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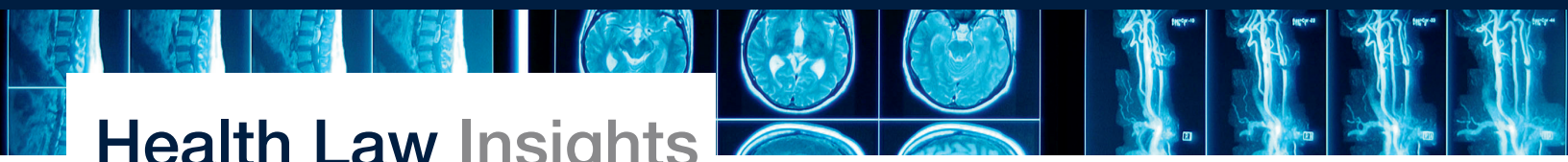

Health Law Insights

ISSUE | 5

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FOCUS

Federation of State Medical Boards Releases Final Interstate Licensure Guidance for Telemedicine

The Federation of State Medical Boards (FSMB) released the Interstate Medical Licensure Compact (Compact) as model legislation to address physician concerns of treating patients who are located in a different state than that in which they are licensed to practice. Typically, physicians must be licensed in the state where their patient is located, thus making interstate telemedicine services nearly impossible for physicians who are not licensed in multiple states. The Compact is not meant to step on the toes of state legislatures, but reduce the barriers to gaining licensure in multiple states.

Recently, the FSMB released a telemedicine model that they referred to as "common-sense guidelines," but, in some cases, were still criticized for being inflexible. The release addressed issues including i) determining when a physician-patient relationship is established; ii) securing privacy of patient data; iii) guaranteeing proper evaluation and treatment of the patient; and iv) limiting the prescribing and dispensing of certain medications. Further, the FSMB set guidelines on an array of topics including licensure, establishing a patient-physician relationship, informed consent, medical records, and disclosures on online services being provided for telemedicine purposes.

In regard to licensure, a physician must be licensed or under the jurisdiction of the medical board where a patient is located and being treated. Additionally, a physician-patient relationship must be established. A physician-patient relationship is created when a physician agrees to undertake the diagnosis and treatment of the patient and, likewise, the patient agrees to be treated by the physician. When evaluating and treating a patient via telemedicine, a physician is held to the same standards that apply to an in-person encounter. Issuing a prescription based solely on an online questionnaire does not constitute an acceptable standard of care. Prescribing medications is at the discretion of the physician, but in the absence of a traditional physical examination, doctors must implement cautionary measures to ensure patient safety.

According to the Compact, a physician can designate a member state as their principal license state to register for an expedited license if their principal state is i) the state of primary residence for the physician; ii) the state where at least 25% of the physician's practice of medicine occurs; iii) the location of the physician's employer; or iv) if a state does not qualify in the first three mentioned sections, the state designated as the state of residence is the one used for purposes of federal income tax.

Physicians who wish to practice telemedicine in a state that lacks specific licensure requirements for telehealth providers may be required to seek a full medical license. There are many states that require telehealth providers to seek a full medical license in order to practice medicine in that state. New Jersey is one of those states.

The New Jersey Board of Medical Examiners has not adopted the Compact at this time, but as telemedicine grows in stature, it is important to pay attention to the Compact's impact on medical boards across the country.

FEDERAL UPDATE

EHR Final Rule Loosens Certification Requirements and Program Incentives

On September 10, 2014, the United States Department of Health and Human Services (HHS) released final rule requirements for electronic health records (EHR). This final rule modifies the existing 2014 certification requirements for EHR developers, so their software products may be used by physicians and hospitals in Medicare and Medicaid meaningful use programs.

These are some of the key changes that appear in the final rule:

- Providers may be able to use previous editions of certified EHR technologies to meet 2014 reporting requirements under the EHR incentives program.
- Stage 2 of the EHR Incentive Program has been extended a full calendar year to October 1, 2016, for institutional providers and to January 1, 2017, for noninstitutional providers.

HHS decided not to adopt the voluntary standards proposed by the Office of the National Coordinator of Health Information Technology earlier this year. Instead, this final rule aims to add flexibility and clarity to the current 2014 Edition EHR certification criteria.

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CMS Announces Dates for Ambulance Prior Authorization Requirements

On September 15, 2014, the Centers for Medicare and Medicaid Services (CMS) officials announced a prior authorization model demonstration program for nonemergent ambulance repetitive transport. The program requires Medicare preauthorization and will begin November 15, 2014, in South Carolina and December 15, 2014, in New Jersey and Pennsylvania. The demonstrations are targeted at testing whether prior authorization can lower costs while maintaining quality of care.

Ambulance providers may begin submitting prior authorization requests on October 30, 2014, in South Carolina and December 1, 2014, in New Jersey and Pennsylvania.

CMS Releases ACO Data

CMS recently released Accountable Care Organization (ACO) quality and financial performance results for the Medicare Pioneer (Pioneer) and Medicare Shared Savings Programs (MSSP). The data shows that Medicare ACOs have been successful in improving the quality of care to Medicare beneficiaries through both the Pioneer and MSSP models.

Pioneer ACO data came from 23 participating organizations, while MSSP data was compiled from 220 participating ACOs.

Court of Appeals for D.C. Will Rehear ACA Subsidy Challenge

The U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit) has agreed to rehear an issue pertaining to a clause in the Affordable Care Act (ACA) that says Americans who purchase their insurance through an exchange "established by the State" will be provided with subsidies to help pay for their insurance premiums. The ACA omits any mention of the federal exchange.

ACA opponents have made the argument that without expressly stating the "federal exchange," the federal government lacks the authority to issue insurance subsidies in states that do not run an exchange. Thirty-six states do not run their own exchanges.

Previously, a three-member panel of the U.S. Court of Appeals (D.C. Circuit) agreed with ACA opponents and struck down the federal government's ability to provide subsidies. The en banc rehearing will provide a second opportunity for the Obama administration to argue its position of federal backing for the states regardless of the current language drafted in the ACA.

HHS Data Shows 25 Percent Increase in ACA Insurers for 2015

HHS released a report on September 23, 2014, stating that there will be a 25 percent increase in the number of insurers providing health plans in the ACA health insurance marketplaces for 2015. The new insurers will begin offering plans on November 15, 2014, when the second enrollment period opens.

The 25 percent translates to seventy-seven new issuers offering coverage on the ACA exchanges. Fifty-seven of these insurers will be on the federally facilitated marketplace.

ACA Tax Implications for Employers

Starting in 2016, tax provisions of the ACA will mandate employers to report more than the usual W-2 and 1099 forms. The 2016 filings will include 2015 calendar data. Employers should take steps now to review the forms and instructions as well as ensure that they have the necessary reporting capabilities and resources to handle the tax reporting changes.

Section 6055 of the Internal Revenue Code (Code) sets forth an individual mandate that requires "minimum essential health coverage" or a tax penalty. To assist with enforcement of the tax penalty and ensuring coverage of individuals, certain employers that sponsor health plans for their employees are required to include health plan information for each employee with their tax filing.

Section 6056 of the Code addresses employer shared responsibility. This section requires applicable larger employers, or an employer with an average of fifty full-time employees or equivalent, to file annual returns with the Internal Revenue Service (IRS) and give annual coverage statements to their full-time employees.

As mentioned, the ACA tax reporting requirements will add 1094 and 1095 forms to an employer's annual tax filings. Forms 1095-B and 1095-C will include employee health coverage information and are to be filed with the respective transmittal form, 1094-B or 1094-C. Small employers with self-insured health plans, such as those covered in Section 6055 of the Code, will use the 1094-B and 1095-B forms. Larger employers with self-insured health plans, such as those covered in Section 6056 of the Code, will use the 1094-C and 1095-C forms. Electronic filing is mandated for an employer filing 250 forms or more with the IRS. The IRS has released both drafts and instructions for the forms.

Congress Passes Bill Requiring Post-Acute Providers to Collect Data

On September 16, 2014, the United States House of Representatives passed a bill under the Improving Medicare Post-Acute Care Transformation Act (IMPACT) designed to strengthen Medicare's post-acute care (PAC) system. IMPACT would require providers to submit standardized patient assessment and quality data by 2019 to allow Medicare to compare quality across PAC settings.

IMPACT is anticipated to assist in PAC reform. HHS and the Medicare Payment Advisory Commission would be required to give recommendations to Congress for a new PAC payment system using the IMPACT data findings. The bill is currently awaiting approval from the executive branch.

HHS Grants Chronic Disease Prevention $211.6 Million

HHS made an announcement this month that it will be awarding $211.6 million in grants to programs intended to prevent major chronic diseases. This initiative is partially funded by the ACA in hopes of reducing the nation's overall health care bill.

These grants will be administered by the Centers for Disease Control and Prevention (CDC) and organized by the most prevalent and costly diseases, such as obesity, diabetes, and heart disease.

President Order to Combat Antibiotic-Resistant Bacteria

President Obama implemented a federal regulatory initiative by signing an executive order urging federal departments and agencies to combat antibiotic-resistant bacteria. The order calls for a five-year plan and task force to enhance prevention and containment of outbreaks, while investing in research and development for next-generation diagnostics, antibiotics, and vaccines. In addition to the task force, the plan also offers a $20 million award for creating a test to identify resistance.

Seventh Circuit Dismisses Obamacare Mandate Lawsuit

The United States Court of Appeals for the Seventh Circuit threw out a lawsuit challenging the postponement of the ACA employer mandate. The court said the plaintiffs, the Association of American Physicians and Surgeons (AAPS), had no standing.

AAPS argued that the federal government could not use its power to delay the mandate for employers to provide their employees with health insurance if the government was not going delay the individual mandate in tandem. Plaintiffs also asserted that a delay in enforcing the mandate hurts AAPS members financially because when people pay the penalty they have less income to buy medical care.

The three-judge panel made the decision in late September, reasoning that the United States Supreme Court has often held there is no standing in lawsuits made by individuals to protect the interests of a third party. Judge Easterbrook wrote for the panel, stating, "The Supreme Court has rejected efforts by one person to litigate about the amount of someone else's taxes (or someone else's subsidies, which are taxes in reverse)."

STATE UPDATE – NEW JERSEY

New Jersey Supreme Court Says Hospitals' Internal Reviews Are Not Discoverable

On September 29, 2014, the Supreme Court of New Jersey (NJ Supreme Court) held in a 4-3 decision that all materials prepared "exclusively" for internal use and "as a process of self-critique analysis" are entitled to an absolute privilege from discoverability under the Patient Safety Act. The case before the NJ Supreme Court addressed whether a hospital staff memorandum investigating an adverse event is discoverable in a malpractice suit against the hospital. The NJ Supreme Court said that the ability of hospitals to maintain privacy of their own internal documents is necessary because it promotes transparency for health care providers when a mistake is made.

The retention of internal documents conforms to the Patient Safety Act, because the overarching goal of the Act is not to replace the preexisting evaluative processes hospitals use, but to minimize adverse events occurring from system failures in hospital. The NJ Supreme Court continued by stating that the materials in dispute meet these goals because they aid in future patient safety and medical staff training, and therefore are privileged and not discoverable.

New Jersey Passes Bill Mandating Hospitals to Educate Families of Discharged Patients

A bill requiring hospitals to give instructions to designated caretakers when a relative or friend is discharged from the hospital is now headed to Governor Chris Christie's office after a 72-0 vote of approval from the New Jersey legislature.

The intent behind the requirement for instructing family members and friends is to ensure that discharged patients receive the care they need when they leave the hospital. The piece of legislation was originally requested by AARP after it made a statement to make caretaking law a priority, stating the average person does not inherently know how to give post-care treatment.

New Jersey Medical Device Tax Proposal

On September 15, 2014, the New Jersey Division of Taxation published a notice of its proposal of a new rule under N.J.A.C. 18:24-37, which would clarify the categories of drugs and durable medical equipment exempt from New Jersey sales and use tax. Certain subcategories of pharmaceuticals and medical devices are already exempt from New Jersey sales and use tax.

Deadline Extension for New Jersey Physicians' Use of New Paper Prescription Blanks

The New Jersey Division of Consumer Affairs granted a final extension for physicians to transfer to using the newly approved prescription blanks. As of November 3, 2014, all physicians must be using the new blanks for issuing prescriptions.

The extension comes after some delays in printing and receiving the new blanks, due to high demand. Physicians who have received the new blanks should begin using them immediately.

New Jersey Bill for Medicaid and FamilyCare Telemedicine

A bill was introduced to the New Jersey Senate in August that would provide coverage and reimbursement under New Jersey Medicaid and New Jersey FamilyCare for health care services provided through telemedicine.

New Jersey is one of seven states that do not provide Medicaid reimbursements for telemedicine. The bill recognizes same and creates flexibility for the insured's health care options.

STATE UPDATE – NEW YORK

New York Health Regulators Propose Revisions for Health Care Collaboration

New York State's Department of Health proposed regulations for entities to obtain a Certificate of Public Advantage (COPA) under Public Health Law Article 29-F. The intent of the proposed regulation is to promote state supervision in the collaboration among health care competitors and to provide state action immunity against federal antitrust laws. State action immunity is applicable when the collaborating parties can show a clear state policy for displacing competition with regulation and the state has the ability to oversee their conduct.

Court of Appeals to Determine Hospital's Liability in Car Crash

This July, the Appellate Division, Second Department, answered the question of whether a bus driver could sue a hospital for malpractice after the hospital treated a patient and gave her medication some time before she was involved in an accident with the bus driver. The Appellate Division, Second Department, held that the bus driver could not sue because he was not the hospital's patient.

The Court of Appeals has now agreed to take this case. New York courts have generally held that there is no duty to control the conduct of third parties and to prevent them from injuring others, except in special circumstances. Routinely, the Court of Appeals hears a case about a year after giving approval of appeal.

A relatively new law passed in Massachusetts this summer will limit the number of patients assigned to nurses working in the intensive care unit to "no more than two."

STATE UPDATE – MASSACHUSETTS

Massachusetts Medical Society Presses for Proposed EHR Legislation

In an announcement on September 29, 2014, the Massachusetts Medical Society (MMS) urged the State Board of Registration in Medicine (BRM) to adopt proposed regulations that would help physicians meet "meaningful use" requirements for health information technology. Chapter 224 requires that physicians "demonstrate proficiency in the use of computerized physician order entry, e-prescribing, electronic health records and other forms of health information technology, as determined by the board." The statute further suggests that in order to fulfill the proficient requirement, physicians must be compliant with the federal "meaningful use" requirement, set for January 15, 2015.

The proposed regulations set forth alternative ways for a physician to meet the "meaningful use" and proficiency requirements. Alternative methods include meeting necessary skills through employment, being an authorized participant on the Massachusetts Health Information Highway, and completing three hours of continuing medical education credits in electronic health records. Among alternative methods, the BRM also included exceptions and provisions for physicians newly coming into the state.

The MMS claimed that of the 40,000 licensed physicians in Massachusetts, approximately 15,000 would be able to meet the meaningful use requirements. With 60 percent of the state's physicians violating the statute, MMS argues that patient access to care would be severely harmed without the adoption of provisions that allow for a broader interpretation.

Massachusetts Law Limits ICU Nurses to Two Patients

A relatively new law passed in Massachusetts this summer will limit the number of patients assigned to nurses working in the intensive care unit to "no more than two." The Massachusetts Nursing Association backed the staffing-ratio legislation.

An acuity tool will be used to monitor the number of nurses assigned to any one patient. The acuity tool will assess the stability of the patient and account for the nurses on staff. Some questions are yet to be addressed, such as whether a hospital will need to bring in off-duty nurses if every nurse on staff is at capacity with two patients. The Massachusetts Health Policy Commission will issue further regulation on implementation of the law.

HIPAA UPDATE

Federal and State Guidance on HIPAA Privacy for Same-Sex Spouses

HHS' Office for Civil Rights (OCR) issued a statement providing HIPAA guidance for covered entities, stating that they should treat persons in same-sex marriages in the same manner they would treat persons in other marital relationships.

OCR's statement follows the U.S. Supreme Court decision in *U.S. v. Windsor* that held Section Three of the Defense of Marriage Act unconstitutional. In *Windsor*, the U.S. Supreme Court held that "covered entities must consider the following law regarding lawfully married same-sex spouses and same-sex marriage," in which the U.S. Supreme Court continued by addressing HIPAA and affirming that covered entities would be permitted to share an individual's health information with a family member and under certain circumstances.

OCR is expected to release more information in the upcoming months, which will officially amend the HIPAA privacy rule to include same-sex marriage provisions.

HIPAA Audits As an Enforcement Tool

OCR has announced that HIPAA audits are coming and are planned as an "enforcement tool." The anticipated audits will include covered entities and their business associates. The goal of the compliance program is to launch investigations into whether health care organizations and their contractors are complying with the privacy and security rules set forth to protect patient health care data.

After a round of pilot audits in 2012, the OCR previously said it was planning to begin a permanent audit program in 2014. The audits are resource reliant and the OCR continues to request more staffing from Congress. There has been no announcement of a start date for the audits.

Business Associate Agreements Must Be Updated

The Department of Health and Human Services (HHS) published its new provisions of HIPAA regulation and final rule for business associate agreements. The final rule increased the privacy and security responsibilities for "business associates."

All agreements that were in compliance with the HIPAA privacy rule before January 25, 2013, were considered grandfathered until September 23, 2014. Therefore, all provider business associate agreements should be updated now.