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FAST BREAK: A YEAR IN REVIEW

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What Did We See in 2020?

1. *Allina*
2. The COVID-19 PHE
3. The Rise of Telehealth and Digital Health Technologies
4. Federal and State Privacy Issues
5. DOJ Focus on Healthcare Fraud and Updated Compliance Guidance
6. CMS and OIG Final Rules on Value-Based Arrangements

Allina

2019 Supreme Court case interpreting the Medicare Act

- The Supreme court relied upon the plain language of the Medicare Act itself, which requires CMS to provide advance notice and a chance to comment on any "rule, requirement, or other statement of policy" that "establishes or changes a substantive legal standard governing . . . the payment for services." 42 U.S.C. §1395hh(a)(2).

- The question is one of what is a "substantive legal standard?"

- Statements of policy expressly *not* substantive under APA; yet Medicare Act includes "statements of policy" in the rulemaking mix

Allina

October 31, 2019 Cleary Memo

- Acknowledges that "Congress has imposed more stringent procedural requirements for certain Medicare rules that would otherwise apply under the APA"
- Indicated that "Some of the payment rules [the agency] develops often form the basis for *enforcement actions*"
  - "Enforcement actions *may* include overpayment collections based on audits, but generally do not included routine claims and cost report procedures." (emphasis added).
- If CMS intends to use particular guidance "in enforcement actions then the guidance must comply with *Allina*."

- More defenses available to providers in overpayment determinations
- Potential opportunities to challenge reimbursement adjustments/reductions based on sub-regulatory guidance

COVID-19 PHE

In February and March 2020, the United States began battling the COVID-19 virus

- Federal and state healthcare regulatory authorities forced to react to spread of the virus and related shut-down orders
  - Focus on virtual care to limit exposure; cessation of elective procedures

- Through the CARES Act and other legislation, Congress established the Provider Relief Fund (PRF) as well as the Paycheck Protection Program (PPP)

- Federal government, mainly through CMS, OIG, and OCR, issued waivers, policies of enforcement discretion, and several emergency final rules to restructure how health care services are provided

COVID-19 PHE

- State Medicaid programs and licensing boards also made significant changes
  - Greater scope of practice and coverage of certain services
  - Allowance for practitioners licensed in other states to provide in-person or virtual services
  - Other flexibilities related to standards of practice
- Gubernatorial orders also had similar effects on the practice of healthcare
- Confusion about role of federal vs. state government in the practice of medicine and allowance for cross-border services

The Rise of Telehealth and Digital Health

- COVID-19 pandemic led to near-instantaneous adoption and acceptance of telehealth as a legitimate practice modality
  - Had the pandemic happened in 2010, we would not have been equipped to handle it in the ways we have

- But even before the pandemic, telehealth and digital health technologies were growing in prevalence
  - CMS expansion of coverage for telecommunications technology services
  - Evolution of state laws on the practice of medicine from 2013 to the present

The Rise of Telehealth and Digital Health

- The main question is – will it remain?
  - Insurers have been rolling back initial coverage of telehealth modality
  - CMS has structured certain Medicare rules in a way that suggests telehealth will remain in the Medicare program, but needs Congress to act to make it a reality
  - Public perception/demand and provider infrastructure suggest that there is continuing pressure to use telehealth

- At the very least, ancillary technologies such as RPM will steadily grow in use and importance to the care process

Federal and State Privacy Issues

- Over the last several years, HIPAA has started to gain considerable "teeth" with audits and enforcement actions from OCR increasing

- Recent proposed rulemaking from OCR will likely clarify how certain disclosures are permitted under HIPAA to promote better coordination of care
  – In line with federal government's general effort to promote value-based coordinated care

"Our proposed changes to the HIPAA Privacy Rule will break down barriers that have stood in the way of commonsense care coordination and value-based arrangements for far too long."

HHS Secretary Alex Azar
(Dec. 10, 2020)

Federal and State Privacy Issues

- States, however, have been going in an opposing direction related to data privacy
- California Consumer Privacy Act (CCPA) went into effect at the beginning of this year
  - Implementing regulations issued in August
  - Amendments further strengthening this law were passed in November
  - Already several enforcement actions by the California AG, typically related to businesses' failure to include a "Do No Sell My Personal Information" link on webpages.
- Other states are actively considering CCPA-style laws with several bills under consideration at state houses this past year

DOJ Healthcare Focus

- The drumbeat of healthcare fraud matters coming out of DOJ continued in 2020
  - Initially, refocused on COVID-related fraud scams even as early as March 2020
  - DOJ also implemented a nationwide, coordinated “takedown” of nearly 400 defendants involved in alleged $6 billion fraud schemes
    - ➢ Telehealth fraud
    - ➢ Pharmaceuticals
    - ➢ Lab testing, especially genetic labs
    - ➢ Orthotics and other DME items

DOJ Healthcare Focus

- In June 2020, DOJ re-released its guidance on how it evaluates corporate compliance programs
- DOJ had issued similar guidance in 2019, but its focus remains on these three core questions:

1	**“Is the corporation’s compliance program well designed?”**
2	**“Is the program being applied earnestly and in good faith?” In other words, is the program adequately resourced and empowered to function effectively?**
3	**“Does the corporation’s compliance program work” in practice?**

CMS and OIG Final Rules on Value-Based Arrangements

- The "Regulatory Sprint to Coordinated Care" has finally finished
  - In late November, CMS and OIG released final rules that intend to shift the incentives in the Medicare program to coordinated, value-based care
  - The federal government intends for these laws to provide broad waivers of fraud and abuse enforcement for those entities that meaningfully engage in value-based arrangements and take on some of the financial risks related to care of their patients

- Rules represent a culmination of various efforts by federal regulators to remove barriers to coordinated care, consistent with efforts to incentivize payments for higher quality care that keeps patients healthier

CMS and OIG Final Rules on Value-Based Arrangements

- We have not yet seen how these rules will be implemented by the healthcare industry, but does create prospect of new opportunities and relationships
- Final rules also included other changes to existing exceptions and safe harbors for things like:
  - Local transportation
  - Patient engagement
  - Limited remuneration up to $5,000
  - "Commercial reasonableness"
  - Cybersecurity technology and services

Join us next month!

Please join us for next month’s webinar:

***Fast Break:* Healthcare Transactions in the Post-COVID Era**

Featuring

Jake Harper, Tara McElhiney, and Banee Pachuca

- Thursday, January 28, 2021 3:00 PM (EST)

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QUESTIONS?

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Thanks and Be Well!

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Jake advises stakeholders across the healthcare industry, including hospitals, health systems, large physician group practices, telehealth companies, 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.