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WELCOME

HOT TOPICS IN HEALTH CARE LAW

M&S Health Care Team



Lisa C. Keenan
*Principal and Practice
Group Leader*



Christopher P. Dean
Principal



Molly E.G. Ferraioli
Principal



Celia Van Lenten
Principal



Leslie M. Cumber
Associate

Health Care Law – Year in Review

Christopher P. Dean

cdean@milesstockbridge.com | 410.385.3490



Agenda – Year in Review-*ish*

Areas of law impacting health care providers

- Decisions from the 2023 Maryland appellate courts
- Legislation from the 2023 Maryland Legislative Session focusing on behavioral health
- Review of the Center for Medicare and Medicaid Innovation in 2023

Year in review-*ish*:

2023 Maryland Appellate Decisions Impacting Health Care

COVID-19 –Still Matters?

Are the COVID-19 pandemic restrictions enough to make a lease impossible?

- Timeline
 - ▶ Brew pub lease: January 1, 2016 to December 31, 2020
 - ▶ Statewide state of emergency restrictions began March 5, 2020
 - ▶ Tenant requested rent abatement and early termination in April 2020:
COVID-19 restrictions made tenancy impossible or sufficiently frustrated
- Statewide restrictions were not enough to make the operation of the brew pub economically impossible.
- If it happened between March 2020 and May 2023, COVID-19 still matters
- *Critzos, II v Marquis*, 256 Md. App. 684 (2023)

Medical Assistance Program Limitation Overruled



Maryland Medical Assistance Program erred when refusing coverage

- Medicaid beneficiary transitioned from a disabled child waiver program to the Rare and Expensive Case Management Program
- Sought 31 more hours of private duty nursing per week for 168 hours per week
- Medicaid response:
 - ▶ 168 hrs / week = 24 hours / day x 7 days
 - ▶ Refused coverage: COMAR requires an available “willing and able caregiver” and if there is 24/7 nursing = no time for a caregiver other than the 24/7 private duty nurse
- Maryland state courts remain a good forum for Medicaid disputes
- *In re Sulerzyski*, 257 Md. App. 215 (2023)

Health Care Whistleblower Case Dismissed- Timelines Matter



How does the Maryland Health Care Whistleblower Protection Act (§§ 1-501 – 1-506 of the Health Occupations Act) protect former employees?

- Timelines matter
- Employee must establish that, absent the “protected disclosure”, the termination would not have occurred
 - ▶ Radiation therapist’s employment terminated May 20, 2018
 - ▶ Therapist raised compliance concerns about a faulty automatic couch used with a radiation therapy treatment machine on May 15
 - ▶ Management decided to terminate the employee on May 10 after investigation into medical record falsification accusations started on May 2
- *Romeka v. RadAmerica II, LLC*, 485 Md. 307(2023)

Evergreen Health's Wind Down- Another Chapter in the ACA Story



What happened to the Health Insurance Co-Ops created under the Affordable Care Act of 2010?

- Evergreen Health was one of 23 health insurance Consumer Operated and Oriented Plans funded by grants from the Affordable Care Act
- Evergreen Health: licensed HMO in 2011; entered liquidation in 2017
- Receiver sought Evergreen Health's security deposit and other funds from landlord
- HMO statutes allow the Insurance Administration to liquidate HMO assets
- Bigger picture – only three Co-Ops remain in largely rural areas – Idaho, Maine, Montana, Wisconsin, and Wyoming
- *Baltimore Cotton Duck, LLC v. Ins. Comm'r of Maryland*, 259 Md. App. 376 (2023)

Stockholder Oppression vs. Fiduciary Duty- or Why Not an LLC?



Maryland Supreme Court re-establishes the legal relationships among stockholders, directors, and corporations

- Eastland Food Corporation's stock closely held by family members
- Son left his engineering job; became an Eastland stockholder, director, and officer
- A family dispute occurred
 - ▶ Son was removed as director and officer
 - ▶ Eastland refused to pay dividends on son's stock
- Lawsuit against Eastland, family members, and directors for stockholder oppression and a breach of the **board of director's fiduciary duties**

Stockholder Oppression vs. Fiduciary Duty- or Why Not an LLC?



Why this case now?

- Maryland courts periodically confuse individual claims against corporations with derivative claims brought by a stockholder on behalf of the corporation against the Board of Directors
- The fiduciary duties of directors remain elusive, despite statutes defining this duty... clearly?
- Minority stockholder oppression seems viable- if the facts are sufficient
- Just another reason to form limited liability companies?
- *Eastland Food Corp. v. Mekhaya*, 486 Md. 1 (2023)

Year in review-*ish*:

2023 Legislation... Behavioral Health Emphasis

9-8-8 Behavioral Health Hotline

- Maryland designated 9-8-8 as the statewide Behavioral Health Crisis Hotline in 2022
 - ▶ Initial 9-8-8 Trust Fund appropriated \$5.5 million annually
 - ▶ Initiated state-wide coordination of behavioral health crisis response services
- 2023 increased the 9-8-8 Trust Fund appropriation to \$12 million in 2025
- 9-8-8 Trust Fund Funding, Chp 261 Md. Laws

Behavioral Health and Alternate (Payment) Models...



- Certified community behavioral health clinics (CCBHCs)
 - ▶ CCBHCs treat any patient regardless of ability to pay, place of residence, or age
 - ▶ Maryland Department of Health authorized to use resources to apply for Substance Abuse and Mental Health Services Administration grant funding for a SAMHSA demonstration project in 2026
- Establish behavioral health value-based purchasing pilot program- VBP Pilot Program
 - ▶ Department of Health commission on intensive care coordination model program
 - ▶ Requires a minimum 3-year program to terminate by November 30, 2027
- CCBHC Planning Grant Funds and Demonstration Application, Ch. 275 Md. Laws; Treatment and Access (Behavioral Health Model for Maryland), Ch. 290 Md. Laws

Tools You Can Use– Mental Health Advanced Directives, Telehealth



- Directs the Behavioral Health Administration to study and make recommendations on how first responders can access electronic mental health advanced directives when responding to a behavioral health crisis
- Start a public awareness campaign on mental health advance directives
- Extends statewide behavioral health telehealth benefit to 2025 for Medicaid and commercial payors
- Mental Health Advance Directives – Awareness and Statewide Database, Ch. 297, Md. Laws; Treatment and Access (Behavioral Health Model for Maryland), Ch. 290 Md. Laws

Year in review-*ish*:

2023 Centers for Medicare and Medicaid Innovation

CMMI: 5 Strategic Objectives

- Drive accountable care
- Advance health equity
- Support innovation
- Address affordability
- *Partner to achieve system transformation*



CMMI, Payment Models: Where & What?



- Where is the information?
 - ▶ Federal Register
 - Medicare Shares Savings Program (MSSP) Accountable Care Organization
 - Proposed Rule for episode based behavioral health model (88 Fed. Reg. 45872 July 18, 2023).
 - ▶ The CMMI website- includes requests for applications (RFAs)
- What kinds of programs?
 - ▶ Maryland Total Cost of Care Model
 - ▶ MSSP ACO, ACO REACH, etc.

CMMI: What's New?

- State-wide models (2023-ish)
 - ▶ The Innovation in Behavioral Health Model
 - ▶ Advancing All-Payer Health Equity Approaches and Development Model (the AHEAD Model)
- Specific disease models
 - ▶ ESRD Treatment Choices Model (ETC)
 - ▶ Kidney Care Choices Model (KCC)
- Specific Industry - Home health – Expanded Home Health Value-Based Purchasing Model

Last Thoughts for Today...

1990's: America's health care system is neither *healthy, caring, nor a system.*

-Walter Cronkite

2000's: Health care costs are on the rise*consumers are not involved in the decision-making process... there is no market forces involved with health care.*

- President George W. Bush

2020's: [Health transformation] requires working across CMS and the entire federal government, as well as *working hand-in-hand with health care teams and payers, purchasers, states, providers, patient advocates and patients.* Success hinges on multi-payer alignment on clinical tools, outcome measures, payment, ... and building the capacity to transform health care.

- CMMI, Strategic Refresh

Consolidation in Health Care and Telehealth Flexibilities

Leslie M. Cumber

lcumber@milesstockbridge.com | 410.385.3704



Agenda – Consolidation and Telehealth

- Consolidation in the health care market
 - New Merger Guidelines
 - FTC's proposed ban on for-profit non-competes
- Telehealth
 - Extension of certain Medicare telehealth flexibilities
 - What can we expect as of January 1, 2025?

Year in Review:

Continued Consolidation in the Health Care Market

Consolidation

Did you know?

- The top ten health systems now control nearly a quarter of the market;
- Cross-market and cross-sector deals are on the rise;
- Hospitals continue to drive physician practice consolidation, but private equity is increasing its market share;
- More than a quarter of all emergency departments in the U.S. are staffed by private equity-backed staffing companies.



The New Merger Guidelines



- On December 18, 2023, the U.S. Department of Justice and the Federal Trade Commission adopted new Merger Guidelines.
- Importantly, the new Merger Guidelines:
 - Lower the threshold for the presumption of illegality; and
 - Increase scrutiny where a firm engages in a “pattern or strategy of multiple acquisitions in the same or related business lines.”
- What does this mean for healthcare providers?

The FTC's Proposed Ban on For-Profit Non-Competes



- Generally, prohibits for-profit employers from using non-compete clauses
 - Applies to independent contractors
 - Would require for-profit employers to rescind existing non-competes
- Even if the FTC votes on its final rule this year, legal challenges will likely follow.
- Regardless of the outcome, more states are moving to restrict, or at least further limit, non-competes (we're looking at you, D.C.).

Year in Review:

Medicare Telehealth Flexibilities Post-PHE

Telehealth - Medicare



It's the end of the world, ahem PHE, as we know it...

- The walls are back
- RPM for established patients only
- Direct supervision no longer met through “virtual presence”

But, certain telehealth flexibilities, authorized by CMS during the PHE, have been extended through December 31, 2024...

Extension of Certain Medicare Telehealth Flexibilities



- Patients can continue to receive telehealth services from home;
- All providers eligible to bill Medicare for professional services can provide distant site telehealth;
- Telehealth can continue to be used to conduct recertification of eligibility of hospice care;
- Prescribing of controlled substances without an in-person examination can continue; and
- Some telehealth services will continue to be reimbursable when provided using audio-only technology.

So, what happens on January 1, 2025?

Certain Behavioral/Mental Telehealth Flexibilities Made Permanent



- FQHCs and RHCs can serve as a distant site provider for behavioral/mental telehealth services;
- Medicare patients can receive behavioral/mental telehealth services from their homes;
- Behavioral/mental telehealth services can be delivered using audio-only communication technologies.

Will other non-behavioral/mental telehealth flexibilities follow?

Health Care Privacy and Cybersecurity Update

Celia E. Van Lenten

cvanlenten@milesstockbridge.com | 410.385.3419



Agenda – Health Care Privacy and Cybersecurity Update



- Artificial intelligence (“AI”) in health care
- Website tracking technologies
- Office for Civil Rights (“OCR”) HIPAA enforcement
- HIPAA breaches

Privacy and Cybersecurity Update:

AI in Health Care

AI in Health Care

- AI is not new, but its use has exploded since 2022.
- Many opportunities and innovations, but concern persists over governance, use cases, bias, privacy and security, and intellectual property.
- 10/30/2023: President Biden issued an Executive Order with a variety of directives to establish standards for AI safety and security.
- 12/14/2023: White House announced that 28 health care provider and payor organizations made voluntary commitments to help move toward “safe, secure, and trustworthy purchasing and use of AI in health care.”
- New state laws focused on the use of AI in health care are emerging.
- There will be more to come as the law catches up with the technology, but health care companies should put together a governance strategy in the meantime.

Privacy and Cybersecurity Update:

Website Tracking Technologies

Website Tracking Technologies

- Health care companies meet their patients, members and the public on their websites.
- An analytics tacker is a piece of code that is used to monitor and collect information about a user's interactions with a website or mobile application (e.g., pixels, cookies).
- Benefits of analytics trackers:
 - Understand how users interact with websites
 - Monitor whether a website is operating properly and efficiently
 - Improve website function and design
 - Enhance user experience

Website Tracking Technologies

June
2022:
Dobbs
decision

July
2022:
Class
action
litigation
starts

Feb.
2023:
FTC fines
GoodRx
\$1.5M

Mar.
2023:
FTC
requests
\$160M
for
health
privacy

July
2023:
OCR and
FTC joint
privacy
warning

June
2022:
The
Markup
article

Dec.
2022:
OCR
guidance

Mar.
2023:
FTC fines
BetterHe
lp \$7.8M

May
2023:
FTC fines
Premom
\$100k

Nov.
2023:
AHA and
others
sue
federal
gov't

Website Tracking Technologies

- According to OCR in its December 2022 guidance, when a third-party tracking technology has access to PHI, the disclosure is subject to HIPAA and is prohibited without a BAA or HIPAA authorization.
- OCR broadly defines PHI to include IP address, geo-location, medical device ID or any other unique identifying code.
- According to OCR, when a regulated entity collects a website user's IP address or other unique identifier through its website or mobile app, the information connects the website user to the regulated entity because "it is indicative that the individual has received or will receive in the future health care services or benefits" from the regulated entity.

Website Tracking Technologies

- User-Authenticated Web Pages (e.g., Patient Portal): Third-party tracking technology has access to PHI, so HIPAA applies.
- Unauthenticated Web Pages: Third-party tracking technology “may have access to PHI” on the following unauthenticated pages:
 - Web pages that include a login for a patient portal or a user registration page.
 - Web pages that permit individuals to search for doctors or schedule appointments.
 - Web pages that address specific symptoms or health conditions.
 - **PRACTICAL PROBLEM: The most commonly-used third-party tracking tech vendors will not sign BAAs!**
- Mobile Apps: HIPAA applies if the app is offered by a regulated entity and the tracking technology collects PHI.

Website Tracking Technologies

Observations:

- Governance is key. Establish an oversight process that includes marketing, legal, privacy, compliance, IT and InfoSec.
- Continued pressure to disable website tracking technologies hosted by third-parties who will not sign BAAs. (And additional pressure on those vendors to develop a HIPAA-compliant solution.)
- Either move to a HIPAA-compliant vendor or disable tracking completely.
- Cyber insurance carriers are asking underwriting questions about the use of tracking technologies and governance related to their use.
- Some cyber insurance carriers are excluding coverage for use of tracking technologies.
- OCR and FTC are actively investigating health care companies regarding their use of tracking technologies.
- Expect more regulatory and litigation activity on this issue in the coming year.

Privacy and Cybersecurity Update:

OCR HIPAA Enforcement

OCR HIPAA Enforcement

- In 2023, OCR settled cases with eight Covered Entities and four Business Associates.
- Fines ranged from \$15,000 to \$1.3 million (total of \$4,176,500), plus 1- to 3-year corrective action plans.
- Most allegations of non-compliance centered around violations of the HIPAA Security Rule.
- The HIPAA Right of Access Initiative has remained a top enforcement priority.
- Other issues: responding to online patient reviews, insider breaches, hacking and phishing.
- Not published: thousands of complaints and compliance reviews that did not result in a formal enforcement action.

Privacy and Cybersecurity Update:

HIPAA Breaches

HIPAA Breaches

- 553 “large” breaches reported on OCR breach portal in 2023.
- Over 109 million individuals affected (compare to 55 million individuals affected in 2022).
- Ransomware and hacking are the primary cyber threats in health care.
- Majority of breaches were reported by health care providers (approx. 65% of reported breaches).
- Breaches will happen, but having a strong HIPAA privacy and security program will hopefully minimize their effect and serve as a mitigating factor if OCR investigates.



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HOT TOPICS IN EMPLOYMENT LAW

April 11, 2024

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Managing Director



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PANELIST DISCUSSION

HOT TOPICS IN HEALTH CARE LAW