SAUL EWING ARNSTEIN & LEHR LLP

Alert

HEALTH CARE PRACTICE

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2019 HEALTH CARE PREDICTIONS

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INTRODUCTION

The Saul Ewing Arnstein & Lehr, LLP health care practice group includes attorneys that handle regulatory, compliance, transactional and litigation needs for clients across the entire health care delivery system, including: academic medical centers, hospitals, ambulatory surgery centers, private practices, licensed professionals, medical associations and boards, health care entrepreneurs and payors. Below are 2019 predictions for health care policy issues at the federal and state levels from some of our health practice group colleagues. Enjoy!

A Big Picture Perspective

Bruce Armon

As always, health care will be a central feature of policy discussions at the federal and state levels. The ongoing realignment of hospitals, payors and providers (physicians and pharmacies) internally and with one another will create opportunities and challenges. Private equity and venture capital firms seeking investment opportunities across the health care delivery system will continue. If unemployment levels remain "low", there will be fewer Medicaid beneficiaries resulting in fewer covered lives for Medicaid payors, however, the remaining beneficiaries may have more acute health care needs requiring extensive and expensive medical assistance. Medical practice consolidations intended to reduce administrative costs and to increase leverage in negotiating more favorable terms with commercial payors will also likely persist. Fraud and abuse settlements are also likely to continue, and every million dollar plus settlement reached will be a reminder to all to revisit, revamp and remind staff of the importance of maintaining robust compliance plans. Relatedly, the increasing number and severity of data breaches across all industry sectors – including health care – and the competing state laws may prompt Congress to propose a national data protection legislation. Debates on the merits of the Affordable Care Act will also be ongoing – though it is unclear whether any substantive changes will occur. HHS's and CMS's willingness to embrace alternative payment models by considering changes to the Stark Law and Anti-Kickback statute, as well as modifications to the HIPAA Privacy Rule, is also likely. Increasing access to quality health care will continue to promote telemedicine and telehealth into the mainstream and more payors will begin to reimburse providers utilizing such technology. Artificial intelligence efforts will attract private investment and innovation by large academic medical centers and entrepreneurs. Lastly, large employers will continue to seek ways to ensure comprehensive and affordable health care for their employees which may further disrupt traditional payor-provider systems of care.

Antitrust

Michael Finio

Health care markets will not escape the overall changing sands in the FTC's and DOJ's approaches to antitrust enforcement, or the subtle, but significant, shifts in remedial preferences and adjustments in competition policy being espoused by these agencies. The following trends are developing and will continue to influence competition issues in the health care arena in 2019:

1. There is likely to be an increase in enforcement agency scrutiny of information exchanges between competitors, no matter the forum in which the exchanges occur or what methods are used for the collection, analysis or distribution of such information. Specifically, the agencies are looking for the anticompetitive effects of such exchanges and have advised that competitors should not exchange current and future price information, strategic plans, cost information, information about future product offerings, expansion plans and customer-specific information. As health care providers continue to innovate through the use of group purchasing organizations and other forms of collaboration and affiliation, the agencies have warned that they are reviewing the use of cutting-edge technologies, data analytics, algorithms, etc., and that their traditional focus remains: do the exchanges promote efficiencies and competition, or do they facilitate collusion or other concerted action? By way of analogy, last year, broadcasters were sharing "pacing information" – which compares a station's revenues for a certain time period to the same time period in the prior year – which allowed them to determine whether their competition was likely to move spot advertising prices, enabling a competitor to be better positioned to negotiate with advertisers, and thus upsetting the normal competitive process. (see https://www.justice.gov/opa/pr/justice-department-requires-six-broadcast-television-companies-terminate-and-refrain-unlawful). While there was no financial aspect to the settlement, it has a seven-year term and provides the DOJ with significant involvement and oversight with each defendant's ongoing operations –
a not insignificant new expense in terms of internal company resources devoted to the monitoring effort.

2. The Hart-Scott-Rodino ("*HSR*") minimum deal threshold has no bearing on whether a transaction merits competition scrutiny – deals below the threshold are being challenged both before and after they close. In one ongoing case, agency investigation was prompted by a large customer's complaint about a transaction involving microprocessor-equipped artificial knees.

3. Merging parties remain exposed to antitrust liability after a deal closes even if HSR approval is obtained. The most notorious of such cases in 2018 was the Parker Hannifin–CLARCOR merger – a $4.3 billion dollar transaction in which the HSR waiting period expired with no agency action, leaving the parties free to close. Nonetheless, post-closing, the DOJ sued with respect to a very small piece of the deal involving "aviation filtration products" and ultimately, Parker Hannifin settled by agreeing to divest that piece of the deal.

4. Challenges to vertical mergers are on shaky ground as a result of the DOJ's loss in the AT&T–Time Warner merger challenge in the USDC for the District of Columbia. This is the first merger loss for the DOJ in almost 15 years, and while it is currently on appeal, the loss prompted DOJ to drop investigations of the CVS-Aetna and CIGNA-ExpressScripts mergers. At the same time, the DOJ, in the Bayer-Monsanto merger, focused on and obtained "structural remedies" – which the agency's Antitrust Division Chief has clearly said DOJ favors over "behavioral remedies." On the other hand, the FTC seems still willing to work with behavioral remedies. If the agencies have an enforcement and remedy duel on the horizon, it will certainly affect vertical merger practice, and the approach taken by counsel will be different depending on which agency is reviewing the deal. Vertical mergers are fairly common in health care markets and behavioral remedies in the health care arena would add compliance burdens to an already complicated compliance environment. Structural remedies, more cut and dry, would seem more desirable. Therefore, merging parties will need to be acutely aware of where the agency conducting a merger investigation stands with respect to structural (e.g., divestitures) vs. behavioral (e.g., internal firewalls) remedies, and be prepared to adjust strategies necessary to get a deal approved when issues are raised.

Cybersecurity and HIPAA Predictions

Karilynn Bayus

Cybersecurity for health care providers, payors and vendors is increasingly complex and the cyber threat landscape continues to evolve. Entities in the health care delivery system are especially challenged by complex networks of connected devices, large volumes of sensitive data, numerous individuals (employees and vendors) with network access, and mobile devices, among other things. Unfortunately, the persistence of threats is unlikely to change in 2019 and cybersecurity should remain a top priority.

In 2018, ransomware attacks continued to plague health care providers and their vendors. In addition to financial and reputational harm, ransomware attacks have the ability to directly impact a health care provider's ability to deliver vital health care services to its patients. The beginning of a new year is a good time for health care entities and vendors to review existing cybersecurity controls (physical, administrative and technical), HIPAA risk assessments and incident response plans. Businesses who are just beginning a cybersecurity program or are updating their existing program are encouraged to review guidance released by the U.S. Department of Health and Human Services ("*HHS*") at the end of 2018 -- Health Industry Cybersecurity Practices: Managing Threats and Protecting Patients.

Relatedly, health care providers and their business associates can expect continued enforcement of HIPAA by the Office for Civil Rights ("*OCR*"). In 2018, the OCR recorded its largest-ever settlement of $16 million and completed the year with three settlements in just over a 30-day period.

2019 may also bring proposed changes to the HIPAA regulations. In December of 2018, HHS issued a Request for Information on ways to modify HIPAA to facilitate care coordination and promote transformation to value-based care. Interested parties have until February 12, 2019 to submit comments and SEA&L attorneys are available to assist you in preparing comments if you would like. Additionally, SEA&L will monitor what, if any, changes to HIPAA HHS proposes based on the responses it receives.

How Change to the National Practitioner Data Bank Could Affect You in 2019

Karen Harris

In 2018, the National Practitioner Databank ("*NPDB*") updated the NPDB Guidebook, a manual that provides guidance on the requirements established by the laws governing the NPDB. Although most of the 2018 revisions reflect minor changes, there are a number of new sections and clarifications that could affect health care providers in 2019 if they are not aware of these changes.

Established in 1986, the NPDB is a repository for reports of medical malpractice payments and certain adverse actions related to health care practitioners, providers and suppliers.

The NPDB assures disclosure of adverse information about physicians, dentists and other healthcare practitioners. It is a central repository which assures that hospitals, health plans and licensing boards are aware of adverse actions such as medical malpractice payments, adverse licensure, clinical privileges and professional society membership actions related to professional competence and conduct, as well as Drug Enforcement Administration certification actions and exclusions from participation in Medicare, Medicaid and other federal healthcare programs, against physicians. To assure the NPDB is complete, hospitals, health care entities with peer review committees, health

plans, and others are required to report certain adverse actions to NPDB. Reporting to the NPDB (or failing to report) has serious consequences to both mandatory report entities and practitioners that are reported. Entities that report improperly may face lawsuits from reported practitioners and reported practitioners who appear on the NPDB may have lasting career and reputational effects.

The updates to the NPDB Guidebook clarified that a voluntary agreement not to exercise privileges during an investigation is now considered a reportable restriction/resignation of privileges. Similarly, the updates made clear that, in the case of an impaired physician, while waiting for a board/regulatory authority to take an adverse action and then entering into a treatment or rehabilitation program is a reportable event, if the physician voluntarily enters a treatment or rehabilitation program and agrees with such program not to practice, this is not a reportable event. A thorough discussion of these and the other updates to the NPDB Guidebook is available in our recent Alert.

In sum, since a report to the NPDB can have a significant negative impact on a healthcare provider's reputation and career, before resolving an investigation, surrendering privileges, withdrawing a renewal application, or settling a malpractice claim, a practitioner should consult knowledgeable health care counsel for guidance on how to minimize the potential damage. Similarly, failure to report or inaccurately reporting by those required to report can result in penalties and, perhaps more importantly, revocation of a reporting entity's reporting immunity for three years. As a result, individuals and entities involved in reporting to the NPDB should also become familiar with new reporting requirements and policy guidance found in the 2019 NPDB Guidebook to help understand when a report is required and seek guidance from health care legal counsel.

The Evolution of Physician "Super Groups"

Marshall Paul

In 2019, industry observers will assess whether the wave of medical group roll-ups has crested from the pace of several years ago. At this time, there doesn't appear to be enough "inventory" of quality small practice targets left for acquisition in many specialty areas.

On the other hand, 2019 may be a year in which there is an increasing number of combinations of larger groups, particularly if the private equity backers of those groups are looking to implement their exit strategies. This, of course, may mean that 2019 is also a year of greater Federal Trade Commission scrutiny when it comes to medical group combinations.

Many physicians whose practices have been absorbed by large groups in recent years may be unsatisfied or restless with their new professional relationships. It is possible that, in situations where the physicians' contracts give them the ability to withdraw without being subject to enforceable restrictions, more and more physicians may begin to look for greener professional pastures. The ability to find "greener pastures," however, may prove difficult, if there are not viable options. There are some hospitals in communities that continue to seek to acquire physicians from select specialties. It is likely a much more difficult proposition to encourage a physician to separate from a larger practice and start his/her own practice in a community. Physicians looking for a change of scenery will need to carefully review options in their community and consider short and long-term challenges and opportunities.

Cannabis: Continuing to Grow

Jonathan Havens

It seems that nearly every day brings an announcement of yet another state establishing or expanding its cannabis program. At last count, medical cannabis is authorized in 33 states and the District of Columbia ("D.C."). Ten of these states – Alaska, California, Colorado, Maine, Massachusetts, Michigan, Nevada, Oregon, Vermont and Washington – and D.C. have also authorized adult (i.e., recreational) use of cannabis. Recently, the governors of New York and Rhode Island announced plans to roll out adult-use cannabis programs in their respective states.

Lest anyone think that cannabis programs are only in the coastal states, or those in the northeast or northwest; traditionally conservative states are also getting in on the action. Oklahoma and Utah, for instance, recently established medical programs. Thus, anyone who assumes that only "blue" states support cannabis programs does so at their own peril. In fact, an October 2018 Gallup poll revealed that 66 percent of Americans – or 75 percent of Democrats and 53 percent of Republicans – support legalizing cannabis. Those numbers are even higher when respondents are asked about support for medical cannabis, specifically, with some estimates reaching as high as 89 percent of Americans.

One interesting development among some state medical cannabis programs is the attempt to shift patients from opioids to medical cannabis. Several states, including Illinois, Pennsylvania, New Jersey and New Mexico, have already made or plan to make opioid addiction a qualifying condition to obtain medical cannabis, and a number of other states (e.g., Maryland and Ohio) are considering following suit. When Pennsylvania added opioid addiction to its list of medical cannabis qualifying conditions, becoming the first state to do so, Secretary of Health Dr. Rachel Levine said that "[b]y adding opioid-use disorder as an approved medical condition under the program, we not only give physicians another tool for treatment of this devastating disease, but we allow for research to be conducted on medical marijuana's effectiveness in treatment." As other states continue to think of creative ways to battle the opioid epidemic, more may pursue approaches similar to the ones discussed above.

In addition to watching state cannabis program expansion this year, including with regard to the addition of qualifying conditions, we are also monitoring closely explosive growth in the hemp and hemp-derived products spaces. Such growth was spurred in large part by the enactment of the Agriculture Improvement Act of 2018 (the "Farm Bill") in late December of last year. As explained in our recent blog post, the Farm Bill removed hemp from the definition of "marihuana" (marijuana) in the Controlled Substances Act ("CSA"), thus removing it from Schedule I. One of the biggest misconceptions regarding the Farm Bill is that now that hemp is "legal," people can do whatever they want with it and its derivatives. This is incorrect. While national and international hemp markets will open as a result of the Farm Bill, there continue to be restrictions on what can be done with hemp and hemp derivatives (e.g., hemp-derived cannabidiol ("CBD")). This is especially true when it comes to the addition of CBD or delta-9 tetrahydrocannabinol ("THC") to products regulated by the U.S. Food and Drug Administration ("FDA") (e.g., foods, dietary supplements, and cosmetics). Specifically, since the Farm Bill did not change the FDA's authority to regulate products containing cannabis or cannabis-derived compounds under the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), FDA continues to take the positions that: (1) it is a prohibited act under Section 301(ll) of the FD&C Act to introduce into interstate commerce a food to which CBD or THC has been added; and (2) THC and CBD products are excluded from the dietary supplement definition under sections 201(ff)(3)(B)(i) and (ii) of the FD&C Act. FDA's position is based on the fact that CBD and THC are active ingredients in FDA-approved drugs and were the subject of substantial clinical investigations before they were marketed as foods or dietary supplements. In June 2018, FDA approved, for the first time, a cannabis-derived drug, Epidiolex, for the treatment of seizures associated with two rare and severe forms of epilepsy. In his statement in response to the passage of the Farm Bill, FDA Commissioner Scott Gottlieb, M.D.,

left open the possibility that the FDA could pivot (i.e., issue a regulation allowing the use of CBD in a food or dietary supplement). However, he indicated that FDA would only consider doing so if it is able to determine that all other requirements in the FD&C Act are met, including those required for food additives or new dietary ingredients. FDA intends to hold a public meeting in the near future for stakeholders to share their experiences and challenges with products in this space and we will continue to closely monitor developments regarding hemp's new legal status.

We encourage those interested in staying abreast of the developments in the cannabis law space to subscribe to our Regulatory Roundup blog, sign up for our Cannabis Law e-mail list, and connect with our practice group leadership on LinkedIn and Twitter.

State Government Predictions

Joe Ourth

Shifts in Political Balances of Power. The "Blue Wave" of the 2018 mid-term elections not only had ramifications for the federal government, but also affected the balance of power in many state capitols. These shifts will have policy implications for health care providers. For example, Illinois went from a divided government to one where the Governor, all statewide office holders and a "super majority" in the House and Senate are Democrats. This shift will particularly affect labor issues, where the new administrations have prioritized a $15 hour minimum wage. Tort reform changes, including malpractice liability changes, which were blocked under Illinois' previously divided government, are more likely to occur now that it is under one-party control.

Many in the human services provider community are hopeful that funding will increase, both to expand services and to potentially increase provider rates. In order to fund such program expansion and new programs, Illinois' new Governor has proposed two major revenue enhancements—legalization of recreational cannabis and a graduated income tax to replace a flat income tax. The potential legalization of recreational cannabis has already generated significant interest as potential investors and cannabis providers vie to position. SEA&L attorneys will be closing monitoring the legislative process and provide updates as this legislative session unfolds.

Illinois Hospital Transformation Program. For the first time many years, the Illinois General Assembly, with considerable input from the Illinois Hospital Association, rewrote the Hospital Assessment Program ("*HAP*"). Similar to many other states, Illinois has a program that essentially taxes hospitals to generate federal matching funds under the Medicaid program and then, using a complex formula, allocates the funds back to hospitals. A significant portion of HAP funding was used to assist struggling hospitals, often ones considered "safety net hospitals". One significant change in the new HAP program is the creation of a $262 million Hospital Transformation fund. This fund is designed to incentivize hospitals that may not be financially sustainable to transform their operations. For example, the program envisions that some hospitals will convert from a general medical surgical operation to one that concentrates on mental illness or substance abuse, or instead will convert to a Freestanding Emergency Center. Many hospitals will qualify for some transformation funding, however, since the rules and regulations have not yet been written, there are still some unknowns. Nonetheless, we anticipate that a number of hospitals will consider and pursue projects that will qualify for this transformation funding and SEA&L attorneys will be working closely with their clients on these endeavors.

Tax Predictions

Richard Fraizer

There are several tax issues that are likely to affect the healthcare industry:

First, for tax-exempt entities, the IRS will refine its guidance/regulations regarding unrelated business income tax ("*UBIT*") to reflect the changes enacted at the end of 2017, including the definition of what constitutes a separate business and whether like-businesses can be aggregated. Larger healthcare tax-exempt entities will also face the prospect of a tax on compensation in excess of $1 million, as well as excess parachute payments and the distinction between administrative duties and medical services.

In the taxable sector of the industry, the conversion of pass-through entities to "C" corporations, the 20 percent deduction for pass-through entities, and the limitation on the ability to deduct interest will confound both big and small players. Of particular note will be determining what is the service of providing healthcare, which is key to the availability/non-availability of the 20 percent deduction for pass-through entities.

Both tax-exempt employers and taxable employers will be affected by the changes to the rules applicable to parking and other fringe benefits, with some employees losing their benefits entirely, and some employers facing hard decisions about whether to change their operating policies in order to preserve tax benefits for some, but not for others.

Finally, states will continue to tighten the rules for tax-exempt healthcare entities to qualify for real estate tax exemptions, as well as other state and local taxes.

Taxes never go completely away, but they do evolve, and SEA&L's Healthcare Practice Group will continue to provide tax guidance to help navigate these changes.

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