Health Law Update For Hospitals

Alabama Hospital Association
Presented by:
Gilpin Givhan, PC
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Health Law Update For Hospitals

Gilpin Givhan Health Care Team Presenters:



John W Weiss



Chris Richard



Gregg Everett



Taylor Steen





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Health Law Update For Hospitals

COVERING....

- OIG/DOJ Enforcement Update
- HIPAA EMR Access Issues
- State Law Update
- On the Hospital Radar



Annual Health Law Update For Hospitals

OIG/DOJ YEAR IN REVIEW



John W. Weiss, Esq (334) 409-2218 jweiss@gilpingivhan.com





- FY 2023 Government Summary
- Government enforcement activities
- DOJ/OIG Cases, Settlements and Patterns
- Compliance Reminders









DOJ Health Care Fraud Recoveries		
Fiscal Year	Total Fraud Recoveries	Health Care Fraud Recoveries
2015	\$3.5 Billion	\$1.9 Billion
2016	\$4.7 Billion	\$2.5 Billion
2017	\$3.7 Billion	\$2.4 Billion
2018	\$2.8 Billion	\$2.5 Billion
2019	\$3.6 Billion	\$2.6 Billion
2020	\$2.2 Billion	\$1.8 Billion
2021*	\$5.6 Billion	\$5.0 Billion
2022	\$2.2 Billion	\$1.9 Billion
2023	\$2.68 Billion	\$1.8 Billion



- Fiscal Year 2023 OIG Semi-Annual Report
 - 707 Criminal Actions
 - 746 Civil Actions
 - Whistleblowers
 - 712 qui tam suits filed 2023
 - 2023 judgements of \$2.3 Billion
 - Excluded from Federal Programs: 2,112



Continuing Trends:

- Whistleblower Cases
- Fraud recovery efforts still result in significant return on investment
- Continuing focus on physicians, executives,
 owners and those behind the fraudulent action
- Opioid Actions
- COVID-19





National Health Fraud Day Week Action June 27, 2024

2024 National Health Care Fraud Enforcement

Action

- Joint effort: DOJ, OIG, FBI, DEA
- 193 charged defendants across 32 Federal Districts
- 76 licensed medical providers and physicians
- \$2.75 billion in alleged false claims











2024 National Health Care Fraud Enforcement Action

THAN \$2.75 BILLION

INTENDED **FRAUD LOSS**

MORE \$23 | MILLION | CASH AND OTH ASSETS SEIZED

CASH AND OTHER

CASES CHARGED

DEFENDANTS 193 **CHARGED**

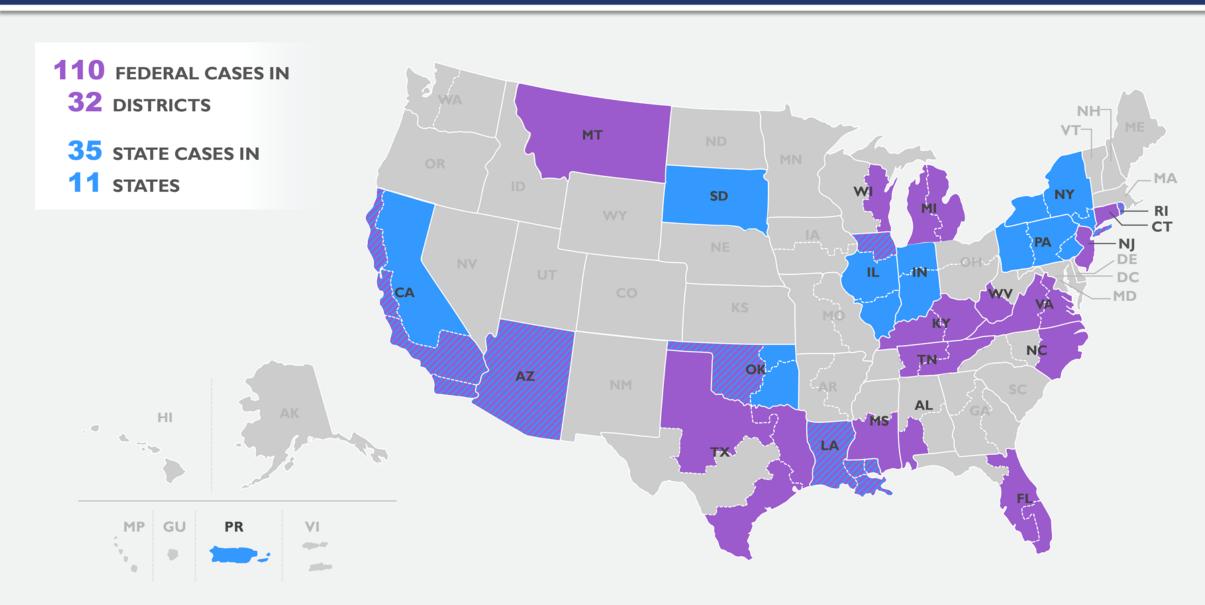
FEDERAL DISTRICTS 32 INVOLVED

LICENSED MEDICAL PROFESSIONALS CHARGED

ADMINISTRATIVE ACTIONS AGAINST MEDICAL PROVIDERS



2024 National Health Care Fraud Enforcement Action – Federal and State Cases



National Health Fraud Day Week Action June 27, 2024

- Wound Care Scheme
 - 2 defendants
 - \$900 million in fraudulent claims
- Distribution of Adderall
 - Distribution over the internet
 - 1.5 million pills by one NP
- Telemedicine and laboratory
 - Charges against 36 defendants
 - Kickbacks for referral orders of genetic tests
 - Over \$1.1 billion in false billings









National Health Fraud Day Week Action June 27, 2024

- Other Health Care fraud and opioid distribution
 - 126 defendants
 - \$450 million
- Distribution of Adulterated/misbranded HIV drugs
 - \$90 million in fraudulent claims











US v. Brosius - HIV Medication Fraud Scheme



Telemedicine Schemes

- Covid -19 has had a major impact on use of telemedicine
- However, beware.....



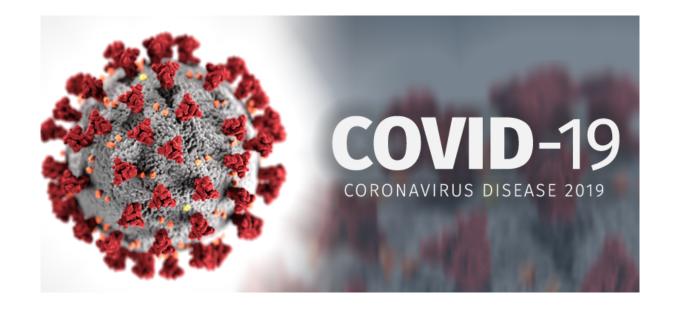


DOJ Telemedicine Operations

- Operation Brace Yourself (international DME)
- Operation Double Helix (genetic testing)
- Operation Rubber Stamp (DME)
- Operation Happy Clickers (DME & cancer testing)









COVID-19 Money

- Families First Coronavirus Response Act (FFCRA)
- Coronavirus Aid Relief and Economic Security (CARES) Act
- Paycheck Protection Program (PPP)
 and Health Care Enhancement Act
- Paycheck Protection Program (PPP)
 Flexibility Act
- Consolidated Appropriations Act of 2021
- American Rescue Plan

COVID-19 Money

COVID-19 Fraud Enforcement Task Force (CFETF) May 2021

- Over 3,500 defendants criminally charged
- Over 400 civil settlements/judgements
- Over \$1.4 billion in fraudulently obtained

CARES Act funds seized

Using new integrated, data driven approach

Cases and Settlements

- Hospitals
- Hospice/Home Health
- Laboratories
- Etc.





Hospitals – Qui Tam

- Erlanger Health System
 - Government joined Qui Tam
 - Employed Physician compensation well above FMV
 - Violated Stark which resulted in false claims



Hospitals – Self-Disclosure

- Baptist Health System (Fla) 5/6/24
 - Subsidiaries provided discounts up to 50% in exchange for purchase or referral of services
 - Settlement: \$1.5 million



<u>Hospitals – Self-Disclosure</u>

- **St Peter's Health (Mt)** 8/30/24
 - Submitted false claims by employed oncologist whose compensation was based on claims made and inconsistent with FMV (Stark)
 - \$10.8 Million Settlement
- Presence Chicago Hospitals Network (II) 4/1/24
 - Provided physicians:
 - Free or below market rent
 - Free medical record copying
 - Free or below market furniture, technology and staff
 - \$577,433.52 settlement



Hospitals – Self-Disclosure

- St Agnes Hospital (Md) 5/21/24
 - Free office space to referring physician
 - Remuneration to group for clinical service on patients in research studies and double billed for those services
 - Settlement: \$69,627.15
- St John Medical Center (Ok) 5/8/24
 - On call payments above FMV
 - Settlement \$556,717.50



<u>Hospitals – Self-Disclosure</u>

- Bridgeport Hospital (Ct) 6/6/24
 - Physician group compensation for:
 - medical director services that were unnecessary, excessive, not provided and not commercially reasonable.
 - Management services that were not commercially reasonable and were not provided.
 - Free PA staff to perform surgical post-op visits.
 - Settlement: \$10,783,559



<u>Hospitals – Self-Disclosure</u>

- Baptist Medical Center South (Al) 5/7/24
 - Submitted false claims for occupational therapy services without plan of care or unsigned plan of care
 - And "other self-disclosed issues"
 - Settlement: \$247,542
- DCH Healthcare Authority (Al) 2/20/24
 - Claims not certified or recertified by physician.
 - Settlement: \$384,901



Hospitals – HIPAA

- Cedar Rapids ER Physician
 - Obtained PHI of several patients.
 - Sent picture of a patient on Snapchat
 - Pled guilty
 - Maximum possible sentence of 5 years, fine of \$250,000, with 3 years supervised release



Hospitals – Exclusion

- United Memorial Medical Center (TX) 12/14/23
 - Agreed to 10 year exclusion
 - For:
 - Distorting inpatient cost outlier reports
 - Concealing excess reimbursement (60 day rule)
 - False claims for Covid -19 tests
 - Duplicate claims to State



Hospitals

- Hospital Focus
 - Technical compliance with Stark
 - Hospital / physician arrangements
 - Basic kickback schemes
 - Beware of internal decreased focus on Stark compliance



- Hospice and Home Health
- Admitting non-terminally ill patients
 - Nevada physician/hospice owner pled guilty to submitting \$4 million in fraudulent claims for Hospice patents that did not meet criteria
 - <u>Intrepid USA</u> submitted claims for patients who are not qualified



- Hospice and Home Health
- Admitting non-terminally ill patients
 - <u>Kindred</u> retained overpayments for services to patients who were not eligible, payments to consulting physician for referrals



- Hospice and Home Health
- Admitting non-terminally ill patients
 - <u>Elara Caring</u> submitted claims and retained overpayments for services to patients who were not eligible,



- Hospice and Home Health
- Old fashion Kickback



- Rehab Therapy SNFs
- Same Patterns
 - Grand Health Care—billing for rehab services that were unreasonable, unnecessary, unskilled or did not occur.



- <u>Labs</u>
- Marketing Arrangements
 - <u>Carnaggio</u>- Marketing company offered kickbacks to physicians as office space rental and phlebotomy payments to induce referrals
 - <u>Carralejo</u>- kickbacks to Physicians disguised as consulting and medical director fees



Other Patterns

- <u>Labs</u>
- Marketing Arrangements
 - RDx Bioscience Charged with 5 types of disguised kickbacks paid:
 - 1. Commissions based on volume and value of referrals to marketers
 - 2. MSO payments
 - 3. Consulting and medical director fees
 - 4. Payments to clinic owners for referrals
 - 5. Specimen collection fees



• <u>60 Day Rule</u>

• Optimus Health Care

- Identified overpayments and did not report or return the overpayments
- Settlement: \$353,000

• Lorien Health Services

- Failed to timely report and return identified overpayments.
- Settlement: \$55,000





Self Disclosure Reminder:

DOJ Corporate Enforcement and Voluntary Self-Disclosure (CEP) Policy (updated 1/2023)

- Guidelines for declination, recommendation for reduced fines, etc.
- Focus on voluntary self-disclosure, full cooperation, and timely and appropriate remediation
- Compliance is an important part of this:
 - Mitigating factor
 - Part of remediation efforts
 - May eliminate need for corporate monitor
- Compliance role in due diligence and M&A activities







Self Disclosure Reminder

DOJ Guidelines for Evaluation of Corporate Compliance Programs (updated 3/2023)

Impact on: (1) resolution of prosecution; (2) monetary penalties; and
 (3) compliance obligations in resolution

- Three Questions:
 - (1) Is the Compliance Program well designed?
 - (2) Is the Compliance Program adequately resourced and empowered / being applied earnestly and in good faith?
 - (3) Does the Compliance Program work in practice?
- "The company's top leaders the board of directors and executives set the tone for the rest of the company."



Compliance Reminder

General Compliance Program Guidance (updated 11/2023)

- Important and valuable resource for compliance team
- Reviews major applicable laws (Stark, kickback, etc)
- Highlights the Seven elements that make up an effective compliance Program







Compliance Reminder

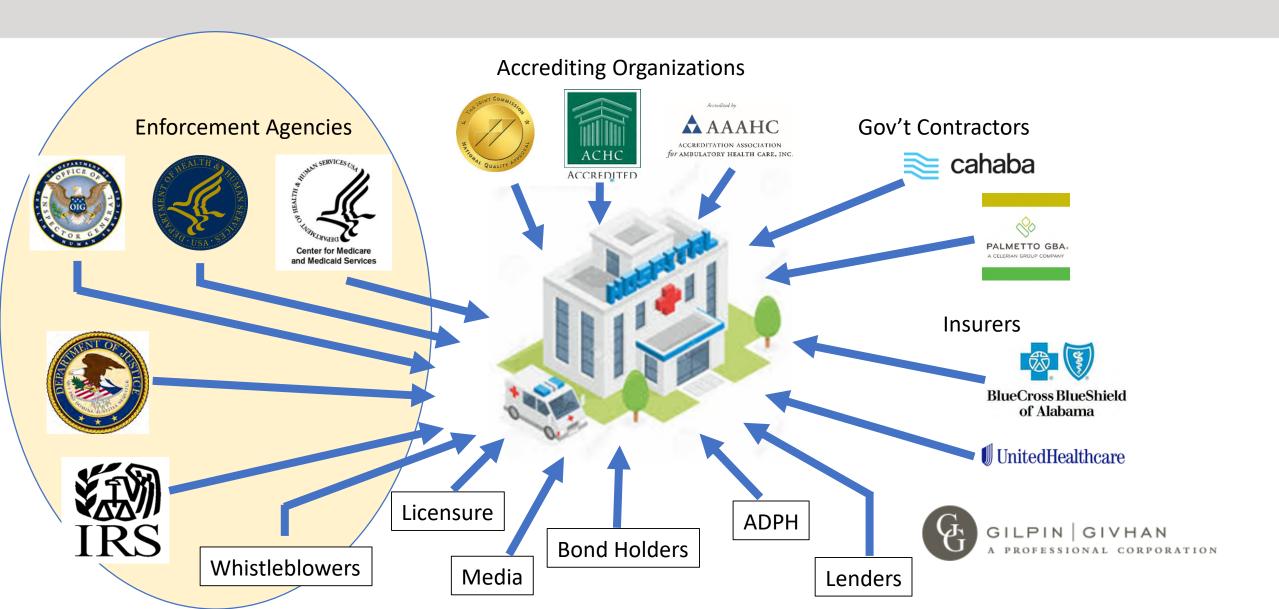
DOJ Public Comments

• DOJ wants to see "compliance-promoting criteria" in compensation and bonus plans.

We expect companies to find innovative, effective, and targeted ways to use compensation to incentivize good corporate behavior and deter misconduct, usir their own mix of carrots and sticks. Deputy Attorney General Marshall Miller

- Suggested elements:
 - Prohibitions on bonuses for employees who do not satisfy compliance performance requirements;
 - Incentives linked to demonstration of full commitment to compliance process.
 - Disciplinary measures and clawbacks for those who violate applicable law







DOJ/OIG Trends to Watch:

- 1. COVID Money audits and Fraud Investigations
 - Anything Pandemic related
- 2. Opioid Crisis
- 3. Continued focus on individuals/Individual Liability
 - Owners, CEOs, CFOs, practitioners, recruiters
- 5. Telemedicine abuses
 - Operation ______.
- 6. Renewed focus on FMV compensation
- 7. Over 700 qui tam cases filled last year
- 7. Don't forget "they" have your.....









Trends to Watch:

DATA



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John W. Weiss, Esq (334) 409-2218 jweiss@gilpingivhan.com



On the Hospital Radar: Quick Hits on Managed Care Contracting and the New EMTALA Enforcement Paradigm

2024 Gilpin Givhan Annual Health Law Update



Christopher L. Richard (334) 409-2233 crichard@GilpinGivhan.com
Web: GilpinGivhan.com





On the Agenda



Managed Care Contracting

By the Numbers

Program Structure

Contracting and Compliance



EMTALA Compliance and Enforcement Updates

EMTALA Overview

New Resources and Enforcement Mechanisms

Managed Care Contracting:

By the Numbers

Program Structure

- Contracting and Compliance
- Updates for 2025



Managed Care Contracting: By the Numbers

2007

8 million enrollees

19% of Medicare-eligible individuals

2023

30.8 million enrollees

>51% of Medicare-eligible individuals

\$454 billion

54% of total Medicare spend

Beneficiaries on average have access to 43 different plans

Nancy Ochiena et al., KFF, Medicare Advantage in 2023: Enrollment Update and Key Trends (Aug. 9, 2023)

Managed Care Contracting: By the Numbers

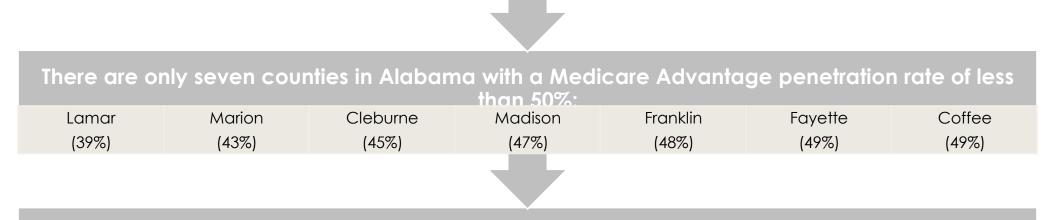
High Concentration

- UnitedHealthcare (29%) and Humana (18%) account for 47% of all Medicare Advantage enrollees nationwide
 - In **32% of counties**, UnitedHealthcare and Humana account for at least 75% of all Medicare Advantage enrollment
- BCBS affiliates (including Anthem BCBS plans) account for 14% of enrollment
- The average Medicare beneficiary had a choice of Medicare Advantage plans offered by 9 firms in 2023; 40% of beneficiaries had a choice of Medicare Advantage plans offered by 10 or more firms



Managed Care Contracting: By the Numbers

Alabama is one of three states where more than 60% of Medicare-eligible individuals are enrolled in a Medicare Advantage plan (along with Michigan and Hawaii)



Most Alabama counties have a Medicare Advantage penetration rate of 60-70%

Managed Care Contracting: Program Structure

In a Nutshell

- Medicare-approved plan offered by a private company that bundles Part A (inpatient/facility), Part B (outpatient), and usually Part D (prescription drug) services
- Frequently limits care to in-network providers
- Frequently requires PA for certain drugs or services
- May have lower or higher out-of-pocket costs than original (FFS) Medicare; may require additional premium
- Plans may offer certain extra benefits that original Medicare does not cover (e.g., certain vision, hearing, and dental services)

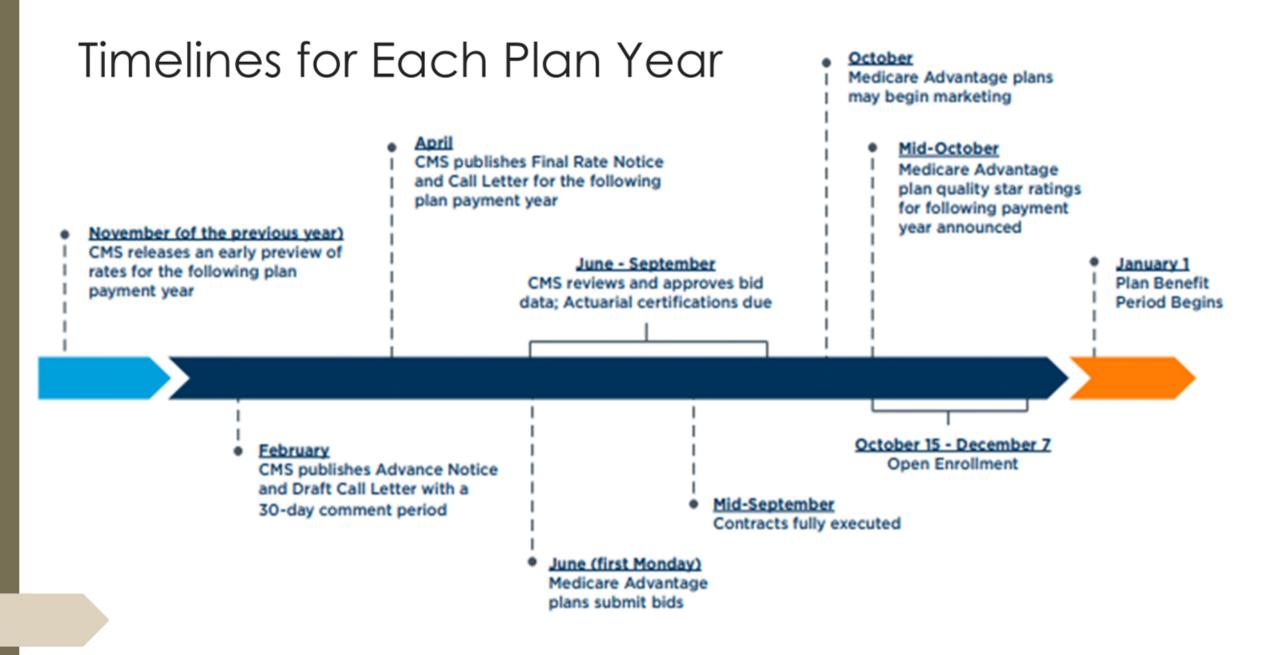


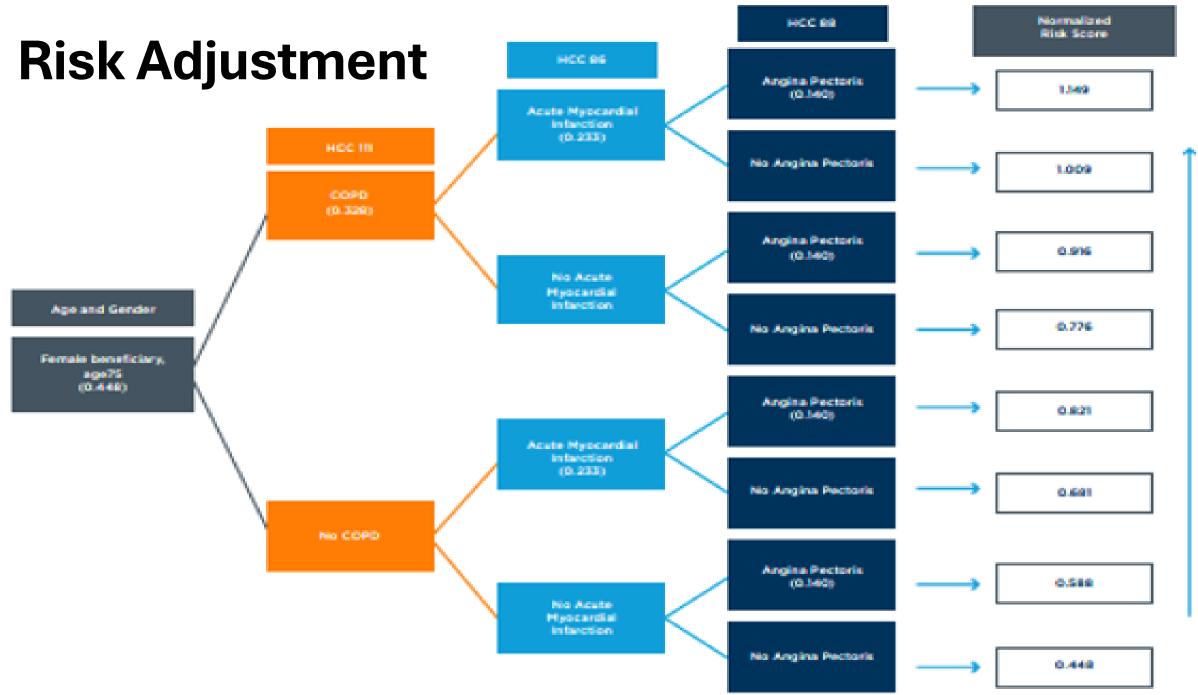
Managed Care Contracting: Program Structure

How MA Plans Get Paid

- CMS pays capitated/fixed amount per member per month (PMPM)
- Rates are negotiated annually through a bidding process that tracks spending in FFS Medicare
 - Early Preview of Rate Notice: Early November-December before plan year
 - Advance Notice and Draft Call Letter: 60 days prior to final Rate Notice and Call Letter
 - Rate Notice and Call Letter: Second Monday in April
- PMPM rates comprised of:
 - Base Rate: lesser of plan bid or benchmark (by county, based on percentage historical FFS spend and adjusted for geography, demographics, and quality)
 - Risk Adjustment: base rates for each enrollee adjusted based on their risk score
 - **Premiums:** cannot under-bid benchmark and make up in premiums, but can charge additional premiums if bid comes in over benchmark
 - **Rebates:** equal to a percentage of the amount the plan bid below the benchmark; must be used to provide additional services to beneficiaries







General

- Read before you sign!
- Know your rights and obligations under the contract
- Know your rights and obligations under the MA plan regulations
- Compare those rights and obligations to MA plan regulations:
 - Is the MAO asking you to do more than what is required under the MA regulations?
 - If asked to do more, what is the additional cost to your organization to comply?
 - Does the contract include any provisions that are prohibited under the MA regulations (*i.e.*, certain indemnification provisions, prohibited terms for physician incentive plans, etc.)?



General

- Know your leverage points:
 - Where does your facility fit with respect to the MA Plan's needs?
 - Is your facility necessary to meet time/distance or minimum number requirements for access to care and plan adequacy requirements?
 - Is your facility an "essential hospital"?
 - Are you in a position to help the MA plan provide better quality care to patients?
 - Are there quality incentives in the contract associated with your efforts?
 - Does the contract provide compensation commensurate with the complexity of the patients you care for and the risk associated with those patients?
- Don't push the wrong buttons:
 - Negotiate in good faith
 - Be mindful of antitrust limitations, where applicable:
 - No sharing rates or competitively sensitive information
 - No boycotts or concerted refusals to deal



Specific Contract Terms: Eligibility and Claims

- Member eligibility verification
- Definition of "clean claim"
 - What is required?
- Timely claims filing limitation
 - Plan will want shorter window, but for hospital, the longer the better
- Late Payment
 - Push for interest payments



Specific Contract Terms: Medical Necessity and PAs

- Medical Necessity
 - Industry and/or local standards
 - Not tied to cost of care
- PAs
 - Items and services for which required
 - Substantive standards
 - Process for obtaining
- Plan requests for additional info
 - Notices and time to respond



Specific Contract Terms: Retrospective Reviews

- Retrospective Medical Necessity Reviews
 - Limited to circumstances outlined in regulation
- Health plan audits of claims
- Health plan requests for refund of overpayments
- Appeals timeline and procedure



Specific Contract Terms: Dispute Resolution

- Dispute resolution
 - Time limitations for filing and triggers
 - Requirements for informal dispute resolution before elevating to more formal proceedings
 - AAA or AHLA
 - Carve-outs for willful conduct (antitrust, systemic conduct, etc.)
 - Fee-shifting provisions
 - Award of interest



Specific Contract Terms: Other Contract Terms

- Health plan changes to provider manual
 - plan rights to change unilaterally (should be limited)
 - Require notice and opportunity to object/negotiate on other types of changes
- Contracting with specific plans offered by same MAO
 - Ability to participate in and/or terminate some (but not all)



Contract Negotiation Playbook

- Payor-specific vs. state lawspecific
- Clear description of timelines
- Create template appeal letters
- Playbook
 - Provider profile
 - Preferred, acceptable, unacceptable terms
 - Created by legal team under protection of attorney-client privilege and attorney work product



Compliance: MA Plan Risk Adjustment Fraud Cases

- Dr. Isaac Kojo Anakwah Thompson (2016)
 - Contracting PCP for Humana MA Plan diagnosed 387 enrollees with ankylosing spondylitis, a rare chronic inflammatory disease of the spine
 - Resulted in \$2.1m in excess capitation fees to Humana, Thompson got 80%
 - 46 months in prison and \$2.1m in restitution



Compliance: MA Plan Risk Adjustment Fraud Cases

- HealthSun and Kenia Valle Boza
 - Certified coder and former Director of Medicare Risk Adjustment Analytics at HealthSun accused of falsely diagnosing MA plan members with various chronic conditions that impacted risk adjustment and capitated payments to HealthSun, even though these conditions were not diagnosed by a physician
 - \$53m overpayment as a result of false risk adjustment data
 - DOJ declination to indict HealthSun: DOJ Corporate Enforcement and Voluntary Self-Disclosure Policy



Compliance: MA Plan Risk Adjustment Fraud Cases

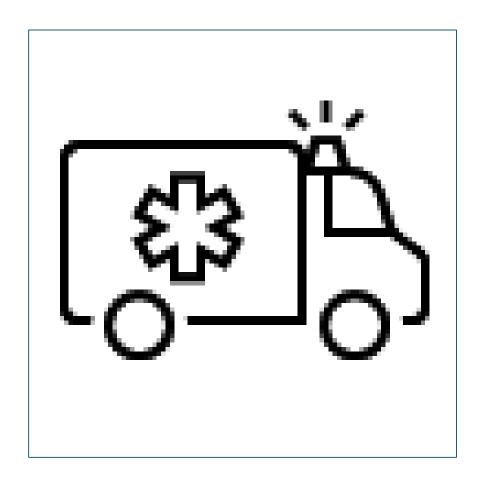
- DOJ press release on 2023 FCA recoveries
 - Medicare Advantage Singled Out
 - Cigna settlement for \$172m related to knowing submission and failure to withdraw inaccurate diagnosis codes that impacted risk adjusted payments (one-way chart review program)
 - Martin's Point Health Care Inc. settlement for \$22.5m for similar conduct (submission of diagnoses not supported in patient medical record)



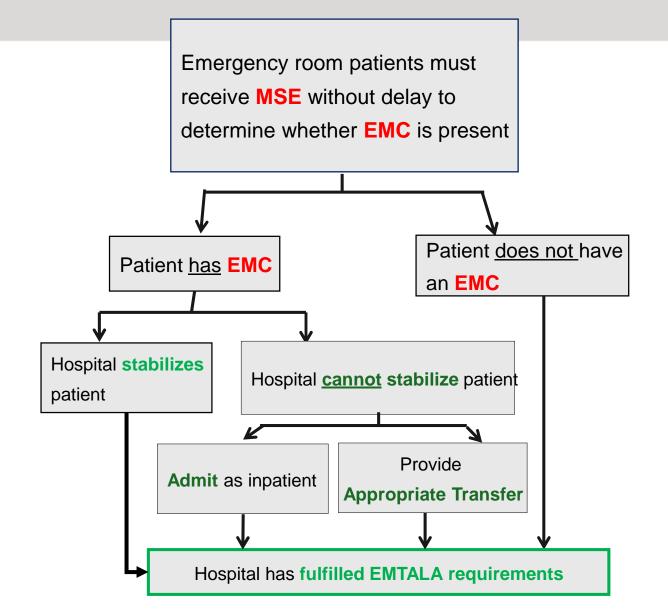
The New EMTALA

EMTALA Overview

 New Resources and Enforcement Mechanisms

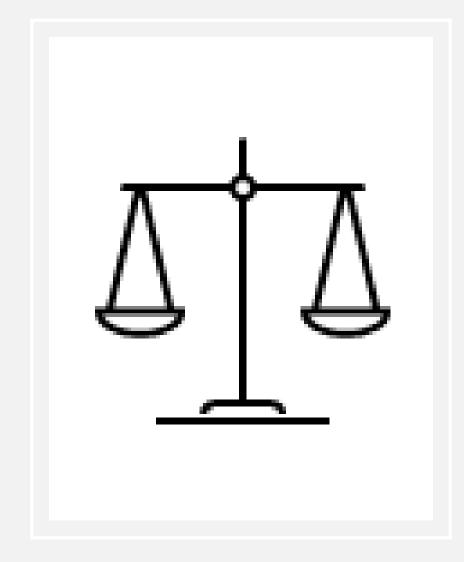


EMTALA Overview



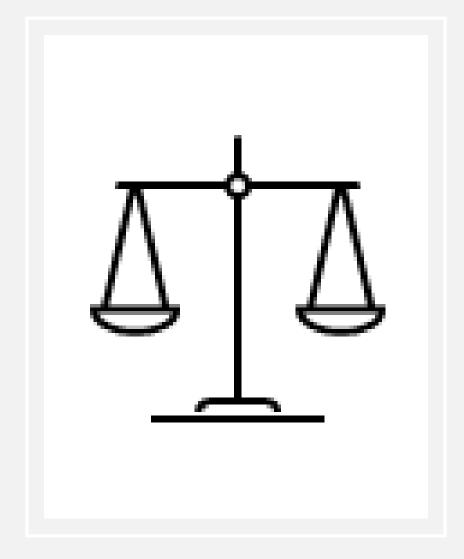
ENFORCEMENT

- CMS (through arrangement with ADPH) investigates complaints
- Issues Notice of Deficiency (90 or 23 day notice)
- Threaten to terminate Medicare provider agreement
- Publish letter in local paper
- Hospital submits corrective action plan
- Detailed and specific with accountability



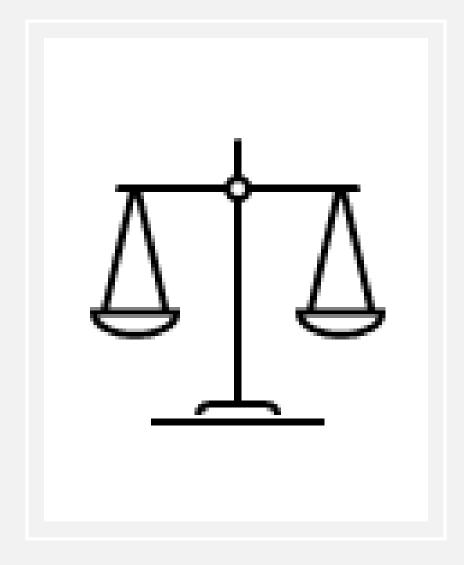
NEW EMTALA RESOURCES

- HHS/CMS Comprehensive Plan (Jan. 2024):
 - New informational resources to help patients understand their rights and the process for submitting complaints if they are denied emergency medical care
 - Training materials produced through partnerships with CMS and hospital and provider associations
 - Discussion of best practices with hospital and provider associations
 - Dedicated team of HHS experts to support EMTALA compliance efforts



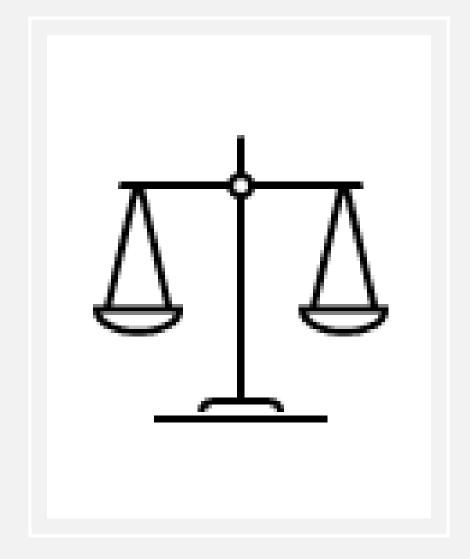
NEW EMTALA RESOURCES

- CMS Website Patient Informational Page
 - Explains patient right to MSE and either stabilizing treatment or appropriate transfer
 - Defines key terms such as "stabilized" and "emergency department"
 - Provides information and a link to file complaints
 - Provides information and a link to file a civil rights complaint with HHS-OCR for discrimination or unfair treatment
- Tends to make it easier/more likely that patients will file complaints



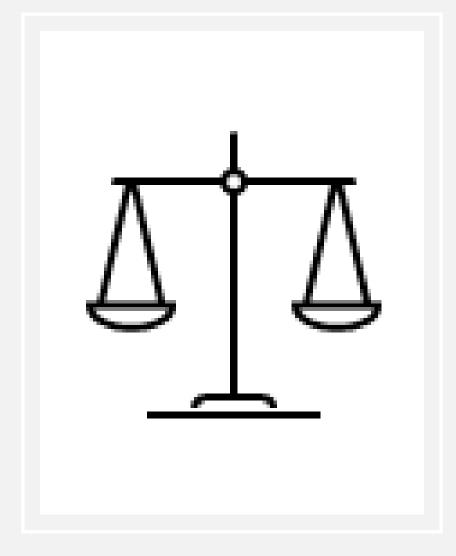
NEW EMTALA RESOURCES

- Online Complaint Filing Process (May 2024)
 - Two methods to file complaint:
 - State Survey Agency (links and contact number for provider complaints in all 50 states provided)
 - Online Portal
 - Relationship to patient (optional; may file anonymously)
 - Estimated 5 minutes to complete (super-easy)
 - What to expect after filing
- Appears to be open not just to patients, but to family members, physicians, hospital workers, etc.



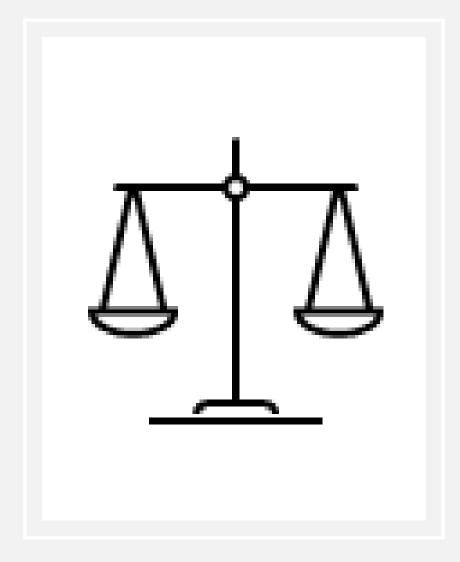
ENFORCEMENT

- When you get a complaint survey . . .
- AQAF (QIO) hearing if medical opinion is necessary
- QIO report delivered to CMS and OIG
- OIG then determines whether to assess a CMP
- \$129,232 + per violation (\$64,618 + hospitals under 100 beds)
- Factors:
 - Seriousness of condition of the individual
 - Culpability of hospital or doctor
 - Evidence of other noncompliance with EMTALA
 - Financial condition
 - Nature and circumstances of violation



ENFORCEMENT

- Also reports to:
 - Office of Civil Rights
 - Department of Justice
 - Internal Revenue Service
 - Joint Commission



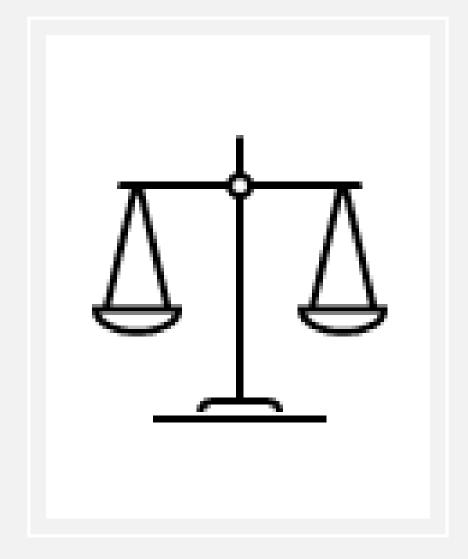
ENFORCEMENT

Issues in CMP reported cases since 2019

- 91% failed to provide MSE
- 78% failed to provide stabilizing treatment
- 17% improper or failure to accept transfers

OIG Reported CMP Cases:

- 2008-2024
 - Region 4 56% of all CMP cases
- 2024
 - Region 4 100% of all CMP cases



Questions?

Christopher L. Richard (334) 409-2233 crichard@GilpinGivhan.com GilpinGivhan.com



AlaHA Federal & State Health Law Update 2024

Health Legislation of Interest Cases of Interest

Presenter: Gregg B. Everett, Esq.

Date: September 25, 2024





AlaHA Federal & State Health Law Update 2024

Health Legislation of Interest Cases of Interest

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"We don't have the abridged version, but we do have the long-story-short edition."



Act No. 2024-384 (HB21)

Relating to Consumer Privacy. Genetic testing companies, requiring consent to release customers' genetic data.

Act No. 2024-80 (HB69)

Relating to controlled substances. Controlled Substances Prescription Database; access by certain representatives of a dentist authorized.

Act No. 2024-344 (HB73)

<u>Relating to ad valorem taxation</u>. Caps property tax increases at 7% each year, sunsetting in 2027, after 3 years of the program. The bill started with a much lower cap.



Act No. 2024-208 (HB77)

<u>Relating to newborn screening</u>. Will require newborn screenings to include the Recommended Uniform Screening Panel (RUSP) regulated by rules that would be developed by the Department of Public Health.

Act No. 2024-391 (HB131)

Relating to the Department of Revenue. Sales and use tax, durable medical equipment and medical supplies revised.

Act No. 2024-428 (HB144).

Relating to conditional appropriation for fiscal year ending September 30, 2024. The legislature passed over \$11 billion in education related spending for the 2024 legislative session. Among many things included in the ETF was a 2nd version of the Alabama Centers for Rural Healthcare Opportunities that was supported by \$18 million in funding.

Act No. 2024-192 (HB163)

Relating to the Alabama School of Healthcare Sciences in Demopolis. Establishes the Alabama School of Healthcare Sciences in Demopolis. The express intent in creating the school is to address the chronic healthcare workforce shortage in Alabama.

Act No. 2024-385 (HB232)

Relating to the practice of physical therapy. The legislation, which was a compromise between PTs and Doctors, removes the requirement to <u>have</u> a referral before seeing a PT if the PT has a doctorate or a master's with 10 years of experience.



Act No. 2024-214 (HB324)

Relating to emergency medical transport providers. Emergency medical transport providers, [tax] assessment period extended through the fiscal quarter starting July 1, 2024. Medicaid for ambulance payouts.

Act No. 2024-250 (HB234)

Relating to the Board of Nursing. Board of Nursing membership revised to include a certified registered nurse anesthetist.







Act No. 2024-437 (HB407)

Relating to income taxes. Ends the current overtime methodology from last year's bill (Act 2023-421) as of September 30, 2024, and then switches over to using the FLSA definition of "overtime" (which permits hospitals and residential care facilities to use a 14-day period for computing overtime under the "8 and 80" rule) from October 1, 2024, to June 30, 2025.



Act No. 2024-249 (SB25)

Relating to the Board of Nursing. Board of Nursing, authorized by rule to clarify scope of practice. Will give the Alabama Board of Nursing authority to formally recognize Nursing Support Technicians. This will serve as a recruiting aid for more than 2,000 vacancies in the state.

Act No. 2024-37 (SB15)

Relating to the Board of Pharmacy. Board of Pharmacy, compounding pharmacies, number of pharmacy technicians regulated by Board rule; may make changes.





"I'm OK with a non-compete, but this give-up-and-quit clause..."



Act No. 2024-355 (SB67)

Relating to the General Fund Budget. The General Fund for 2024 eclipsed \$3.3 billion in overall spending. Medicaid received \$955,138,325 (an increase of over \$90 million) from FY 2024 budget. The Department of Mental Health was budgeted \$237,965,500, which is an increase of \$24 million over the previous budget year.

Act No. 2024-114 (SB59)

<u>Relating to Public K-12 Education</u>. Public K-12 education; hands on instruction in CPR and the use of AEDs, required in health classes; State Board of Education, authorized to adopt rules.

Act No. 2024-414 (SB72)

<u>Relating to off-label medical treatment</u>. Off-label medication treatment; adverse action by occupational licensing board because of recommendation, prohibited; patient informed consent, required; cause of action, provided. – To help with Covid-19 mediation issues.

Act No. 2024-330 (SB105)

Relating to Civil Liability. Amending Alabama Code to limit the liability of members of any community emergency response team who perform emergency care at the scene of an accident or disaster. Amended the "Good Samaritan Law."



Act No. 2024-247 (SB128)

Relating to the State Committee of Public Health. Public Health Department State Board of Health, entity abolished and duties transferred to State Committee of Public Health; membership of committee revised; State Health Officer duties and qualifications. Abolishes the State Board of Health and shifts its responsibilities to the State committee of Public Health. The bill also changes the make-up of the Committee in a phased in approach over 3 years. In year one, it is comprised of 11 physicians appointed by MASA, one from each congressional district and four at large appointments, 1 physician appointed by the Alabama State Society of Anesthesiologists, and the 4 chairs of the four existing councils. In year two, 9 physicians appointed by MASA, one from each congressional district and two at large appointments.

Act No. 2024-247 (SB128) – Cont'd.

Chapter of the American College of OB/GYN, and the 4 chairs of the four existing councils. In the final year, and moving forward, the Committee will be comprised of one physician from each Congressional district appointed by MASA, 1 physician appointed at large by the Minority Physician section of MASA,1 physician appointed by the Alabama State Society of Anesthesiologists, 1 physician appointed by the Alabama Academy of Family Physicians, 1 physician appointed by the Alabama Chapter of the American College of OB/GYN, and the 4 chairs of the four existing councils of MASA. Starting with the next Health Officer, the Governor will choose from a list of names submitted by the Committee; and allows for the Governor, Lieutenant Governor, Speaker, and Pro Temp to petition the Committee to see if the State Health Officer should be disciplined or removed if at least two of the mentioned office holders jointly agree.

Act No. 2024-358 (SB135)



<u>Relating to Veterans Affairs</u>. Establishes the Veterans Mental Health Steering Committee, charged with developing a comprehensive plan to address Alabama veterans' behavioral health needs and to provide funding if money is available. – Task force in lieu for separate veterans Tx scheme.

Act No. 2024-20 (SB159)

Relating to in vitro fertilization. Civil and criminal immunity for death or damage to an embryo provided to persons when providing or receiving services related to IVF. – Waiting on a case.

Act No. 2024-366 (SB207)

Relating to multistate practice for dietitians. Creates new interstate compact to ease multistate practice for dietitians. Seven states must approve compact before it goes into effect. Eleven states are considering, including Alabama.

Act No. 2024-298 (SB208)

Relating to multistate practice by social workers. This Act provides that Alabama will join the interstate compact to ease multistate practice for social workers in regard to social work licensure.

Act No. 2024-300 (SB244).



Relating to licensure of physicians. Existing law states that an individual seeking a license to practice medicine or osteopathy must submit to a background check, but current law did not define the term expedited license. This bill provides that definition for "expedited license."

Act No. 2024-278 (SB270)



Relating to Government Administration, Public Record Requests. Sets a timeline for state agencies and governmental entities, which would include Health Care Authority Hospitals, to receive and respond to public records requests. There are now two types of records requests: (1) standard requests, which would take less than eight hours to process; and (2) a Time-Intensive request that would take more than eight hours to process the volume of material requested.

Act No. 2024-324

Medical Cannabis. Alabama removed the obligations placed upon the Alabama Department of Agriculture and Industries (AGI) that it originally added when the Alabama Legislature approved medical cannabis in Alabama. The Legislation places the primary responsibility for the regulation, licensure and enforcement of medical cannabis on the Alabama Medical Cannabis Commission (AMCC) in Alabama. The only obligation left for the AGI is to cooperate with the AMCC, if the AMCC seeks such cooperation. – Much litigation & more to come; blame it on the legislature.



Act No. 2024-308 (SB336)

Relating to research and development. Creates a new designation termed "Research and Development Corridors." This bill authorizes counties and Class I municipalities to authorize the incorporation of Research and Development Corridors within the county or the municipality, as a public corporation.

Developments & Trends in Health Care Law 2024



ALABAMA CASES
OF INTEREST
(2024)

WORKER'S COMPENSATION:

Dean Leader and William Durall v. Crescenio Pablo

2024 Ala. LEXIS 152; Case No. SC-2022-0736; Supreme Court of Alabama; August 30, 2024

Co-employee liability under the Worker's Comp. Law is not dead yet. Catalina Estillado suffered fatal injuries in a workplace accident while running a machine. Her husband brought a wrongful death claim in Jefferson County against two of her coworkers under Section 25-5-11, Code of Alabama 1975, which allows lawsuits against other employees in addition to or outside workers compensation law in limited situations. The trial court found for the plaintiff and awarded \$3,000,000. The Alabama Supreme Court reversed saying there was no proof that anyone willfully removed a safety guard or safety device.

Meeks v. Opp Health & Rehab., LLC

Case No. CL-2023-0239; Court of Civil Appeals of Alabama; January 31, 2024

In 2021, Meeks filed a Workers' Compensation Act complaint, alleging that while working in the line and scope of her duties as a certified nurse's assistant (CNA), she was exposed to and diagnosed with Covid-19 and suffered lung injuries that left her permanently disabled. The complaint did not state how she was exposed to Covid-19. The trial court entered a judgement in favor of the rehab center because even though Meeks's injuries were not alleged as an "occupational disease," it found that Covid-19 was not compensable as an occupational disease. The trial court did not address whether Covid-19 could be compensable as a nonaccidental injury. The Court of Civil Appeals noted that other states have allowed Covid-19 to proceed under workers' compensation claims. Thus, Meeks is entitled to pursue her claim that she contracted Covid-19 while working within the line and scope of her employment.

Victoryland v. Arnold Worker's Comp

Case No. CL-2023-0340; Court of Civil Appeals of Alabama; January 5, 2024

The employee filed a petition for workers' compensation benefits on account of a back injury she allegedly suffered while working for her employer, Victoryland. They reached an agreement, and Victoryland paid for the reasonably necessary medical treatment incurred by the employee for her back injury. Twelve years later, she was involved in a motor-vehicle accident and her doctor described those injuries as an aggravation of the old back injury. Victoryland filed a motion for relief from the judgment approving the workers' compensation settlement. The trial court denied the motion for relief. On appeal, the Court noted that the trial court's judgment contains no findings of fact or conclusions of law related to the issues. Thus, the judgment of the trial court is reversed and remanded.

JURISDICTION: STATE IMMUNITY

Ex parte Bd. of Trs. of the Univ. of Ala., et. al

2024 Ala. LEXIS 150; Supreme Court of Alabama; August 30, 2024;SC-2024-0210

An associate professor at UAB filed a complaint against "The University of Alabama at Birmingham" and eight fictitiously named defendants. The defendant later added the board and other parties in the litigation. The board sought to dismiss the complaint based on absolute immunity under Article 1, Section 14, of the Alabama Constitution of 2022. The trial court denied the motion and a mandamus petition followed. The court noted that Dr. Thompson's original complaint named only UAB and fictitious parties, which raised concerns about subject matter jurisdiction. The Supreme Court noted that actions against the state or its agencies, such as UAB are 'void ad initio'.

Defendant later added the board and other parties in the litigation. The board sought to dismiss the complaint based on absolute immunity under Article 1, Section 14, of the Alabama Constitution of 2022. The trial court denied the motion and a mandamus petition followed. The court noted that Dr. Thompson's original complaint named only UAB and fictitious parties, which raised concerns about subject matter jurisdiction. The Supreme Court noted that actions against the state or its agencies, such as UAB are 'void ad initio' and that later amendments to a void complaint do not establish jurisdiction. The court found that the original case was void from the beginning, dismissed the action for lack of subject matter jurisdiction and granted the mandamus petition.

McGilvray v. Perkins – ABME Case

2024 Ala. LEXIS 137; Supreme Court of Alabama; June 21, 2024; SC-202-0966

The Alabama Supreme Court found that a circuit court case was properly dismissed based upon res <u>judicata and constitutional provisions</u>. <u>McGilvray</u>, a former investigator for the Alabama Board of Medical Examiners (ABME) filed multiple lawsuits after being terminated from his position for emailing sexually explicit material to coworkers. Initially, McGilvray sued the executive director of the ABME and the CEO of the local government health insurance board and sought retiree health insurance benefits. The circuit court ruled against McGilvray ruling that his claims were time barred. Gary filed a second lawsuit against the Executive Director of the ABME and its board members, individually and officially. He sued for relief to receive health insurance benefits and for breach of contract. The ABME sought dismissal asserting defenses of res judicata and immunity. The circuit court granted the motion to dismiss, and this appeal followed. The Court upheld the dismissal.

ELDER ABUSE PROTECTION ORDERS

P.T.S. v. S.S.

2024 Ala. Civ. App. LEXIS 65; June 14, 2024; CL-2023-0673

The Court of Civil Appeals upheld an Elder Abuse protection order issued by the Lee County Circuit Court. After trial, a permanent protection order was issued under the "Elder Abuse Protection Order and Enforcement Act" (enacted in 2017). Under this act elder abuse can include financial exploitation. There was evidence that the stepson had withdrawn \$25,000 from a joint account with his stepmother without permission, when he had no ownership rights in the money.

MEDICAL MALPRACTICE In re Hare, Wynn, Newill & Newton, LLP

2024 Ala. LEXIS 118; May 24, 2024; SC-2023-0908

A medical malpractice case was initially filed in 2017 by David Leon Ashford and Hare Wynn on behalf Joel Wesly. Wesley had suffered from a stroke and the complaint alleged a breach of the standard of care. Several defendants were named, as well as fictitiously named defendants. In January 2022 Ashford and Hare Wynn withdrew from the case. The trial court later granted summary judgement for the named defendants. The plaintiffs then named additional defendants, and their claims were dismissed in January 2023, leaving only the fictitiously named defendants. In May 2023, the plaintiffs moved to amend their complaint to add Ashford and Hare Wynn alleging legal malpractice. Ashford and Hare Wynn moved to dismiss arguing that the January 23 order was a final judgement. They argued that the trial court had lost jurisdiction of the case. The trial court denied their motion and they filed a mandamus petition. The Supreme Court agreed the trial court had lost jurisdiction in January 2023.

Mottern v. Baptist Health Sys., Inc.

2024 Ala. LEXIS 154; September 6, 2024; SC-2024-0148

This was a wrongful death case arising out of a patient receiving contaminated Total Parenteral Nutrition (TPN). The TPN was outsourced to a compounding pharmacy (Meds IV) a vendor with whom Baptist had a longstanding relationship. In March 2011, there was a national shortage of amino acids, a key ingredient for TPN. Unbeknownst to Baptist, Meds IV began mixing their own amino acids. This practice took Meds IV from being a medium risk pharmacy to a high-risk pharmacy. When the TPN arrived at Baptist, a bacterium already contaminated it, Serratia *Marcescens*. A number of patients received the contaminated TPN and unfortunately nine died. This case involved one of them.

Two of the claims advanced by the plaintiff were products liability claims based upon breach of implied warranty and the "Alabama Extended Manufacturer's Doctrine." The hospital moved to strike those two counts as the plaintiff was seeking to impose strict liability (no need to prove negligence) on a hospital for providing a medicine developed by an outside entity that can only be provided to a patient based on a physician's prescription.

The judge dismissed all four of the plaintiff's claims and the plaintiff appealed to the Alabama Supreme Court. The Supreme Court reversed the trial court as to all four counts and sent the case back for further action. Three of the Justices voted to reverse the trial court and explained that no matter what type of claim is made in a medical malpractice case, the plaintiff must prove what is the standard of care and that the defendant breached the standard of care. Three other justices agreed with the result but would have used different rationales. Two of the justices dissented.

Mobile Infirmary Ass'n v. Fagerstrom

Case No. SC-2023-0355; Supreme Court of Alabama; November 17, 2023

Fagerstrom, now deceased, developed a tumor on her brain at age 85. The tumor was removed by Mobile Infirmary Medical Center (MIMC), but her recovery did not go well. She developed a pressure injury in her sacrum while at MIMC that progressed to a Stage 3 pressure ulcer. The plaintiff alleged that the nurses breached the standard of care and caused her pressure injury because she was not turned frequently enough. Eventually, while at another hospital, the ulcer developed to a Stage 4 pressure ulcer due to not being turned frequently enough, according to the plaintiff. Fagerstrom died three and one-half months after her brain surgery at MIMC. At trial, the plaintiff's expert testified that the defendants breached the standard of care and caused Fagerstrom to develop the ulcer which eventually caused sepsis that resulted in her death. The defendants, however, assert that the plaintiff failed to present sufficient evidence of proximate cause, and the claim should not have been submitted to a jury. They argued the opinion that Fagerstrom died from sepsis caused by the ulcer was based on mere speculation instead of "objective data." The testimony or brief for the plaintiff did not clearly explain how the vital signs showed that she died from sepsis. Their expert's opinion was based on the "typical progression and end result of the sort of infection Sylvia had." Moreover, experts for the defendant indicated that medical tests revealed plenty of objective vital signs that the plaintiff's expert was not aware of. The trial court ruled in favor of the estate of Fagerstrom. The Alabama Supreme Court reversed the judgment and remanded for the entry of a judgment as a matter of law in favor of the hospital because the <u>plaintiff</u> was required to present substantial evidence of causation.



"Do you mean like stat? Or stat stat?"

Springhill Hosp., Inc. v. West

Case No. SC-2022-0719; Supreme Court of Alabama; August 4, 2023

West cut the tip of his left thumb and had it surgically repaired at Springhill Hospital. His surgeon wrote an order for Percocet, and another order for up to four milligrams of a powerful opioid if Percocet failed to control the pain. He was given four milligrams of the opioid and then she administered an additional four milligrams two hours later. West was not monitored as ordered and was later found unresponsive and not breathing. The patient should have been identified as being at high-risk for opioid-induced respiratory depression and received respiratory monitoring. The hospital did not train the staff on how to protect patients from known fatal dangers of opioid-induced respiratory depression. An expert testified and said, "Well, if you were planning on killing somebody, that would be a dose that would be expected to do the job." The Alabama Supreme Court unanimously agreed that Springhill's conduct breached the standard of care. Moreover, it upheld the award of \$10 million in punitive damages because according to the Court given the degree of reprehensibility, the fact that West lost his life as a result of Springhill's conduct, the amounts of previously affirmed awards, the reality of inflation, the goal of punishing the defendant in conjunction with the apparent lack of economic impact on Springhill, and the cost incurred by his wife after six years of litigation.

ALABAMA MEDICAL CANNABIS

Ex parte Ala. Med. Cannabis Comm'n Petition for Writ of Mandamus

2024 Ala. Civ. App. LEXIS 94; August 23, 2024; CL-2024-0463

In this case the Alabama Medical Cannabis Commission (AMCC) petitioned the Court of Civil Appeals for a writ of mandamus ordering the Circuit Court to dismiss the case filed by Jemmstone Alabama, LLC. The petition looked to dismiss the case and to vacate a temporary restraining order. The Court granted the petition in part and denied the petition in part.

Jemmstone had applied for one of five integrated facility licenses. The AMCC was the sole defendant, however contained in the body of the complaint were also the individual members of the AMCC in their official capacities. The circuit court granted Jemmstone's motion to consolidate the action with other cases. On January 3, 2024, the Circuit Court entered a TRO in the master case. The AMCC argued that the case was void because the complaint only named the AMCC as a defendant.

The circuit court denied the motion to dismiss and decided that Jemmstone had properly named the members of the AMCC in the body of the complaint. Because of the manner of filing the Court of Civil Appels upheld the circuit' court decision to uphold the TRO. The Court of Civil appeals reversed the circuit court's denial of a motion to dismiss the AMCC based on sovereign immunity, because the individual AMCC Board members were named in the body of the complaint. However, it did not rule on the issue of whether naming the members of the AMCC in the body of the complaint was sufficient.

Ex parte Ala. Med. Cannabis Comm'n

2024 Ala. Civ. App. LEXIS 71; June 21, 2024; CL-2024-0073

This complaint was filed on June 22, 2023. The Alabama of Civil Appeals dismissed the petition for mandamus by the AMCC as being moot. The petition sought to compel the circuit court to vacate two orders. One order was to consolidate multiple cases under this case and the other was to allow the other numerous parties to intervene in the case. In this case Alabama Always commenced the master case by filing a complaint naming the AMCC as the lone defendant. The Court of Civil Appeals held that the complaint did not invoke the jurisdiction of the circuit court because of constitutional sovereign immunity.

Redbud Remedies, LLC v. Ala. Med. Cannabis Comm'n

2024 Ala. Civ. App. LEXIS 37; March 29, 20024; CL-2023-0352 and CL-2023-0697

In this appeal the Court of Civil Appeals dismissed two consolidated appeals of a judgement of the Montgomery County Circuit Court which denied a request for declaratory and injunctive relief in an action against the AMCC. The dispute in this case arose from Redbud's failure to file a timely application for a medical cannabis dispensary license and the refusal of the AMCC to accept a tardy application. Redbird argued that the delay in filing the application was caused by the negligence of the AMCC. The complaint named AMCC as the the sole defendant. The case went to trial and the circuit court ruled in favor of the AMCC. The appeal followed. The Court of Civil Appeals requested letter briefs on the question of sovereign jurisdiction in the appeals. The Court ruled that the complaint filed solely against the AMCC was nullity and void ab initio.

Verano Ala., LLC v. Ala. Med. Cannabis Comm'n

Ala. Civ. App. LEXIS 43; April 19, 2024; CL-2023-0831

On June 12, 2023, the AMCC awarded Verano Alabama, LLC an integrated facility license. On August 10, 2023, the AMCC rescinded the award. Verano appealed to the Montgomery Circuit Court which upheld the decision to resend Verano's award. Verano Appealed to the Court of Civil Appeals, which affirmed the circuit court's decision. The decision was based on a determination by the Court of Civil Appeals that Verano had waived an argument which required an automatic affirmance.

Ex parte Ala. Med. Cannabis Comm'n

Ala. Civ. App. LEXIS 70; June 21, 2024; CL-2024-0292

The AMCC petitioned the Court of Civil Appeals to issue a writ of mandamus ordering the circuit court to vacate an order allowing Alabama Always to file a petition for judicial review per Section 41-22-20 (d), Code of Alabama 1975. The Court denied the mandamus petition. The procedural history of this case is quite complex. Alabama Always had initially filed suit after it was not awarded an integrated facility license on any of the three dates such licenses were approved on January 3, 2024. After discovering there were jurisdictional problems, Alabama Always dismissed its complaint without prejudice. A new complaint was filed on January 9, 2024. On March 28,2024 Alabama Always filed a motion to dismiss all its pending actions, which the circuit court granted the motion on April 1, 2024. On April 3, 2024, filed a new complaint and a motion for an order allowing judicial review. On April 8, the AMCC filed an objection to the motion and the circuit court granted the motion for judicial review. The AMCC looked to have that order vacated in its petition, based upon the timeliness of Alabama Always request. The Court of Civil Appeals denied that petition

OPIOIDS:

Ex parte McKesson Corp

Case No. SC-2023-0289; Supreme Court of Alabama; December 22, 2023

The plaintiffs are thirty-four entities that own or operate hospitals in Alabama. They commenced actions against various manufacturers and distributors of prescription opioids. The plaintiffs allege that by flooding the communities withopioids, by pushing false narratives surrounding the safety of opioids, and by failing to take steps to prevent diversion of opioids, they have created an epidemic of misuse, abuse, addiction, and death. Moreover, the average cost of providing care for patients diagnosed with opioid use disorder is eight times higher than for those without opioid use disorder. They further alleged that the opioid pandemic constituted a continuous and abatable public nuisance. The trial court denied the defendants' motion to dismiss on statute-of-limitation grounds.

Developments & Trends in Health Care Law 2024



"Frankly, we're stumped. So, we'd like to try turning you off and then on again."

IN VITRO FERTILIZATION:

LePage v. Ctr. For Reprod. Med., P.C.

Case No. SC-2022-0515; Supreme Court of Alabama; February 16, 2024

The plaintiffs are parents of several embryonic children, each of whom was created through in vitro fertilization ("IVF) and, up until the incident giving rise to these cases, had been kept alive in a cryogenic nursery while they awaited implementation. Their embryos were placed in the cryogenic nursery and stored at extremely low temperatures.

The plaintiffs allege that the Center was obligated to keep the nursery secured and monitored at all times. A patient at the hospital wandered into the Center's fertility clinic through an unsecured doorway. The low temperatures burned the patient's hand, causing the patient to drop the embryos on the floor, killing them. The parents brought suit, asking the court to find a cryopreserved in vitro embryo to be a "child." The trial court granted motions dismissing the claims because the embryos in this case do not fit within the definition of child and therefore the loss could not give.

The plaintiffs allege that the Center was obligated to keep the nursery secured and monitored at all times. A patient at the hospital wandered into the Center's fertility clinic through an unsecured doorway. The low temperatures burned the patient's hand, causing the patient to drop the embryos on the floor, killing them. The parents brought suit, asking the court to find a cryopreserved in vitro embryo to be a "child." The trial court granted motions dismissing the claims because the embryos in this case do not fit within the definition of child and therefore the loss could not give rise to a wrongful-death claim.

The Alabama Supreme Court, on the other hand, ruled that the <u>Wrongful Death of a Minor Act</u> applies on its face <u>to all unborn children</u>, <u>without limitation</u>. It said unborn children are "children" under the Act, without exception based on developmental stage, physical location, or any other ancillary characteristics. Therefore, under the Act, the court concluded the wrongful death lawsuit against an IVF clinic employee whose actions resulted in the destruction of plaintiff's embryos was appropriate.

HOSPITAL LIEN:

Board of Trustees of the University of Alabama for its Division UAB v. Richards

Case No. CL-2023-0849; Court of Civil Appeals Alabama; June 7, 2024

An amended complaint added the VA, UAB, and UAHSF as defendants in a personal injury lawsuit. A second amended complaint noted a settlement agreement and requested determination of the funds' distribution, involving UAB. The estate of the plaintiff moved for a hearing on fund disbursement, outlining respective liens. UAB responded, asserting its hospital lien, and submitting relevant documents. The trial court issued a judgment ordering fund disbursement, outlining respective liens. UAB appealed, contending that the trial court lacked authority to reduce UAB's recovery below its reasonable charges because the funds were sufficient to satisfy its lien the Court held that the Alabama Code § 35-11-370 provided hospitals with an automatic lien for reasonable charges, subject to attorney's fees. The trial court's judgment, dividing settlement proceeds, violated the statute by limiting UAB's lien amount and barring its right to seek lien satisfaction post-judgment. The trial court's judgment was reversed, allowing UAB to pursue full satisfaction of its lien.

HOSPITAL IMMUNITY:

Ex Parte Triad of Ala., LLC

Case No. 2023-0395; Supreme Court of Alabama; January 26, 2024

Triad rendered infusion therapy to Covid-19 patients, and it directed the patients to enter through a preexisting entrance designated as the infusion entry. That entrance has been created in a 2014 construction project and neither the entrance nor the concrete lamp leading up to it has been modified since then. Askew was exiting the entrance and her foot caught the edge of the concrete ramp, causing her to fall and sustain serious injuries. She sued and Triad claimed an affirmative defense of civil immunity. The Supreme Court of Alabama held that the plain language of Code of Ala. §§ 6-5-794(a)(13) and 6-5-792(a) mandate Triad's entitlement to immunity.

Questions?

Gregg B. Everett, Esq.
Gilpin Givhan, PC
P. O. Drawer 4540 (36103-4540)
2660 EastChase Lane, Suite 300
Montgomery, Alabama 36117

Telephone: (334) 244-1111
Direct Dial: (334) 409-2228
Fax: (334) 244-1969
E-mail: geverett@GilpinGivhan.com

Web: GilpinGivhan.com
Follow us on Twitter! @GG_HealthLaw

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ALABAMA UPDATE: DO YOU KNOW WHAT HAPPENED IN 2024?

September 25, 2024

Gregg B. Everett, Esq. Gilpin Givhan, PC

Phone: (334) 409-2228

Email: <u>geverett@gilpingivhan.com</u>
[Full Version =Wldx # 1516507]

ePHI: Navigating HIPAA to Optimize EMR Access

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R. Taylor Steen
(334) 409-2231
tsteen@GilpinGivhan.com
Web: GilpinGivhan.com



Road Map

The Basics

Security Rule:
Administrative
Safeguards

Security Rule:
Physical
Safeguards

Security Rule: Technical Safeguards Privacy Rule Considerations
& Best
Practices

The Basics:

Federal Regulatory Framework

Security Rule Ensure confidentiality, integrity and availability of ePHI

Privacy Rule

Specifies limitations and requirements for uses and disclosures of ePHI

Security Rule: Safeguards

Administrative

 Internal policies and procedures to maintain the integrity, confidentiality and availability of ePHI

Physical

 Precautions taken to secure and protect physical locations where ePHI is stored and/or accessible

Technical

 Policies and procedures specific to the technology where ePHI is stored and/or accessed

A Deeper Look: Administrative Safeguards

Administrative actions, policies and procedures, to manage the selection, development, implementation, and maintenance of security measures to protect electronic protected health information and to manage the conduct of the covered entity's workforce in relation to the protection of that information

- 9 different standards:
 - Security Management Process
 - Assigned Security Responsibility
 - Workforce Security
 - Information Access Management
 - Security Awareness and Training
 - Security Incident Procedures
 - Contingency Plan
 - Evaluation
 - Business Associate Contracts and Other Arrangements

Security Management Process

Risk Analysis*

- Identify potential security risks
- Determine probability of occurrence and magnitude of risk

Risk Management*

- Identify and implement security measures to reduce risk
- Not "one size fits all"

Sanction Policy*

 Policies in place that outline consequences for failing to comply with security procedures & deter noncompliance

Information System Activity Review*

- Review activities to uncover impermissible uses or disclosures of ePHI
- Complement to the risk management strategy

Assigned Security Responsibility

Identify an individual to ensure that the organization complies with Security Rule

Can be the same individual as the Privacy Officer, but does not have to be

Workforce Security

Authorization and/or Supervision

- Determine whether an individual has the right to access information systems and ePHI
- Create checks and balances to make sure levels of access to ePHI are appropriate

Workforce Clearance Procedure

 Match job descriptions to level of access

Termination Procedures

 Restrict access or remove privileges as necessary

Information Access Management

Access Authorization

Complements the Workforce Clearance
Procedures Standard by ensuring users have
the right to access systems or information
based on job description and responsibilities

Multiple Layers:

- Is the user authorized to access information or a system?
- Who is authorized to grant access privileges?
- What is the process for granting privileges?

Access Establishment and Modification

Implement procedures to continually review access authorizations and privileges to workstations, programs, and information.

Complement to the Termination Procedures Standard

Security Awareness & Training

- 1. Security Reminders
 - Periodic security updates & re-trainings as necessary
 - Digital or printed updates to staff and users
- 2. Protection from Malicious Software
 - Viruses or other programs designed to interfere with the operations of your information system
 - Frequently found in email attachments
- 3. Log-in monitoring
 - Inappropriate or unsuccessful log-in attempts
 - Document and log suspicious attempts
- 4. Password Management
 - Train staff and users on safeguarding ePHI

Security Incident Procedures

Response & Reporting*

Develop procedures to identify, report, and respond to suspected or known security incidents, and mitigate risk exposure and harmful effects

Security Incident: The attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system

Contingency Plan

Data Backup Plan*

- How will you create backup files for ePHI?
- Must be exact copies

Disaster Recovery Plan*

 How will you retrieve ePHI in the event the original is no longer accessible or data is lost?

Emergency Mode Operation Plan*

 How will you access and protect security of ePHI during an emergency?

Testing & Revision Procedures

 Make sure contingency plan is effective and meets the needs of the organization

Applications and Data Criticality

• Identify software applications in use and prioritize importance for data backup, recovery, etc. for continuing operations in an emergency

Evaluation

Perform a periodic technical and nontechnical evaluation, based initially upon the standards implemented under this rule and subsequently, in response to environmental or operations changes affecting the security of electronic protected health information, that establishes the extent to which an entity's security policies and procedures meet the requirements of the Security Rule

In other words...

Look at your plan addressing the Security Rule Safeguards and make sure everything is working together as intended.

Reviews should be periodic and ongoing

A Deeper Look: Physical Safeguards

Physical measures, policies and procedures, and procedures to protect a covered entity's electronic information systems and related buildings and equipment, from natural and environmental hazards, and unauthorized intrusion.

- 4 different standards:
 - Facility Access Controls
 - Workstation Use
 - Workstation Security
 - Device and Media Controls

Facility Access Controls

1. Contingency Operations

- Physical security measures activated in the event a contingency plan is in operation
- Make sure that facility is accessible, in a manner that maintains security of ePHI, to allow for data restoration

2. Facility Security Plan

- Make sure your facility is protected from unauthorized physical access and tampering
- Document the use of physical access controls

3. Access Control and Validation Procedures

- Role-based controls and validation procedures
- Align with the facility security plan

4. Maintenance Records

Document maintenance and changes to physical portions of the building providing security measures

Workstation Use & Workstation Security

Workstation Use

Make sure workstations are being use appropriately and only for authorized purposes

Improper use could increase risks for a security incident

Workstation Security

How are workstations physically protected from use by unauthorized users?

Effective procedures depend on the size and structure of an organization

Device & Media Controls

Disposal*

Any devices
 containing ePHI
 must be unusable
 and/or
 inaccessible

Media Re-Use*

- Alternative to disposal
- Make sure existing ePHI is removed before re-using

Accountability

 Document movements of hardware and media that contain ePHI

Data Backup and Storage

- Similar to Data Backup Plan Administrative Safeguard
- Make sure there is a retrievable, exact copy of ePHI

A Deeper Look: Technical Safeguards

The technology and the policy and procedures for its use that protect electronic protected health information and control access to it

- 5 different standards:
 - Access Control
 - Audit Controls
 - Integrity
 - Person or Entity Authentication
 - Transmission Security

Access Control

Unique User Identification*

Unique identifier assigned per user to track user activity

Emergency Access
Procedure*

 Instruct users on ways to gain access to ePHI in the event of an emergency

Automatic Logoff

Automatic log-off after period of inactivity

Encryption and Decryption

Encrypt ePHI when sending to another authorized party

Audit Controls

- Implement hardware, software, and/or procedures to record and examine activity in your information software, and access and use of ePHI
- Functionality may already be baked into your information system through audit reporting
- Important to evaluate whether audit controls align with policies and procedures developed under the Information System Activity Review Standard (Administrative Safeguard)

Integrity

Integrity is defined as "the property that data or information have not been altered or destroyed in an unauthorized manner."

Mechanisms to
Authenticate Electronic
Protected Health
Information

Data can be compromised by both technical and non-technical sources, so develop security procedures to maintain integrity taking all factors into account.

Person or Entity Authentication

 Make sure individuals and entities accessing ePHI are who they claim to be

- Methods of ID verification could include:
 - Password or PIN;
 - Smart card, token, or key;
 - Biometric ID.

Transmission Security

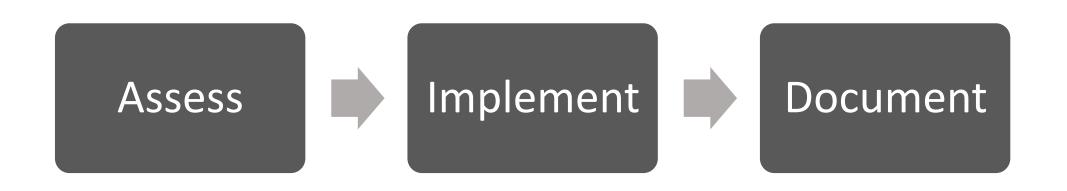
Integrity Controls

- Make sure information is not improperly modified during or after transmission
- Discuss with IT professionals, vendors, etc.

Encryption

- Various types of encryption technology available on the market
- Sending party and receiving party must use the same or compatible technology to make transfers effectively

Three Steps to Implementing Successful Safeguards



The Privacy Rule

Covered Entity

Its own treatment, payment and health care operations purposes

Health Care Provider

Treatment activities

Granting Access to Third-Parties: Key Considerations

- Verify that access is appropriate:
 - consistent with facility policies and procedures in place under the Security Rule.
 - Have a treatment relationship with the patient (Privacy Rule).
- Limit access to the minimum necessary under the circumstances.
 - Probably not a best practice to grant global system access.
- System security does not stop at the facility doors.
 - Make sure you have ways to maintain security of your information systems if they are being accessed off-site.

Granting Access to Third-Parties: Key Considerations

- Require adherence to hospital policies and procedures
 - Have training programs in-place to educate on facility policies and procedures.
 - Review third-party's policies and procedures to ensure information is protected appropriately
- Audit system use
 - Make sure third-parties are accessing the information system appropriately
 - Take corrective action when necessary
- Document!
 - The Security Rule requires covered entities to consistently document decision rationales, responses, and implementing actions.

Access Responsibly!

R. Taylor Steen
(334) 409-2231
tsteen@GilpinGivhan.com
Web: GilpinGivhan.com
Follow us on Twitter! @GG_HealthLaw



ALABAMA HOSPITAL ASSOCIATION

FEDERAL & STATE HEALTH LAW UPDATE 2024

(Held September 25, 2024)

--- Virtual ---

ALABAMA HEALTH LEGISLATION AND CASES OF INTEREST

(in 2023/2024)

Gregg B. Everett, Esq. Gilpin Givhan, PC geverett@gilpingivhan.com

LEGISLATION

1. Act No. 2024-384 (HB21)

<u>Relating to Consumer Privacy</u>. Genetic testing companies, requiring consent to release customers' genetic data.

EFFECTIVE DATE: 10/01/2024.

2. Act No. 2024-80 (HB69).

<u>Relating to controlled substances</u>. Controlled Substances Prescription Database; access by certain representatives of a dentist authorized.

EFFECTIVE DATE: 10/01/2024.

3. Act No. 2024-89 (HB70).

<u>Relating to the Board of Dental Examiners of Alabama</u>. Will allow for a special volunteer license for eligible dentists and dental hygienists to practice under the supervision of a licensed dentist during an organized charity event. The bill would also increase the registration fee for hygienists and establish one for the volunteer license.

EFFECTIVE DATE: 04/17/2024.

4. Act No. 2024-344 (HB73).

<u>Relating to ad valorem taxation</u>. Caps property tax increases at 7% each year, sunsetting in 2027, after 3 years of the program. The bill started with a much lower cap, but several associations, working with local governments and schools, were able to negotiate the increased cap and a sunset provision in the bill.

EFFECTIVE DATE: 10/01/2024.

5. Act No. 2024-208 (HB77).

<u>Relating to newborn screening</u>. Will require newborn screenings to include the Recommended Uniform Screening Panel (RUSP) regulated by rules that would be developed by the Department of Public Health following passage of the bill. The bill gives a three-year timeline to update the screenings.

EFFECTIVE DATE: 10/01/2024.

6. Act No. 2024-81 (HB 126). Relating to individuals with sensory needs and invisible disabilities. Fire-protection personnel and emergency medical services personnel, annual training related to individuals with sensory needs and certain disabilities, required. EFFECTIVE DATE: 01/01/2025.

7. Act No. 2024-391 (HB131).

<u>Relating to the Department of Revenue</u>. Sales and use tax, durable medical equipment and medical supplies revised.

EFFECTIVE DATE: Immediately (Enacted May 16, 2024).

8. Act No. 2024-428 (HB144).

Relating to conditional appropriation for fiscal year ending September 30, 2024. The legislature passed over \$11 billion in education related spending for the 2024 legislative session. Among many things included in the ETF was a 2nd version of the Alabama Centers for Rural Healthcare Opportunities that was supported by \$18 million in funding. This partnership between hospitals and the Alabama Community College System produced over a dozen new hospital-based education programs in 2023.

EFFECTIVE DATE: Immediately (Signed by Governor on May 16, 2024).

9. Act No. 2024-192 (HB163).

Relating to the Alabama School of Healthcare Sciences in Demopolis. Alabama School of Healthcare Sciences Bill. Establishes the Alabama School of Healthcare Sciences in Demopolis. The express intent in creating the school is to address the chronic healthcare workforce shortage in Alabama. It should help with all aspects of the healthcare workforce, from physicians and nurses to lab and x-ray technicians, pharmacists, and other healthcare professionals. Funding from the school comes from a philanthropic donation and money appropriated from the Education Trust Fund.

EFFECTIVE DATE: Approved by Governor May 3, 2024. Has gone into effect.

10. Act No. 2024-385 (HB232).

Relating to the practice of physical therapy. Scope of practice of physical therapists. Expands the scope of practice for physical therapist (PT). The legislation, which was a compromise between PTs and Doctors, removes the requirement to have a referral before seeing a PT if the PT has a doctorate or a master's with 10 years of experience.

EFFECTIVE DATE: 06/01/2024.

11. Act No. 2024-250 (HB234).

<u>Relating to the Board of Nursing</u>. Board of Nursing membership revised to include a certified registered nurse anesthetist. Revises the membership of the Board of Nursing to include a permanent seat for a Certified Nurse Anesthetist.

EFFECTIVE DATE: 10/01/2024.

12. Act No. 2024-392 (HB290).

Relating to sudden cardiac arrest. Public and non-public schools, sudden cardiac arrest, required to develop and implement cardiac emergency response plan. EFFECTIVE DATE: 10/01/2024.

13. Act No. 2024-214 (HB324).

<u>Relating to emergency medical transport providers</u>. Emergency medical transport providers, [tax] assessment period extended through the fiscal quarter starting July 1, 2024. EFFECTIVE DATE: 06/01/2024.

14. Act No. 2024-302 (HB346).

Relating to taxation. Establishes the Alabama Workforce Housing Tax Credit. This bill was a part of a larger package pushed by the Governor to help get more participation in the workforce. It provides a state tax credit for developers of low-income housing that aligns with the federal low-income housing tax credit. The state tax credits are subject to a relatively low aggregate cap (\$5,000 over 10-year credit periods).

EFFECTIVE DATE: 10/01/2024.

15. Act No. 2024-303 (HB358).

<u>Relating to childcare and workforce development</u>. Relating to childcare and workforce development; to establish the employer tax credit and childcare provider tax credit; to make legislative findings.

EFFECTIVE DATE: 01/01/2025.

16. Act No. 2024-437 (HB407).

Relating to income taxes. Ends the current overtime methodology from last year's bill (Act 2023-421) as of September 30, 2024, and then switches over to using the FLSA definition of "overtime" (which permits hospitals and residential care facilities to use a 14-day period for computing overtime under the "8 and 80" rule) from October 1, 2024, to June 30, 2025. EFFECTIVE DATE: 10/01/2024.

17. Act No. 2024-426 (HB479).

Relating to Supplemental Appropriations from the Opioid Treatment and Abatement Fund. Supplemental appropriations from the Opioid Treatment and Abatement Fund for the fiscal year ending September 30, 2023.

EFFECTIVE DATE: Immediately (Enacted May 17, 2024).

18. Act No. 2024-37 (SB15).

<u>Relating to the Board of Pharmacy</u>. Board of Pharmacy, compounding pharmacies, number of pharmacy technicians regulated by Board rule; may make changes. EFFECTIVE DATE: June 1, 2024.

19. Act No. 2024-249 (SB25).

Relating to the Board of Nursing. Board of Nursing, authorized by rule to clarify scope of practice. Will give the Alabama Board of Nursing authority to formally recognize Nursing Support Technicians. The goal is for facilities to move existing staff and align the multitude of titles to the extent possible. This will serve as a recruiting aid for more than 2,000 vacancies in the state.

EFFECTIVE DATE: 10/01/2024.

20. Act No. 2024-40 (SB26).

<u>Relating to the Board of Nursing</u>. Board of Nursing, technical change of term "nurse educator" to "advanced practice nurse" in the Alabama Loan-Repayment Program for Advanced Practice Nursing.

EFFECTIVE DATE: Immediately (Enacted April 4, 2024).

21. Act No. 2024-1 (SB28).

<u>Relating to Houston County Healthcare Authority Board</u>. Regarding appointments to the Houston County Healthcare Authority Board. A constitutional amendment applying only to Houston County regarding appointments to the Houston County Healthcare Authority Board. The County must approve the proposed constitutional amendment by vote of the public.

22. Act No. 2024-114 (SB59).

<u>Relating to Public K-12 Education</u>. Public K-12 education; hands on instruction in CPR and the use of AEDs, required in health classes; State Board of Education, authorized to adopt rules.

EFFECTIVE DATE: 10/01/2024.

23. Act No. 2024-355 (SB67).

Relating to the General Fund Budget. The General Fund for 2024 eclipsed \$3.3 billion in overall spending. Medicaid received \$955,138,325 (an increase of over \$90 million) from FY 2024 budget. The Medicaid budget also included the annual \$15,000,000 payment for hospital inpatient and outpatient services, as well as \$7,000,000 for inpatient and outpatient services in rural hospitals. The Department of Mental Health was budgeted \$237,965,500, which is an increase of \$24 million over the previous budget year.

EFFECTIVE DATE: 10/01/2024.

24. Act No. 2024-414 (SB72).

<u>Relating to off-label medical treatment</u>. Off-label medication treatment; adverse action by occupational licensing board because of recommendation, prohibited; patient informed consent, required; cause of action, provided.

EFFECTIVE DATE: 10/01/2024.

25. Act No. 2024-39 (SB100).

<u>Relating to Education Policy</u>. Establishing the Medical Scholarship Awards Fund. Moves the existing Board of Medical Scholarship Awards Fund under the State Treasurer. EFFECTIVE DATE: 10/01/2024.

26. Act No. 2024-330 (SB105).

<u>Relating to Civil Liability</u>. Amending Alabama Code to limit the liability of members of any community emergency response team who perform emergency care at the scene of an accident or disaster. Amended the "Good Samaritan Law."

EFFECTIVE DATE: 10/01/2024.

27. Act No. 2024-247 (SB128).

Relating to the State Committee of Public Health. Public Health Department State Board of Health, entity abolished and duties transferred to State Committee of Public Health; membership of committee revised; State Health Officer duties and qualifications. Abolishes the State Board of Health and shifts its responsibilities to the State committee of Public Health. The bill also changes the make-up of the Committee in a phased in approach over 3 years. In year one, it is comprised of 11 physicians appointed by MASA, one from each congressional district and four at large appointments, 1 physician appointed by the Alabama State Society of Anesthesiologists, and the 4 chairs of the four existing councils. In year two, 9 physicians appointed by MASA, one from each congressional district and two at large appointments, 1 physician appointed by the Alabama State Society of Anesthesiologists, 1 physician appointed by the Alabama Academy of Family Physicians, 1 physician appointed by the Alabama Chapter of the American College of OB/GYN, and the 4 chairs of the four existing councils. In the final year, and moving forward, the Committee will be comprised of one physician from each Congressional district appointed by MASA, 1 physician appointed at large by the Minority Physician section of MASA, 1 physician appointed by the Alabama State Society of Anesthesiologists, 1 physician appointed by the Alabama Academy of Family Physicians, 1 physician appointed by the Alabama Chapter of the American College of OB/GYN, and the 4 chairs of the four existing councils. Starting with the next Health Officer, the Governor will choose from a list of names submitted by the Committee; and allows for the Governor, Lieutenant Governor, Speaker, and Pro Temp to petition the Committee to see if the State Health Officer should be disciplined or removed if at least two of the mentioned office holders jointly agree.

EFFECTIVE DATE: 10/01/2024.

28. Act No. 2024-235 (SB131).

Relating to the Department of Mental Health. Alabama Behavioral Analyst Licensing Board continued pursuant to Sunset Law until October 1, 2026.

EFFECTIVE DATE: 06/01/2024.

29. Act No. 2024-358 (SB135).

<u>Relating to Veterans Affairs</u>. Veterans, to establish and operate a statewide integrated health care system dedicated to Alabama veterans and their immediate family members. Establishes the Veterans Mental Health Steering Committee, charged with developing a comprehensive plan to address Alabama veterans' behavioral health needs and to provide funding if money is available.

EFFECTIVE DATE: 06/01/2024.

30. Act No. 2024-20 (SB159).

<u>Relating to in vitro fertilization</u>. Civil and criminal immunity for death or damage to an embryo provided to persons when providing or receiving services related to IVF. EFFECTIVE DATE: Immediately (was enacted March 7, 2024).

31. Act No. 2024-366 (SB207).

<u>Relating to multistate practice for dietitians</u>. Creates new interstate compact to ease multistate practice for dietitians. Seven states must approve compact before it goes into effect. Eleven states are considering, including Alabama.

EFFECTIVE DATE: 10/01/2024.

32. Act No. 2024-298 (SB208).

<u>Relating to multistate practice by social workers</u>. This Act provides that Alabama will join the interstate compact to ease multistate practice for social workers in regard to social work licensure.

EFFECTIVE DATE: 10/01/2024.

33. Act No. 2024-193 (SB240).

<u>Relating to the Alabama Department of Mental Health</u>. Expands category for involuntary commitment to include individuals with "co-occurring substance use disorders." EFFECTIVE DATE: 01/01/2025.

34. Act No. 2024-300 (SB244).

Relating to licensure of physicians. Existing law states that an individual seeking a license to practice medicine or osteopathy must submit to a background check, but current law did not define the term expedited license. This bill provides that definition for "expedited license," which would mean "a license to practice medicine, a certificate of qualification, a certification of eligibility for a license to practice medicine, or a certification of eligibility for a certificate of qualification that is issued in an accelerated manner."

EFFECTIVE DATE: 06/01/2024.

35. Act No. 2024-115 (SB247).

Relating to the Alabama Department of Workforce. Changes the name of the Alabama Department of Labor to the Alabama Department of Workforce, which would be run by the Secretary of Workforce. The bill would move certain state and federal workforce programs, staff, and assets from the Department of Commerce to the newly named Department of Workforce. The bill also forms a single Workforce Pathways Division, all of the department's workforce development functions and workforce funding mechanisms, including the Alabama Workforce Board; the regional workforce boards; Alabama Career Center System; the Alabama Office of Apprenticeship; Alabama STEM Council; the Office of Education and Workforce Statistics; WIOA programs; the Alabama Committee on Credentialing and Career Pathways; the federal Jobs for Veterans State Grants Program; and the federal Work Opportunity Tax Credit, among several others.

EFFECTIVE DATE: 10/01/2024.

36. Act No. 2024-309 (SB252).

Relating to the Alabama Growth Alliance. Creation of the Alabama Growth Alliance (the "Alliance") as a public corporation designed to enhance the long-term viability of the State's economic development successes through public-private partnerships and other private-sector involvement in long-term strategic planning. The Alliance would be governed by a board of directors comprised of eleven members, including: Governor, Secretary of Commerce, Speaker, Pro Tem of Senate, Chair of Innovate Alabama, and six at-large members appointed by the Governor from the private sector with experience related to economic development.

EFFECTIVE DATE: 10/01/2024.

37. Act No. 2024-126 (SB253).

Relating to the Alabama Workforce Pathways Act. Creates a new workforce pathways diploma for K-12 students. Students in the new workforce pathway would only have to complete two math credits and two science credits, instead of the four math and four science credits currently required. In place of the math and science credits, students who do not plan to attend college or technical school may earn credits in technical and career related courses.

EFFECTIVE DATE: 10/01/2024.

38. Act No. 2024-278 (SB270).

Relating to Government Administration, Public Records. Sets a timeline for state agencies and governmental entities, which would include Health Care Authority Hospitals, to receive and respond to public records requests. There are now two types of records requests: (1) standard requests, which would take less than eight hours to process; and (2) a Time-Intensive request that would take more than eight hours to process the volume of material requested. Both requests would specify fifteen days to provide a substantive response and, if it is a Time-Intensive request, the public officer would be required to disclose to the requester the fees involved with the request. If the requester chooses to proceed, the public officer must provide a response to the request within 45 days. EFFECTIVE DATE: 10/01/2024.

39. Act No. 2024-332 (SB283).

Relating to first responders. Currently, a driver must exercise care and avoid a collision with pedestrians. This bill adds first responders to the requirement. It will also require a driver to yield the right of way to any first responder, the same standard as a pedestrian. EFFECTIVE DATE: 10/01/2024.

40. Act No. 2024-308 (SB336).

Relating to research and development. Creates a new designation termed "Research and Development Corridors." This bill authorizes counties and Class I municipalities to authorize the incorporation of Research and Development Corridors within the county or the municipality, as a public corporation for the purpose of undertaking activities and acquiring property, using public revenues for the establishment, benefit, and support of qualified enterprises within the corridor. These organizations would be exempt from many fees and taxes otherwise imposed.

EFFECTIVE DATE: Immediately (enacted May 9, 2024).

[END OF LEGISLATION PORTION]

CASES

WORKER'S COMPENSATION:

1. Dean Leader and William Durall v. Crescenio Pablo

2024 Ala. LEXIS 152 Case No. SC-2022-0736 Supreme Court of Alabama August 30, 2024

Co-employee liability under the Worker's Comp. Law is not dead yet. Catalina Estillado suffered fatal injuries in a workplace accident while running a machine. She was employed by ABC polymer industries, LLC. Her husband brought a wrongful death claim in Jefferson County against two of her coworkers under Section 25-5-11, Code of Alabama 1975, which allows lawsuits against other employees in addition to or outside workers compensation law in limited situations. The trial court found for the plaintiff and awarded \$3,000,000. The Alabama Supreme Court reversed saying there was no proof that anyone willfully removed a safety guard or safety device.

2. Meeks v. Opp Health & Rehab., LLC

Case No. CL-2023-0239 Court of Civil Appeals of Alabama January 31, 2024

In 2021, Meeks filed a Workers' Compensation Act complaint, alleging that while working in the line and scope of her duties as a certified nurse's assistant (CNA), she was exposed to and diagnosed with Covid-19 and suffered lung injuries that left her permanently disabled. The complaint did not state how she was exposed to Covid-19. The trial court entered judgement in favor of the rehab center because even though Meeks's injuries were not alleged as an "occupational disease," it found that Covid-19 was not compensable as an occupational disease. The trial court did not address whether Covid-19 could be compensable as a nonaccidental injury.

The Court of Civil Appeals noted that other states have allowed Covid-19 exposures to proceed under workers' compensation claims. Thus, Meeks is entitled to pursue her claim that she contracted Covid-19 while working within the line and scope of her employment and the performance of her duties as an employee exposed her to a danger or risk materially in excess of that to which people are normally exposed to in everyday lives.

3. Victoryland v. Arnold

Case No. CL-2023-0340 Court of Civil Appeals of Alabama January 5, 2024

The employee filed a petition for workers' compensation benefits on account of a back injury she allegedly suffered while working for her employer, Victoryland. They reached an agreement, and Victoryland paid for the reasonably necessary medical treatment incurred by the employee for her back injury. Twelve years later, she was involved in a motor-vehicle accident and her doctor described those injuries as an aggravation of the old back injury. Victoryland filed a motion for relief from the judgment approving the workers' compensation settlement, arguing it should not be responsible for providing future medical care. The trial court denied the motion for relief. On appeal, the Court noted that the trial court's judgment contains no findings of fact or conclusions of law related to the issues. Thus, the judgment of the trial court is reversed and remanded for the trial court to enter findings of fact and conclusions of law in compliance with the law.

JURISDICTION:

4. Bd. of Trs. of the Univ. of Ala. v. Univ. of Ala. at Birmingham

2024 Ala. LEXIS 150 Supreme Court of Alabama August 30, 2024 SC-2024-0210

An associate professor at UAB filed a complaint against "The University of Alabama at Birmingham" and eight fictitiously named defendants. The defendant later added the board and other parties in the litigation. The board sought to dismiss the complaint based on absolute immunity under Article 1, Section 14, of the Alabama Constitution of 2022. The trial court denied the motion and a mandamus petition followed. The court noted that Dr. Thompson's original complaint named only UAB and fictitious parties, which raised concerns about subject matter jurisdiction. The Supreme Court noted that actions against the state or its agencies, such as UAB are 'void ad initio' and that later amendments to a void complaint do not establish jurisdiction. The court found that the original case was void from the beginning, dismissed the action for lack of subject matter jurisdiction and granted the mandamus petition.

5. McGilvray v. Perkins

2024 Ala. LEXIS 137 Supreme Court of Alabama June 21, 2024 SC-202-0966

The Alabama Supreme Court found that a circuit court case was properly dismissed based upon res judicata and constitutional provisions. McGilvray, a former investigator for the Alabama Board of Medical Examiners (ABME) filed multiple lawsuits after being terminated from his

position for emailing sexually explicit material to coworkers. Initially, McGilvray sued the executive director of the ABME and the CEO of the local government health insurance board and sought retiree health insurance benefits. The circuit court ruled against McGilvray ruling that his claims were time barred. Gary filed a second lawsuit against the Executive Director of the ABME and its board members, individually and officially. He sued for relief to receive health insurance benefits and for breach of contract. The ABME sought dismissal asserting defenses of res judicata and immunity. The circuit court granted the motion to dismiss, and this appeal followed.

ELDER ABUSE PROTECTION ORDERS

6. P.T.S. v. S.S.

2024 Ala. Civ. App. LEXIS 65 June 14, 2024 CL-2023-0673

The Court of Civil Appeals upheld an Elder Abuse protection order issued by the Lee County Circuit Court. There was an earlier ex parte order which was dissolved following a motion by the stepson. After trial, a permanent protection order was issued under the "Elder Abuse Protection Order and Enforcement Act" (enacted in 2017). Under this act elder abuse can include financial exploitation. There was evidence that the stepson had withdrawn \$25,000 from a joint account with his stepmother without permission, when he had no ownership rights in the money.

MEDICAL MALPRACTICE

7. In re Hare, Wynn, Newill & Newton, LLP 2024 Ala. LEXIS 118 May 24, 2024 SC-2023-0908

A medical malpractice case was initially filed in 2017 by David Leon Ashford and Hare Wynn on behalf Joel Wesly. Wesley had suffered from a stroke and the complaint alleged a breach of the standard of care. Several defendants were named, as well as fictitiously named defendants. In January 2022 Ashford and Hare Wynn withdrew from the case. The trial court later granted summary judgement for the named defendants. The plaintiffs then named additional defendants, and their claims were dismissed in January 2023, leaving only the fictitiously named defendants. In May 2023, the plaintiffs moved to amend their complaint to add Ashford and Hare Wynn alleging legal malpractice. Ashford and Hare Wynn moved to dismiss arguing that the January 23 order was a final judgement. They argued that the trial court had lost jurisdiction of the case. The trial court denied their motion and they filed a mandamus petition. The Supreme Court agreed the trial court had lost jurisdiction in January 2023.

8. Mottern v. Baptist Health Sys., Inc.

2024 Ala. LEXIS 154 September 6, 2024 SC-2024-0148

This was a wrongful death case arising out of a patient receiving contaminated Total Parenteral Nutrition (TPN). The TPN was outsourced to a compounding pharmacy (Meds IV) a vendor with whom Baptist had a longstanding relationship. In March 2011, there was a national shortage of amino acids, a key ingredient for TPN. Unbeknownst to Baptist, Meds IV began mixing their own amino acids. This practice took Meds IV from being a medium risk pharmacy to a high-risk pharmacy. When the TPN arrived at Baptist, a bacterium already contaminated it, Serratia *Marcescens*. A number of patients received the contaminated TPN and unfortunately nine died. This case involved one of them.

Two of the claims advanced by the plaintiff were products liability claims based upon breach of implied warranty and the "Alabama Extended Manufacturer's Doctrine." The hospital moved to strike those two counts as the plaintiff was seeking to impose strict liability (no need to prove negligence) on a hospital for providing a medicine developed by an outside entity that can only be provided to a patient based on a physician's prescription. The judge dismissed all four of the plaintiff's claims and the plaintiff appealed to the Alabama Supreme Court. The Supreme Court reversed the trial court as to all four counts and sent the case back for further action. Three of the Justices voted to reverse the trial court and explained that no matter what type of claim is made in a medical malpractice case, the plaintiff must prove what is the standard of care and that the defendant breached the standard of care. Three other justices agreed with the result but would have used different rationales. Two of the justices dissented.

9. Mobile Infirmary Ass'n v. Fagerstrom

Case No. SC-2023-0355 Supreme Court of Alabama November 17, 2023

Fagerstrom, now deceased, developed a tumor on her brain at age 85. The tumor was removed by Mobile Infirmary Medical Center (MIMC), but her recovery did not go well. She developed a pressure injury in her sacrum while at MIMC that progressed to a Stage 3 pressure ulcer. The plaintiff alleged that the nurses breached the standard of care and caused her pressure injury because she was not turned frequently enough. Eventually, while at another hospital, the ulcer developed to a Stage 4 pressure ulcer due to not being turned frequently enough, according to the plaintiff. Fagerstrom died three and one-half months after her brain surgery at MIMC. At trial, the plaintiff's expert testified that the defendants breached the standard of care and caused Fagerstrom to develop the ulcer which eventually caused sepsis that resulted in her death. The defendants, however, assert that the plaintiff failed to present sufficient evidence of proximate cause, and the claim should not have been submitted to a jury. They argued the opinion that Fagerstrom died from sepsis caused by the ulcer was based on mere speculation instead of "objective data." The testimony or brief for the plaintiff did not clearly explain how the vital signs showed that she died from sepsis. Their expert's opinion was based on the "typical progression and end result of the sort of infection Sylvia had." Moreover, experts for the defendant indicated

that medical tests revealed plenty of objective vital signs that the plaintiff's expert was not aware of. The trial court ruled in favor of the estate of Fagerstrom. The Alabama Supreme Court reversed the judgment and remanded for the entry of a judgment as a matter of law in favor of the hospital because the plaintiff was required to present substantial evidence of causation.

10. Springhill Hosp., Inc. v. West

Case No. SC-2022-0719 Supreme Court of Alabama August 4, 2023

West cut the tip of his left thumb and had it surgically repaired at Springhill Hospital. His surgeon wrote an order for Percocet, and another order for up to four milligrams of a powerful opioid if Percocet failed to control the pain. He was given four milligrams of the opioid and then she administered an additional four milligrams two hours later. West was not monitored as ordered and was later found unresponsive and not breathing. The patient should have been identified as being at high-risk for opioid-induced respiratory depression and received respiratory monitoring. The hospital did not train the staff on how to protect patients from known fatal dangers of opioid-induced respiratory depression. An expert testified and said, "Well, if you were planning on killing somebody, that would be a dose that would be expected to do the job." The Alabama Supreme Court unanimously agreed that Springhill's conduct breached the standard of care. Moreover, it upheld the award of \$10 million in punitive damages because according to the Court given the degree of reprehensibility, the fact that West lost his life as a result of Springhill's conduct, the amounts of previously affirmed awards, the reality of inflation, the goal of punishing the defendant in conjunction with the apparent lack of economic impact on Springhill, and the cost incurred by his wife after six years of litigation.

ALABAMA MEDICAL CANNABIS

11. Ex parte Ala. Med. Cannabis Comm'n Petition for Writ of Mandamus

2024 Ala. Civ. App. LEXIS 94 August 23, 2024 CL-2024-0463

In this case the Alabama Medical Cannabis Commission (AMCC) petitioned the Court of Civil Appeals for a writ of mandamus ordering the Circuit Court to dismiss the case filed by Jemmstone Alabama, LLC. The petition looked to dismiss the case and to vacate a temporary restraining order. The Court granted the petition in part and denied the petition in part. Jemmstone had applied for one of five integrated facility licenses. The AMCC was the sole defendant, however contained in the body of the complaint were also the individual members of the AMCC in their official capacities. The circuit court granted Jemmstone's motion to consolidate the action with other cases. On January 3, 2024, the Circuit Court entered a TRO in the master case. The AMCC argued that the case was void because the complaint only named the AMCC as a defendant. The circuit court denied the motion to dismiss and decided that Jemmstone had properly named the members of the AMCC in the body of the complaint. Because of the manner of filing the Court of Civil Appels upheld the circuit' court decision to uphold the TRO. The Court of Civil appeals reversed the circuit court's denial of a motion to dismiss the AMCC based on sovereign immunity,

because the individual AMCC Board members were named in the body of the complaint. However, it did not rule on the issue of whether naming the members of the AMCC in the body of the complaint was sufficient.

12. Ex parte Ala. Med. Cannabis Comm'n

2024 Ala. Civ. App. LEXIS 71 June 21, 2024 CL-2024-0073

This complaint was filed on June 22, 2023. The Alabama of Civil Appeals dismissed the petition for mandamus by the AMCC as being moot. The petition sought to compel the circuit court to vacate two orders. One order was to consolidate multiple cases under this case and the other was to allow the other numerous parties to intervene in the case. In this case Alabama Always commenced the master case by filing a complaint naming the AMCC as the lone defendant. The Court of Civil Appeals held that the complaint did not invoke the jurisdiction of the circuit court because of constitutional sovereign immunity.

13. Redbud Remedies, LLC v. Ala. Med. Cannabis Comm'n

2024 Ala. Civ. App. LEXIS 37 March 29, 20024 CL-2023-0352 and CL-2023-0697

In this appeal the Court of Civil Appeals dismissed two consolidated appeals of a judgement of the Montgomery County Circuit Court which denied a request for declaratory and injunctive relief in an action against the AMCC. The dispute in this case arose from Redbud's failure to file a timely application for a medical cannabis dispensary license and the refusal of the AMCC to accept a tardy application. Redbird argued that the delay in filing the application was caused by the negligence of the AMCC. The complaint named the AMCC as the sole defendant. The case went to trial and the circuit court ruled in favor of the AMCC. The appeal followed. The Court of Civil Appeals requested letter briefs on the question of sovereign jurisdiction in the appeals. The Court ruled that the complaint filed solely against the AMCC was nullity and void ab initio.

14. Verano Ala., LLC v. Ala. Med. Cannabis Comm'n

Ala. Civ. App. LEXIS 43 April 19, 2024 CL-2023-0831

On June 12, 2023, the AMCC awarded Verano Alabama, LLC an integrated facility license. On August 10, 2023, the AMCC rescinded the award. Verano appealed to the Montgomery Circuit Court which upheld the decision to resend Verano's award. Verano Appealed to the Court of Civil Appeals, which affirmed the circuit court's decision. The decision was based on a determination by the Court of Civil Appeals that Verano had waived an argument which required an automatic affirmance.

15. Ex parte Ala. Med. Cannabis Comm'n

Ala. Civ. App. LEXIS 70 June 21, 2024 CL-2024-0292

The AMCC petitioned the Court of Civil Appeals to issue a writ of mandamus ordering the circuit court to vacate an order allowing Alabama Always to file a petition for judicial review per Section 41-22-20 (d), Code of Alabama 1975. The Court denied the mandamus petition. The procedural history of this case is quite complex. Alabama Always had initially filed suit after it was not awarded an integrated facility license on any of the three dates such licenses were approved on January 3, 2024. After discovering there were jurisdictional problems, Alabama Always dismissed its complaint without prejudice. A new complaint was filed on January 9, 2024. On March 28,2024 Alabama Always filed a motion to dismiss all its pending actions, which the circuit court granted the motion on April 1, 2024. On April 3, 2024, filed a new complaint and a motion for an order allowing judicial review. On April 8, the AMCC filed an objection to the motion and the circuit court granted the motion for judicial review. The AMCC looked to have that order vacated in its petition, based upon the timeliness of Alabama Always request. The Court of Civil Appeals denied that petition.

OPIOIDS:

16. Ex parte McKesson Corp

Case No. SC-2023-0289 Supreme Court of Alabama December 22, 2023

The plaintiffs are thirty-four entities that own or operate hospitals in Alabama. They commenced actions against various manufacturers and distributors of prescription opioids. The plaintiffs allege that by flooding the communities with opioids, by pushing false narratives surrounding the safety of opioids, and by failing to take steps to prevent diversion of opioids, they have created an epidemic of misuse, abuse, addiction, and death. Moreover, the average cost of providing care for patients diagnosed with opioid use disorder is eight times higher than for those without opioid use disorder. They further alleged that the opioid pandemic constituted a continuous and abatable public nuisance. The trial court denied the defendants' motion to dismiss on statute-of-limitation grounds. Thus, they are not entitled to an order dismissing the plaintiffs' claims against them. Whether the plaintiffs will be able to present proof that the defendants engaged in misconduct was not the issue before the Supreme Court. Instead, it denied writ on the statute-of-limitation grounds.

IN VITRO FERTILIZATION:

17. LePage v. Ctr. For Reprod. Med., P.C.

Case No. SC-2022-0515 Supreme Court of Alabama February 16, 2024

The plaintiffs are parents of several embryonic children, each of whom was created through in vitro fertilization ("IVF) and, up until the incident giving rise to these cases, had been kept alive in a cryogenic nursery while they awaited implementation. Their embryos were placed in the cryogenic nursery and stored at extremely low temperatures. The plaintiffs allege that the Center was obligated to keep the nursery secured and monitored at all times. A patient at the hospital wandered into the Center's fertility clinic through an unsecured doorway. The low temperatures burned the patient's hand, causing the patient to drop the embryos on the floor, killing them. The parents brought suit, asking the court to find a cryopreserved in vitro embryo to be a "child." The trial court granted motions dismissing the claims because the embryos in this case do not fit within the definition of child and therefore the loss could not give rise to a wrongful-death claim. The Alabama Supreme Court, on the other hand, ruled that the Wrongful Death of a Minor Act applies on its face to all unborn children, without limitation. It said unborn children are "children" under the Act, without exception based on developmental stage, physical location, or any other ancillary characteristics. Therefore, under the Act, the court concluded the wrongful death lawsuit against an IVF clinic employee whose actions resulted in the destruction of plaintiff's embryos was appropriate.

HOSPITAL LIEN:

18. Board of Trustees of the University of Alabama for its Division UAB v. Richards

Case No. CL-2023-0849 Court of Civil Appeals Alabama June 7, 2024

An amended complaint added the VA, UAB, and UAHSF as defendants in a personal injury lawsuit. A second amended complaint noted a settlement agreement and requested determination of the funds' distribution, involving UAB. The estate of the plaintiff moved for a hearing on fund disbursement, outlining respective liens. UAB responded, asserting its hospital lien, and submitting relevant documents. The trial court issued a judgment ordering fund disbursement, outlining respective liens. UAB appealed, contending that the trial court lacked authority to reduce UAB's recovery below its reasonable charges because the funds were sufficient to satisfy its lien. The Court held that the Alabama Code § 35-11-370 provided hospitals with an automatic lien for reasonable charges, subject to attorney's fees. The trial court's judgment, dividing settlement proceeds, violated the statute by limiting UAB's lien amount and barring its right to seek lien satisfaction post-judgment. The trial court's judgment was reversed, allowing UAB to pursue full satisfaction of its lien.

HOSPITAL IMMUNITY:

19. Ex Parte Triad of Ala., LLC

Case No. 2023-0395 Supreme Court of Alabama January 26, 2024

Triad rendered infusion therapy to Covid-19 patients, and it directed the patients to enter through a preexisting entrance designated as the infusion entry. That entrance has been created in a 2014 construction project and neither the entrance nor the concrete lamp leading up to it has been modified since then. Askew was exiting the entrance and her foot caught the edge of the concrete ramp, causing her to fall and sustain serious injuries. She sued and Triad claimed an affirmative defense of civil immunity. The Supreme Court of Alabama held that the plain language of Code of Ala. §§ 6-5-794(a)(13) and 6-5-792(a) mandate Triad's entitlement to immunity.

DEFAMATION:

20. Watters vs. Birmingham Hematology & Oncology Assocs., LLC

Case No. SC-2022-0907 Supreme Court of Alabama October 13, 2023

Plaintiffs were a nurse and office administrator at Alabama Oncology's St. Vincent's location. There was considerable discord among the staff and the working atmosphere was toxic. Physicians at Alabama Oncology received an anonymous letter setting forth allegations of wrongdoing, including medical malpractice. The executive director contacted legal counsel for advice, and he informed the physicians and staff that an investigation would be occurring at their office. After the investigation, counsel presented the findings to Alabama Oncology's partners and executive management team. Following the presentation, the partnership ultimately voted 13-2 in favor of terminating the plaintiff's employment. The plaintiffs brought a defamation suit and the trial court determined that the alleged defamatory communications occurred between Alabama Oncology's employees, and thus, were not considered to be publications. Even if there had been a publication, the internal communications among management personnel were protected by the absolute litigation privilege. The plaintiffs challenged the summary judgment. The Alabama Supreme Court found that since some of the allegations involved medical malpractice, the legal counsel's presentation of the information that it gathered from its investigation and the employees' receipt of that information was a "legitimate business task" of Alabama Oncology. Summary judgment was affirmed.

ARBITRATION:

21. Jamison v. SNH AL Crimson Tenant, Inc.

Case No. SC-2023-0861 Supreme Court of Alabama May 17, 2024

In July 2022, the Jamisons brought a lawsuit alleging negligent medical care John received while a resident at an assisted-living facility. According to the Jamisons, the assisted living breached the standard of care by conspiring to misdiagnose, overmedicate, and wrongfully certify John as eligible for hospice care. On March 1, 2023, the assisted living facility moved to compel arbitration based on a signed agreement. The Jamisons filed an objection to the motion to compel. The circuit court granted the motion to compel arbitration. The Supreme Court of Alabama noted it could not conclude that the materials appended to the motion to compel arbitration amounted to substantial evidence of the existence to a valid arbitration agreement signed by a representative with authority to bind the Jamisons. Thus, because the circuit court deprived the Jamisons of the opportunity to respond to new materials attached to one of the assisted living's replies, the order compelling arbitration should be reversed pending further development of the factual record.

DAYCARE:

22. Pooh Bear Acad. V. Ala. Dep't of Hum. Res

Case No. CL-2022-0949 Court of Civil Appeals of Alabama November 17, 2023

A licensing consultant that DHR had assigned to Pooh Bear Academy's (PBA) licenserenewal application inspected the day-care center in connection with PBA's license-renewal request. The consultant reported seventy deficiencies, including that an employee had a substantiated child abuse and neglect (CAN) report. Most of the deficiencies were corrected, and PBA was given a 90-day compliance deadline to correct all the deficiencies. After reviewing the records with DHR, the consultant informed PBA that the CAN report could not be waived, and the deficiency would stand until the employee was terminated or a cleared CAN report was received. PBA purportedly fired the employee, but DHR caught her at PBA one day. Moreover, more deficiencies were reported as time progressed. PBA eventually requested a new DHR consultant, which was denied. At subsequent inspection attempts, DHR consultants were denied access to the building. After informing PBA that their license would not be renewed unless they complied with inspections, DHR hand delivered a letter suspending PBA's day-care-center license, effective immediately. The suspension letter noted that the suspension was necessary because of the imminent danger of the health, safety, and welfare of the children. An ALJ upheld the suspension, and the circuit court affirmed. PBA timely filed an appeal. The Civil Appeals Court noted it cannot remedy the temporary suspension of PBA's day-care-center license and dismissed the appeal as moot.

23. Deaton v. S. Highland Child Dev. Ctr., Inc.

Case No. SC-2023-0484 Supreme Court of Alabama June 7, 2024

A divorced father, who did not have custody of his children, took his child to daycare and partially completed the child's pre-admission record. The mother was not listed as the child's biological mother and the daycare did not inquire why the mother was not listed. When the mother found out, she called the daycare to inform them she was the custodial parent, and the daycare representative hung up the phone. The daycare did not do anything to verify the information provided or to contact a state agency. The mother and her attorney went to the daycare and personally served them with the court order appointing her as the custodial parent. The daycare's executive director took the child out of the back door and gave the child to the father.

The mother sued the daycare, alleging negligence, wantonness, the tort of outrage/intentional infliction of emotional distress, and conspiracy. The circuit court set a hearing to resolve amended complaints, but the mother filed this appeal to the Supreme Court. For her negligence claim, she asserts that the daycare had a general duty of reasonable supervision towards children. The daycare argues that they are governed by DHR standards and that it could not violate the "approved pickup list" rule. The Court agreed with DHR on this point and also said the negligence claim fails on res ipsa grounds too.

For the tort of outrage claim, a plaintiff must establish that the conduct was (1) intentional or reckless, (2) was extreme and outrageous, and (3) caused emotional distress so severe that no reasonable person could be expected to endure it. The conduct must be regarded as atrocious and utterly intolerable in a civilized society. The mother argues that the actions of the daycare were tantamount to a kidnapping. The court said she does cite some persuasive authority, but those authorities are all lawsuits against the other parent, not a daycare. Interestingly, the court does say the mother is correct in that this tort may be applicable in more situations than was previously thought. However, the Court had to affirm the trial court's judgment on any grounds supported by the record.

[END OF CASES]

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