

Morgan Lewis

FAST BREAK: **2021 YEAR IN REVIEW**

December 16, 2021



2021 Wrap Up

- This year saw continued change, both as to the pandemic and in other more traditional areas of health law:
 - Evolution of the AKS and the Sprint to Coordinated Care
 - HIPAA enforcement and policy directives
 - Digital health, telehealth, and virtual healthcare technology growth
 - Continued consolidation in healthcare marketplace
 - PRF, PHE flexibilities, and vaccine mandates



Regulatory Sprint to Coordinated Care

After several years of considering potential rules, OIG and CMS released joint rules effective January 2021 to modernize healthcare fraud laws

- **New Stark law exceptions and AKS safe harbors**
- **In-depth treatment of “value-based entities”**
- **Embracing shift from “volume to value”**

Adoption and use of new rules not yet widespread, perhaps due to Covid PHE

AKS Legal Decisions and Guidance

- Several important pronouncements in AKS enforcement over the past year:
 - *Blue Wave* case in the 4th Circuit, holding that commission-based compensation to independent sales contractors violated the AKS
 - Does this require employment of sales agents to rely on the employment safe harbor?
 - Special Fraud Alert on Speaker Programs (*ok, this was November 2020...*)
 - OIG called out drug and device company speaker programs, stating that it was “skeptical about the educational value of such programs.”
 - PhRMA updated its Code to prohibit providing or paying for alcohol in connection with speaker programs.

MD Anderson HIPAA Enforcement

- Nearly a decade ago, an MD Anderson employee had a laptop stolen and another lost a USB drive.
- After disclosing the matter to HHS OCR, MD Anderson was hit with a \$4.3 million fine based on these potential data breaches and generalized “encryption” violations
- Through multiple levels of administrative and judicial review, MD Anderson eventually prevailed at the 5th Circuit, which held that the penalty violated the APA
- Impact on future OCR enforcement actions?

Use of FCA in Civil Cyber-Fraud Initiative

In October 2021, DOJ announced a new Civil Cyber-Fraud Initiative



DOJ intends to use the FCA to pursue cybersecurity related fraud and failures to disclose when involving government contractors and grant recipients.



While the Initiative is aimed more broadly at all government contractors who run into cybersecurity issues, healthcare providers, research institutes, and technology companies will face greater scrutiny and potentially significant exposure under the Initiative



Highlights the growing importance of digital security in our healthcare system

Digital Health Regulation at the FDA

- In September 2020, FDA established the Digital Health Center of Excellence, which focuses on developing and reviewing digital health technologies such as mobile health devices, wearables, and Software as a Medical Device (SaMD)
- Also in September 2020 and updated in May 2021, FDA launched the Digital Health Software Precertification Program
 - Designed to enable streamlined and efficient regulatory oversight of digital technologies from companies that demonstrate commitment to quality and ongoing monitoring
 - Intended to look less at the digital health technology or service and more at the company developing and offering the technology
- FDA still grappling with how to handle AI-driven technology and machine learning, which are difficult to regulate under FDA's existing structure

2021 Telehealth Issues

Face-to-face

What does that mean? Can virtual services be provided face-to-face?

Expansion to Other Fields

Telemental health clear winner here based on CAA provision; will primary care, dermatology, or other specialties follow?

Recognizing the PHE

Ongoing impact of COVID-19 results in extension of telehealth flexibilities until the end of 2023

Reimbursement

Although the PHE enabled greater reimbursement for telehealth, largely temporary

Licensure

Difficulties in cross-state licensing continue to make telehealth difficult to scale

Audio-only

What are CMS (and state) limitations on audio-only coverage?

What's Next for RPM/RTM

1

Remote Patient Monitoring

- Technology has existed for long time (i.e., cardiac telemetry)
- Covered by private payors, Medicaid, and in some cases Medicare

2

Remote Physiologic Monitoring

- Developed by AMA and implemented by CMS in 2019 rulemaking
- Intended to be flexible but evolving and certain barriers

3

Remote Therapeutic Monitoring

- Introduced and implemented in 2021 as RPM 2.0 with a focus on therapy services (physical therapy in particular)
- Greater flexibility in data collection and nature of data

4

RPM and RTM Future

- Additional rulemaking likely
- Revision to “practice expense” methodology for CMS

Healthcare M&A and Consolidation

- Healthcare marketplace remains in flux
 - Changing reimbursement schemes, pandemic difficulties, and evolution of practitioner workforce have impacted the market for healthcare businesses
- Significant vertical consolidation of practitioner groups and health systems in attempts to create greater value propositions and alignment in care continuum, including with private insurer buyers
- Regional consolidation of healthcare businesses including in post-acute care space as a result of more favorable reimbursement schemes
- Digital health start-ups earning significant investment in private equity markets as organizations look to the future

COVID-19 PHE Flexibilities

While many anticipated that 2021 would bring the end of the COVID-19 pandemic and, with that, the end of the PHE, that has not been the case

- Those flexibilities that providers have come to rely on remain in place until the PHE officially sunsets
- CMS has provided a wide berth for flexibilities in the telehealth space, keeping those around until the end of 2023
- Other flexibilities on the state and federal side are sunseting sooner, but remain viable for the short term
 - However, certain states have largely gone back to pre-COVID regulatory processes related to recognition of licenses, telehealth, and processing fees.

PHE Provider Relief Funds

Provider Relief Funds were critical for balancing the books of many healthcare organizations at the start of the COVID-19 PHE.



After many delays, reporting for PRF funds began in earnest in Q4 2021.

In addition, Congress is continuing to release additional rounds of PRF funding for impacted providers that apply.

Several fraud cases for misappropriation of PRF funds have been announced in 2021, including cases against home health agency owners, clinics, and other individuals that received PRF funds and either should not have received them at all or did not use them properly

Expect additional auditing of PRF funds once initial reporting is complete.

COVID-19 Mandatory Vaccination Policies at Healthcare Providers

Courts and governmental agencies have struggled over employer-directed and government-required vaccine mandates

- Earlier this year, states permitted private and state healthcare organizations to insist on COVID-19 vaccinations as a prerequisite to employment for healthcare workers
- In November 2021, CMS released a mandatory vaccination rule, requiring that certain healthcare facilities that are surveyed by CMS require their “staff” to receive a vaccine as a condition of continued employment – no testing option was available
 - Subject of intense litigation, including recent 5th Circuit decision partially upholding mandate for non-litigant states but allowing litigant states to forgo the mandate

Join us next month!

Please join us for next month's webinar:

Fast Break: Civil Cyber-Fraud Initiative

Featuring

Mark Krotoski and Katie McDermott

➤ Thursday, January 27, 2022 3:00 PM (EST)

Thanks and Be Well!



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Jake advises stakeholders across the healthcare industry, including hospitals, health systems, large physician group practices, practice management companies, hospices, chain pharmacies, manufacturers, and private equity clients, on an array of healthcare regulatory, transactional, and litigation matters. His practice focuses on compliance, fraud and abuse, and reimbursement matters, self-disclosures to and negotiations with OIG and CMS, internal investigations, provider mergers and acquisitions, and appeals before the PRRB, OMHA, and the Medicare Appeals Council.