for physicians.

A September 26 article in the Star-Ledger demonstrated the enthusiasm for the proposed legislation among its sponsors and the trepidation about the bill from some of its detractors. The bill's supporters have touted the ability of telemedicine to expand access and reduce costs for consumers. The article quoted Sen. Diane Allen of Burlington County, who noted, "By legalizing telemedicine, we can bring the cost of healthcare down and expand access to a variety of health services for millions of new patients."

However, Wardell Sanders, the president of the New Jersey Association of Health Plans (NJAHP), expressed skepticism over the degree to which the proposed bill would regulate telemedicine. Sanders noted NJAHP's objection to the provision requiring that telemedicine be reimbursed at the same rate as in-person visits, telling the Star-Ledger, "We would argue there should be flexibility to allow for different pay structures," and adding that, while over 30 states have passed telemedicine legislation, "only seven states require reimbursement for telemedicine services to the same extent as for in-person treatments and consultations."

Providers and insurers should take note as the legislation progresses through the legislature, due to its long-term potential implications for health care in New Jersey.

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