

FEBRUARY 2018

2018 Health Law Predictions

SUMMARY

2017 was a year in contrasts for the health care delivery system. Congress and President Trump made several attempts to “repeal and replace” the Affordable Care Act. Controversy about marijuana continued as more states consider legalization of either medical or recreational marijuana programs. Mergers large and small were in the news as the providers scramble to find their niche in the health care delivery system. Medicaid continued to experience duress as states’ balanced budget requirements forced governors and state legislators to create alternative means of delivering care.

So what will 2018 bring for the health care delivery system and how will changes made in 2017 affect payors, providers, employers and government? Several members of our Firm’s health law group (<https://tinyurl.com/yd6pyack>) pulled out their crystal balls and offer the following predictions for how select issues will be “in the news” in 2018 (and probably beyond).

THE INDIVIDUAL MANDATE

The 2017 tax reform legislation, colloquially referred to as the Tax Cut and Jobs Act (the Act), includes a number of provisions that will affect health care organizations, both tax-exempt and for-profit, directly and indirectly. Potentially the most significant change for health care institutions is that the Act essentially repealed the Affordable Care Act’s (ACA’s) requirement that all individuals be covered by health insurance (the “individual mandate”) by eliminating the tax on individuals for failing to obtain minimum essential health care insurance coverage.

There is a belief that by repealing the individual mandate healthier people will be less likely to voluntarily obtain insurance, thereby either increasing premiums for those who do elect coverage through the ACA marketplace and/or increasing the number of the uninsured. In October 2017, President Trump issued an Executive Order directing the Department of Labor (DOL) to study how to make it easier for small businesses, and possibly individuals, to join together and buy health insurance through nationwide association health plans which could counterbalance any such effects. On January 5, 2018, the DOL published proposed rules to implement this Executive Order.

Although the majority of Americans obtain their insurance through their employer or a federal government program (e.g., Medicare or Medicaid), changes in the individual insurance marketplace always attract a significant amount of media attention and have a profound impact on the individuals who are affected as well as the broader health care debate.

AUTHORS

BRUCE D. ARMON
KARILYNN BAYUS
SUSAN L. BARRETT
MICHAEL A. FINIO
KAREN HARRIS
JONATHAN A. HAVENS

MARIJUANA

On January 4, 2018, Attorney General Jeff Sessions issued a memorandum (<http://bit.ly/2m04Ez1>) to all U.S. Attorneys in which the Attorney General rescinded, effective immediately, several previous DOJ guidance documents related to marijuana enforcement, the most notable of which was the 2013 Cole Memorandum (Cole Memo). The Cole Memo directed U.S. Attorneys to utilize their resources prudently, and to use discretion before prosecuting those using medical marijuana in compliance with their states' laws.

While the exact impact of Attorney General Sessions' decision to roll back the Cole Memo and other President Obama-era marijuana policies is unclear, it could mean increased federal enforcement in states that have legalized marijuana use. Despite marijuana's federally-illegal status, more than 50 percent of states have adopted medical marijuana laws, and eight of those states and the District of Columbia have also enacted recreational or "adult use" statutes.

In 2018, Connecticut, Delaware, Michigan, New Jersey, Ohio, and Rhode Island could consider recreational marijuana legalization, while Kentucky, Missouri, Oklahoma, South Dakota and Utah might decide whether to legalize medical marijuana. Soon after Sessions' announcement, Vermont Governor Phil Scott signed into law a recreational marijuana legalization bill, and the New Hampshire House of Representatives approved a similar measure, which may be considered by the State Senate.

Public opinion – 2018 is an election year – may play an important role in the marijuana debate. Last October, Gallup reported (<http://bit.ly/2h8RwWX>) that 64 percent of Americans were in favor of marijuana legalization, the highest level of support recorded in nearly 50 years.

HEALTH CARE AND ANTITRUST

For the last several years, the Federal Trade Commission (FTC) and the DOJ – along with state attorneys general (SAGS) – have been vigorously reviewing virtually every hospital merger, even those mergers that fall below the Hart-Scott-Rodino filing thresholds. There are no indications that the intensive level of scrutiny and

cooperation between the FTC, DOJ and SAGS will diminish any time soon. Merging hospital/provider enterprises should continue to plan for the additional time and expense that governmental scrutiny and cooperation brings to bear on their plans and target closing dates.

In addition, and seemingly at odds with the Trump Administration's general deregulatory bent, is the fact that it is going the *opposite* direction when it comes to antitrust enforcement. There appears to be increased attention upon "conglomerate/vertical mergers." Where, for example, the Obama Administration let the Amazon-Whole Foods deal and the Comcast-NBC deal "sail through," based, more or less, on the historical antitrust premise that the parties simply were not competitors, the Trump Administration has shown an *immediate* willingness to try to stop these kinds of mergers. DOJ has sued to block the AT&T - Time Warner merger, there's been a call to reopen scrutiny of the Comcast-NBC deal, and those are deals that would have been *untouched* over the last many decades of antitrust review.

How is this relevant in the health care world? See the proposed CVS – Aetna merger. This is a classic vertical merger.

As the provider – payor lines blur, there is a premise of reduced competition, and that could mean higher prices and consumer harm to a regulator. All involved in health care industry mergers, acquisitions, affiliations and other consolidations should keep at least one eye clearly focused on what the FTC, DOJ and SAGS are doing, because current activities are dynamic and somewhat unpredictable, except to say: there will be antitrust review.

STATE PREDICTIONS

As Congress and President Trump continue to debate, discuss and disagree with respect to any changes to the ACA, keep an eye out for state governments to continue to be the "laboratories of democracy" and consider their own grand plans and/or initiatives in enacting state-specific health care reforms in 2018.

2018 state legislative initiatives may include: telehealth/telemedicine changes; modified or expanded

scope of practice and responsibilities for health care professionals; increased pricing/cost of health care services transparency; state-specific mandates; Medicaid reform; and, health insurance reform generally. As providers continue to seek opportunities to grow “bigger” state regulators (see the antitrust discussion above) will play an important role. The opioid crisis continues to affect families without regard to geography (rural, urban and suburban) and without regard to gender or race and public health officials will continue to seek solutions for this public health emergency. Employers (private and public sector) will continue to look for means to control their costs of offering health insurance to employees and these efforts may trigger legislative interest and or oversight from state insurance regulators (e.g., limiting co-pays and deductibles and carefully considering payor rate increase requests).

Many times state initiatives do not get the benefit or burden of media attention (compared to their federal counterparts) and therefore all participants in a state’s health care delivery system – whether as a provider, payor, entrepreneur, vendor – need to pay close attention to state reforms in 2018.

CYBERSECURITY AND OCR AND HIPAA GENERALLY

The health care industry was dogged by cybersecurity incidents in 2017. The WannaCry ransomware caused 16 hospitals across the United Kingdom to shut down and affected other health care providers in the United States. According to an article (<http://bit.ly/2pC5Q0A>) by HealthITSecurity, nine of the ten largest breaches reported to the U.S. Department of Health and Human Services, Office for Civil Rights (OCR), in 2017 were caused by hacking or IT incidents.

These cybersecurity incidents are unlikely to stop and will persistently change in form and sophistication. An HHS report (<http://bit.ly/2H9anMQ>) released in 2017 cited cybersecurity as a “key public health concern” requiring “immediate and aggressive attention.” Given how heavily reliant health care providers are on technology and the amount of protected health information (PHI) accessed, stored, transmitted and downloaded by devices, cybersecurity preparedness, including a strong HIPAA Security Rule compliance program is critical.

Expect the OCR to carefully examine covered entities’ culture of HIPAA Security Rule compliance. The OCR has increasingly focused on Security Rule compliance and has repeatedly emphasized the importance of conducting thorough risk analyses and implementing a corresponding security management program. The OCR shows no signs of relaxing its position on Security Rule compliance; already in 2018 the OCR has announced a \$3.5 million settlement relating to Security Rule non-compliance (<http://bit.ly/2BT4MdZ>).

The start of a new year is an optimal time to re-evaluate existing cybersecurity programs, including HIPAA Security Rule plans. Covered entities and business associates should take advantage of guidance material (<http://bit.ly/2uJAcjr>) issued by the OCR on cybersecurity.

EXPANDING TELEHEALTH FOR CHRONIC CARE

Telehealth initiatives continue to expand, but still are under-represented in the health care delivery system. Supporters of expanding telehealth services keep their fingers crossed as the Creating High-Quality Results and Outcomes Necessary to Improve Chronic (CHRONIC) Care Act of 2017 moves from the Senate (where it was approved unanimously) to the House. The CHRONIC Care Act of 2017 aims to reduce Medicare costs by expanding telemedicine for those in need of chronic care. This proposed bill would:

- Extend for two years the Centers for Medicare & Medicaid Services’ Independence at Home demonstration, which establishes home care teams for Medicare participants with chronic conditions;
- Make the Medicare Advantage (MA) Special Needs Program permanent and expand MA plans to cover telehealth services beyond the current restrictions (build these services into the base premium bids);
- Allow patients on home dialysis to receive monthly clinical assessments using telehealth at home or a dialysis center, without geographic restriction;
- Expand telehealth for patients with stroke symptoms by eliminating the geographic restrictions; and
- Increase the geographic location for services delivered by Accountable Care Organizations.

Telehealth initiatives must address state licensure and ensure payment (by government and private payors) for services provided.

2018 NEXT STEPS

Health care expenditures remain a significant portion of the nation's economy and health care providers and payors are the largest employers in many communities. Federal and state policymakers will continue to affect

the health care delivery system and employers and health care entrepreneurs will continue to explore initiatives to improve the health care delivery system.

For more information about the Firm's Health Law Practice, please contact the authors or the Saul Ewing Arnstein & Lehr attorney with whom you are regularly in contact.

This Alert was written by Bruce D. Armon, Chair of the firm's Health Care Practice and Managing Partner of the Philadelphia office, Karilynn Bayus, Vice Chair of the firm's Health Care Practice, Susan L. Barrett, Michael A. Finio, Karen Harris and Jonathan A. Havens, members of the firm's Health Care Practice. Bruce can be reached at 215.972.7985 or bruce.armon@saul.com. Karilynn can be reached at 215.972.1892 or karilynn.bayus@saul.com. Susan can be reached at 412.209.2513 or susan.barrett@saul.com. Michael can be reached at 717.238.7671 or mike.finio@saul.com. Karen can be reached at 312.876.6675 or karen.k.harris@saul.com. Jonathan can be reached at 410.332.8757 or jonathan.havens@saul.com. This publication has been prepared by the Health Care Practice for information purposes only.

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