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HEALTH LAW DISPATCH

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New State Law Authorizes Seven NJ Counties to Assess a New "Fee" on Hospitals

By Divya Srivastav-Seth, Esq.

The "County Option Hospital Fee Pilot Program," established on November 1, 2018 and effective on April 30, 2019 (P.L.2018, Chapter 136) ("Program"), authorizes the Commissioner of Health Services ("Commissioner") to permit the board of freeholders in seven qualified counties to assess a new fee on hospitals within their county borders. The main purpose of the Program is to generate new in-state funds and match them with federal funds, enabling New Jersey to obtain additional federal Medicaid dollars. The Program requires that 90% of the funds raised from the county's assessment be distributed back to the local hospitals to pay for services provided to its low income citizens.

Only counties with a population over 250,000 that have municipalities that can be classified as either First or Second-Class municipalities or Fourth Class municipalities with populations over 20,000 will be eligible for the Program. In addition, each eligible municipality must also have a Municipal Revitalization Index of 60 or more.

In order to qualify, a county must submit a detailed fee and expenditure report, after consulting with the hospitals affected by the possible fee, to the Commissioner for approval. The report must detail how the fee will be imposed and how the funds collected from the fee will be used, including the amount and services the participating county plans to provide with the funds. The affected hospitals will then have a 21-day opportunity for comment. If approved by the Commissioner, the county's board of chosen freeholders has the option to adopt an ordinance providing for the imposition of the fee along with any appropriate administrative sanctions, interest and penalties.

The county then may transfer the revenue raised to the Commissioner through an inter-governmental transfer. The Program specifically requires to Commissioner to use these funds and any matching amount of federal Medicaid funds to increase Medicaid payments to the hospitals in its jurisdiction and/or to make payments to Medicaid managed care organizations for increased hospital or hospital-related payments and for direct costs related to administrative purposes to implement the Program. Managed care organizations are prohibited from retaining any more of the fee than is necessary to offset their administrative costs, subject to any other restrictions under federal law. Subject hospitals are prohibited from passing through any costs of the fee to any third-party payer.

The county also may opt to keep the funds raised. In such event, it will be required to generate the same amounts, in addition to the funds collected from the imposition of the fee that would be generated by the Department of Health through any matching amount of federal Medicaid funds or other federal funds. The total funding amount must also be used to satisfy its Medicaid population.

The Program also directs the Commissioner to obtain whatever waivers from the federal government that may be necessary prior to authorizing the fee. State governments are permitted to assess a fee or tax on healthcare related items to fund the state's share of Medicaid expenditures without jeopardizing federal dollars as long as the tax is (i) broad-based (i.e., imposed on all providers within a class of providers); (ii) uniformly imposed (such that the same tax is applied to all providers within a specified class of providers); and (iii) does not hold the taxpayer harmless by providing (a) for a direct or indirect non-Medicaid payment to the taxpayer that positively correlates to either the tax amount or to the difference between the Medicaid payment and the tax amount; (b) that all or any portion of the Medicaid payment to the taxpayer varies based only on the tax amount, including where Medicaid payment is conditional on receipt of the tax amount; or (c) a guarantee that the revenue raised by the tax will be

returned either directly or indirectly to the taxpayer. See 42 C.F.R. § 433.68(f).

Federal law authorizes the Centers for Medicare and Medicaid Services to extend a waiver, if properly petitioned by the state, of the criteria requiring that the tax be broad-based or uniform. In order to waive either the broad-based or uniform requirement, a state needs to prove that the impact of the tax is generally redistributive and the tax is not directly correlated to Medicaid payments. The federal regulations do not afford a similar waiver of the hold-harmless clause. However, under federal law a violation of the indirect guarantee will not be found if the tax rate assessed generates revenues less than or equal to 6% (current threshold amount) of the net patient service revenues received by the taxpayer attributable to the assessed class of health care items. If the revenue raised is more than the threshold, a violation will occur if 75% or more of the taxpaying providers receive 75% or more of their total tax costs back through enhanced Medicaid rates or other state payments. See 42 C.F.R. § 433.68.

The Program does not identify the seven counties which would be eligible; however, the New Jersey Association of Counties has posited that Atlantic, Burlington, Camden, Gloucester, Essex, Hudson, Mercer, Middlesex, Monmouth and Passaic Counties will meet the eligibility criteria. See http://njac.org/state-house-news-24/. The Program is labelled as a pilot that will expire at the end of five years.

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New Anti-Kickback Law Expands Potential Liability for Some Providers

By Daniel O. Carroll, Esq.

Congress recently passed a new federal law intended to combat the opioid abuse epidemic. Included as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018 ("SUPPORT Act"), the Eliminating Kickbacks in Recovery Act of 2018 ("EKRA") was enacted on October 24, 2018 and is notably directed at services covered by either federal health care programs or private commercial insurers. EKRA is an all-payor statute that prohibits kickbacks related to the solicitation or receipt of remuneration for any referrals (i.e., not just those related to substance abuse treatment) to recovery homes, clinical treatment facilities or laboratories.

As an all-payor statute applicable to all services provided, the scope of potential liability for recovery homes, clinical treatment facilities and laboratories is greatly expanded. While EKRA includes several statutory exceptions, which are similar to those available under the federal Anti-Kickback Statute, EKRA's statutory language is not identical to that of the federal Anti-Kickback Statute safe harbors and therefore creates a gray area that may be interpreted and applied differently. For example, although EKRA does not preempt the federal Anti-Kickback Statute and does not apply to conduct already prohibited by the federal Anti-Kickback Statute, the new law does not reconcile its inconsistencies with the federal Anti-Kickback Statute with respect to conduct that is permissible under and protected by the federal Anti-Kickback Statute (whether by statutory exception or regulatory safe harbor) but is not permissible (at least facially) under EKRA. It is evident that in light of the foregoing, the application and scope of the new law's prohibitions and exceptions require clarification from federal regulators. Without such clarification or guidance from Congress or regulators, providers subject to EKRA cannot merely assume that compliance with the federal Anti-Kickback Statute safe harbors equates to compliance with EKRA.

Recovery homes, clinical treatment facilities or laboratories should review their current arrangements with others subject to EKRA in order to determine their exposure to potential liability and if appropriate or necessary amend those arrangements to ensure compliance. Schenck Price's Health Care Law Group is able to assist with such compliance reviews and any necessary amendments.

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HHS Issues Draft Strategy to Reduce EHR Burden

By Meghan V. Hoppe, Esq.

On November 28, 2018, the U.S. Department of Health and Human Services ("HHS") released a draft strategy designed to help reduce the burden on healthcare providers caused by the use of health information technology and electronic health records ("EHRs"). The draft strategy titled Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs was developed through a partnership between the Office of the National Coordinator for Health Information Technology ("ONC") and the Centers for Medicare & Medicaid Services ("CMS"), in order to fulfill the aims of the 21st Century Cures Act ("Cures Act"). Healthcare providers have identified regulatory and administrative burdens as a contributor to a number of challenges facing the healthcare system, including the high cost of compliance and physician burn-out. Through the Cures Act, Congress required HHS to articulate a plan of action to reduce these regulatory and administrative burdens associated with EHRs.

In a press release announcing the draft strategy, HHS Secretary Alex Azar underscored that "[w]ith the significant growth in EHRs comes frustration caused, in many cases, by regulatory and administrative requirements stacked on top of one another. Addressing the challenge of health IT burden and making EHRs useful for patients and providers, as the solutions in this draft report aim to do, will help pave the way for value-based transformation." Press Release, U.S. Dep't of Health and Human Serv., HHS Issues Draft Strategy to Reduce Health IT Burden (Nov. 28, 2018), available at above hyperlink.

Over the past year, ONC and CMS sought input from stakeholders in the healthcare industry through listening sessions and written feedback regarding current health IT systems and the requirements for documentation, reimbursement, and quality reporting. A number of stakeholders expressed concerns that these burdens negatively affect the end user, and ultimately the care delivery experience, and that the current process may discourage innovation around new measures.

Based on the input ONC and HHS received from stakeholder outreach and engagement, the draft strategy outlines three predominant goals designed to reduce clinician burden:

1. Reduce the effort and time required to record health information in EHRs for clinicians;
2. Reduce the effort and time required to meet regulatory reporting requirements for clinicians, hospitals, and healthcare organizations; and
3. Improve the functionality and intuitiveness (ease of use) of EHRs.

In a post to the Health IT Buzz blog, ONC Chief Clinical Officer Andrew Gettinger, M.D. and CMS Chief Medical Officer Kate Goodrich, M.D. discussed the basis for the strategy and urged the healthcare community to collaborate to reduce the burden of using EHRs. They reiterated that EHRs "have several advantages over paper-based records, from improving continuity of care during a natural disaster to enabling more reliable prescribing. While EHRs can also improve care delivery, quality, and outcomes, many clinicians have told us, and their members of Congress, that EHRs can make it difficult to provide effective patient care." Gettinger and Goodrich, Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs: Released for Public Comment, Health IT Buzz (Nov. 28, 2018), available at the above hyperlink.

The draft strategy is currently open for public comment through January 28, 2019, providing stakeholders in the healthcare industry an opportunity to influence the final strategy.

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OCR Penalizes Florida Provider for Failure to Maintain Business Associate Agreement

By Deborah A. Cmielewski, Esq.

A Florida-based medical provider has agreed to settle potential violations of the HIPAA Privacy and Security

Rules for sharing protected health information with a vendor without having a business associate agreement in place. Advanced Care Hospitalists PL ("ACH"), a covered entity that provides contracted physicians to hospitals and nursing homes in West Central Florida, has agreed to pay $500,000 and to enter into a substantial corrective action plan with the United States Department of Health and Human Services, Office for Civil Rights ("OCR") for disregarding this basic HIPAA requirement.

Between November 2011 and June 2012, ACH contracted with an individual who claimed to be a representative of Doctor's First Choice Billings, Inc. ("First Choice"), a medical billing services company located in Florida. Unbeknownst to First Choice, the individual posed as a company representative and rendered medical billing services to ACH using the First Choice name and website. In February of 2014, a hospital in Florida notified ACH that the names, birth dates and social security numbers of its patients were viewable on the First Choice website. ACH filed an initial breach report with OCR stating that 400 patients were affected; it later filed a supplemental report revealing that another 8,855 patients may have had their information compromised in the incident.

OCR undertook an extensive review, which revealed that no business associate agreement existed between ACH and the medical billing services representative and that ACH failed to maintain HIPAA policies and procedures or to conduct a risk analysis.

By way of corrective action plan, ACH has agreed to undertake significant remedial measures. First, it will identify its business associates, provide a description of the services that they render for ACH and the date that the parties' relationship commenced, and furnish copies of the relevant business associate agreements to OCR. It has agreed to conduct an accurate and thorough enterprise-wide risk analysis and develop a risk management plan and to furnish such items to OCR for review and approval. Moreover, it will develop policies and procedures to comply with the HIPAA Privacy, Security and Breach Notification Rules and submit them to OCR for scrutiny. ACH has also agreed to distribute the policies and procedures, once approved by OCR, to its workforce, to update such policies in conjunction with the OCR for a specified time period, and to train its workforce in accordance with training materials that pass OCR muster. ACH has also agreed to promptly investigate any potential violations of HIPAA by its workforce members and to provide OCR with a report of all actual violations.

The ACH settlement underscores the need for all entities subject to HIPAA to complete their annual compliance plan reviews as we head into the new year.

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RECENT HEALTH LAW LEGAL ALERTS

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