Health Law Update for Hospitals
(2019)

Alabama Hospital Association

Presented by:
Gilpin Givhan, PC
September 19, 2019

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A PROFESSIONAL CORPORATION

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No representation is made that the quality of legal services to be preformed is greater than the quality of legal services performed by other lawyers.

John advises hospitals, physicians and other health care providers on compliance, contracting, joint ventures, recruiting, acquisitions and other matters. John blends an operational understanding of the health care industry with the technical elements of health law practice and is a frequent lecturer on compliance issues such as tax-exempt health care entities, Stark, fraud and abuse, and EMTALA. Outside the health care area, John assists clients with business organization structures and complex financings.

Prior to joining the firm, John served as law clerk (1980-1981) to the Honorable Robert E. Varner of the U. S. District Court, Middle District of Alabama; adjunct Professor in Taxation, Jones School of Law (1985-1989); and general counsel for a large medical center (1981-1983). Outside the office, John is an avid fly fisherman, an elder in his church and has served his denomination in numerous capacities.

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Gregg is a member of the Health Care practice group. Gregg works extensively on trade association compliance matters, Medicare and Medicaid matters, health insurance issues, Joint Commission compliance, quality assurance, physician recruitment and retention, and risk management issues. In addition, he advises on regulatory compliance matters under EMTALA, and the Stark law, and other issues affecting both non-profit and for-profit health care entities. Gregg also advises hospitals across the state on legislative issues. He served as General Counsel and Senior Vice President for the Alabama Hospital Association (AlaHA) 1994 – 2011. For eight years before joining AlaHa, Gregg was the General Counsel for a large hospital where he participated in forging positive relationships between hospitals and physicians as well as developing successful partnerships with administrators and the medical staff. Gregg is a frequent lecturer (locally, statewide, and nationally) on a wide array of health care issues.

Before joining a health service organization, Gregg was law clerk to Senior Associate Justice Hugh Maddox of the Alabama Supreme Court. He is an Adjunct Professor in the Graduate School at Auburn University at Montgomery. He is on the Board of the Gift of Life Foundation.

Brent regularly advises and works with healthcare and other business clients in regard to a variety of matters, including privacy and information security; mergers and acquisitions and other complex business transactions; real estate matters including retail and commercial leasing, property sales and acquisitions and real estate development matters; and various other business planning matters, including tax, corporate and business succession. Brent is a frequent publisher and speaker on these and other issues. He has recently published articles and presented for the Medical Association of the State of Alabama, the American Health Lawyers Association, the Society of Human Resource Management Professionals and the Alabama Hospital Association.

Chris advises hospitals, physician practices, and other health care providers on a variety of regulatory, transactional, and policy issues. He regularly counsels clients on matters regarding regulatory compliance, medical staff privileges and credentialing, billing and payment, contracting, operations, employment, and legislative affairs. Chris' philosophy on delivering exceptional client representation combines a thorough attention to detail with a comprehensive understanding of both the relevant law and the operational realities of his clients' businesses. Chris also speaks and writes frequently about health care regulatory issues.

Federal & State
Health Law Update
For Hospitals

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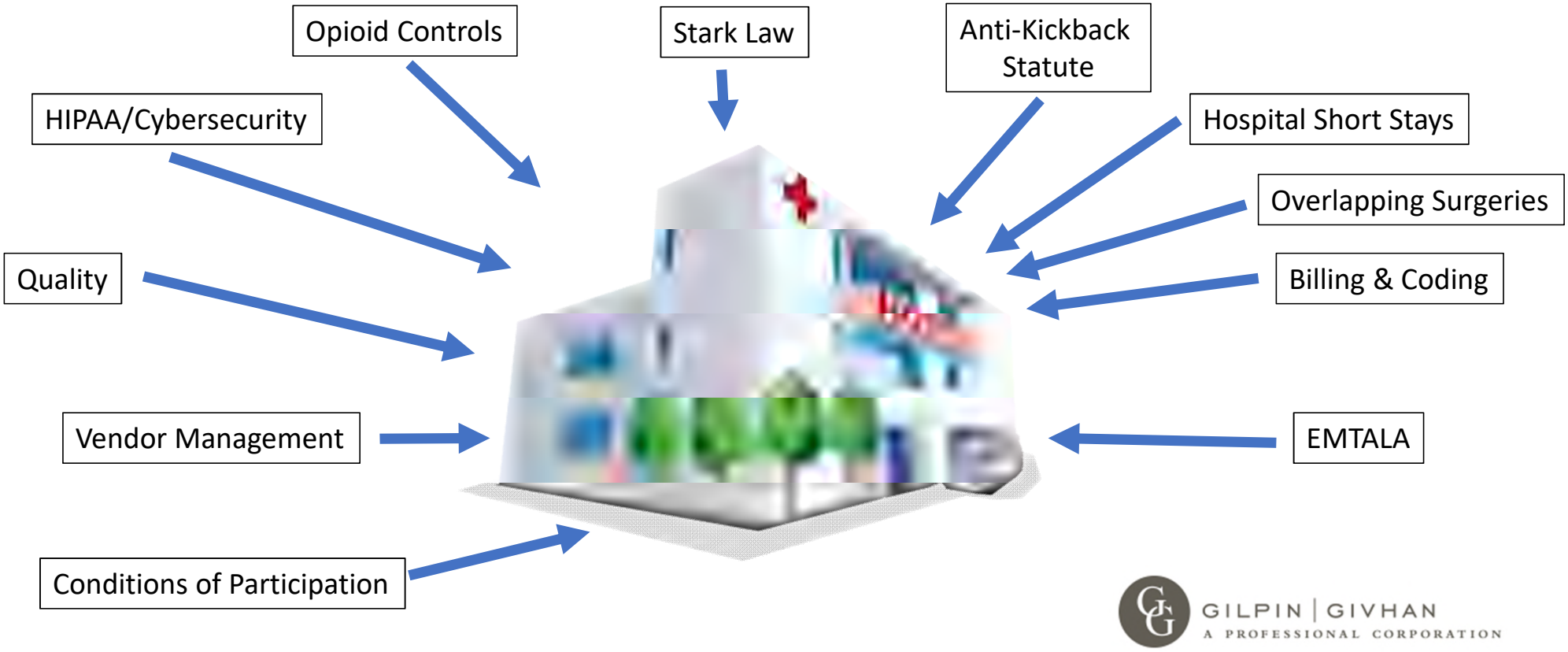

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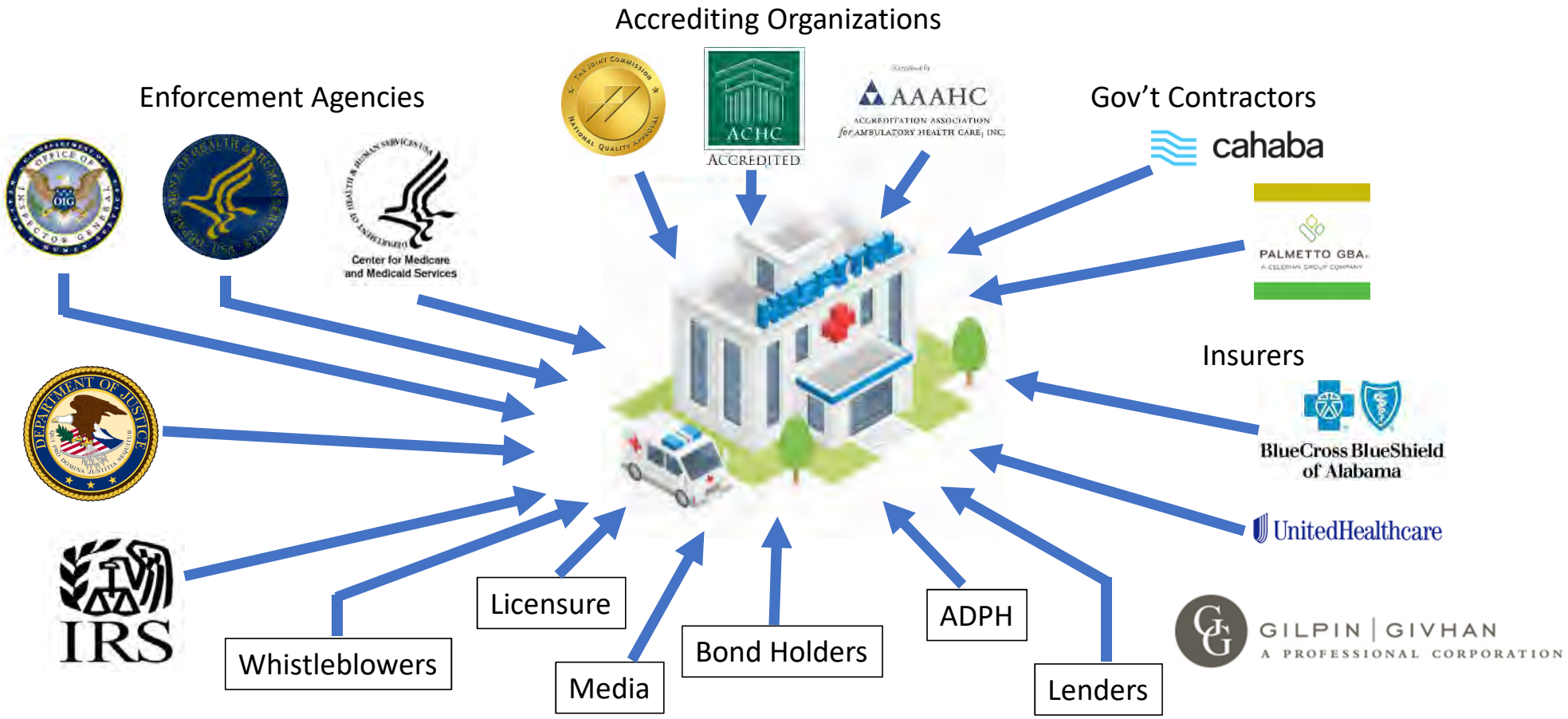

Health Law Update For Hospitals

- OIG/DOJ Update
- HIPAA - Privacy and Security Update
- Current Issues for Hospitals
- Alabama Update
- Opioid Fallout Update
- OIG Work Plan

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Annual Health Law Update For Hospitals

OIG/DOJ YEAR IN REVIEW

(Patterns and Trends)

September 19, 2019
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OIG/DOJ Year In Review

- FY 2018 Government Summary
- DOJ/OIG Cases and Settlements
- EKRA - Kickbacks
- Policy Shifts and Changes Impacting Enforcement

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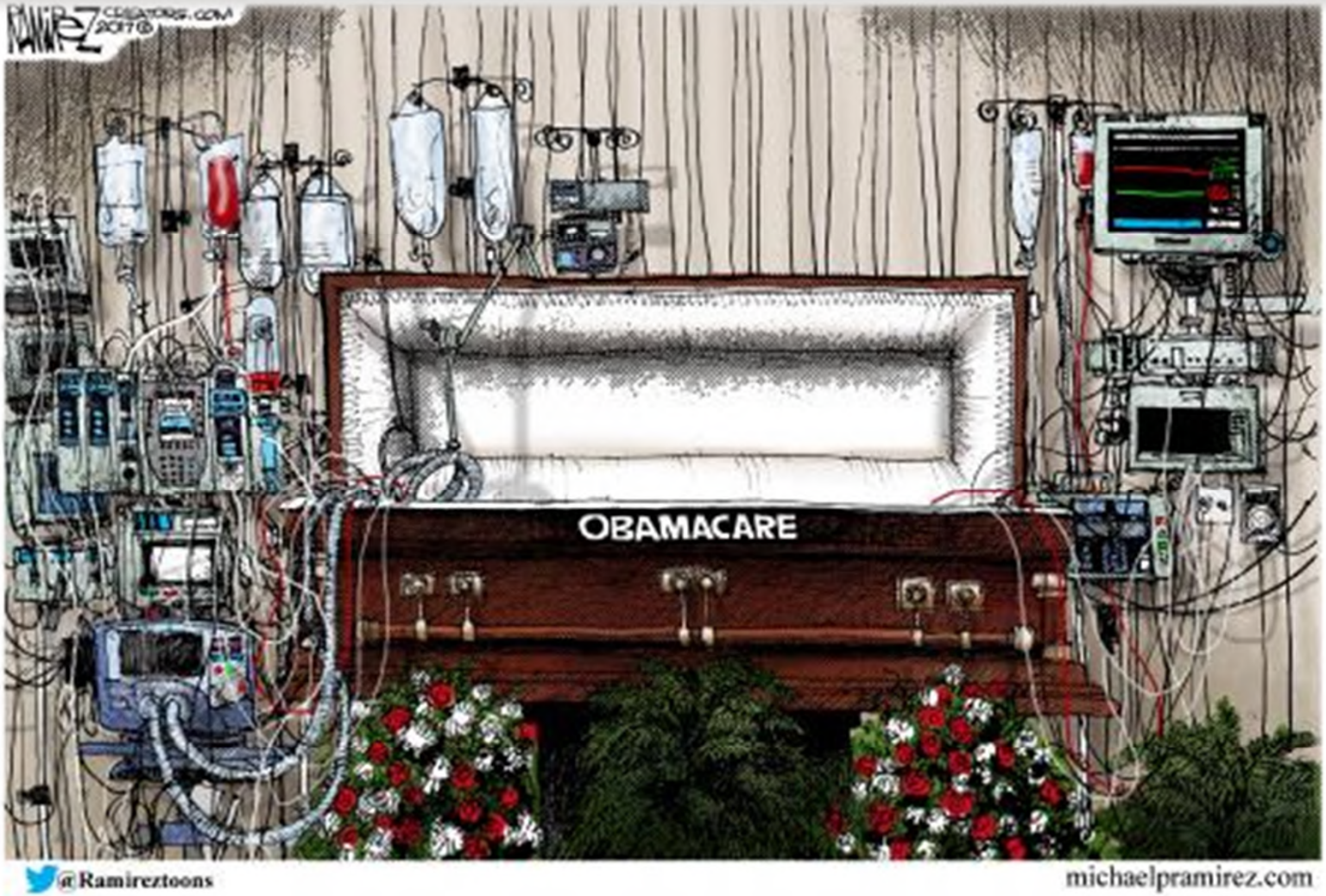
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OIG/DOJ Year In Review

- 2018 Another One in the Record Books

Health Care Fraud Recoveries		
Fiscal Year	Total Fraud Recoveries	Health Care Fraud Recoveries
2013	$3.8 Billion	$2.6 Billion
2014	$5.69 Billion	$2.3 Billion
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

*Ninth consecutive year DOJ's civil health care fraud settlements and judgments were at or around $2 Billion.

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OIG/DOJ Year In Review

- 2018 Another One in the Record Books
  - Medicaid Fraud Control Units
    - Medicaid provider fraud and patient abuse and neglect
    - 1,503 Criminal fraud convictions (’17 - 1528)
    - 810 Civil settlements/judgements (’17 - 961)
    - 974 Individuals and entities excluded (’17 - 1,181)
    - $859 Million recovered (‘17 1.8 Billion)
    - $2.92 for each enforcement $1 spent (’17 - 6.52)
  - Alabama MFCU:
    - 59 investigations; 11 charged/indicted; 18 convictions; $7,827,694 recoveries
    - Expenditures $1,315,157

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OIG/DOJ Year In Review

<u>Continuing Trends</u>:

- Whistleblower Cases (Granston Memo)
- Fraud recovery efforts still result in significant return on investment
- Continuing focus on physicians, executives, owners and those behind the fraudulent action

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OIG/DOJ Year In Review

CASES AND SETTLEMENTS

OIG/DOJ Year In Review

Still having an impact……

Escobar Case

- Implied certification – submitting a claim for payment implies that facility has followed every regulation imposed by the program.
- Implied compliance with all regulatory requirements
- Supreme Court (Thomas): Fashioned middle ground.
- Key is "materiality" of the regulation. Look to whether the government paid the claim and whether provider knew the government viewed the reg as material.
- Implied Certification now a viable avenue for FCA litigation

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OIG/DOJ Year In Review

Post *Escobar*

Cases are pretty evenly split:

Found to be "Material"

- Delay in physician certification for necessary medical services
- Failure to comply with Stark exception requirements
- Medical clinics managed by "excluded individual"
- Hospital failure to supervise services provided by residents

Found to be "Immaterial"

- Risk label error known by FDA
- Medicare paid for device knowing misrepresentations
- Allegations of substandard food and discrimination

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OIG/DOJ Year In Review

Post *Escobar*

- Take Aways:
  1. Materiality is a rigorous but achievable standard to satisfy
  2. Government decision to pay a claim despite actual knowledge of noncompliance with a requirement can be a strong indicator the violation is not material

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OIG/DOJ Year In Review

Nationwide Brace Scam

- Largest health care fraud FBI/OIG investigation 4/19
  - 80 search warrants in 17 Fed Districts
  - 24 Defendants (CEOs, COOs etc)
  - 5 Telemedicine companies
  - Dozens of DME companies
  - 3 licensed professionals
  - Alleged $1.2 billion in loss to Medicare
  - Back, shoulder, wrist and knee braces that are not medically necessary
  - FBI, OIG, IRS, etc
- CMS Action
  - Administrative action against 130 DME Companies
  - $1.7 Billion in claims/ over $900 million

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OIG/DOJ Year In Review

OIG/DOJ Year In Review

More Lab Schemes

- Health Diagnostics Lab and Singulex (SC)
  - Paid remuneration to physicians "disguised as processing and handling fees" ($10-17)
  - Also physicians ordered medically unnecessary tests
  - Jury Trial – **Warning!!!**
  - Judgement: **$114,148,661**
- Lots of fall-out

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OIG/DOJ Year In Review

Other Lab Schemes

Health Diagnostics Lab and Singulex Fall Out

"Processing and handling" payments:

- Missouri – 2 physicians & practice $98,880 (5/19)
- New Jersey – Physician/practice $311,626 (8/19)
- Florida Practice $102,204 6/19
- Colorado Practice & Physicians $152,554 4/18
- S Carolina Practice and Physician $68,500 8/18
- S Carolina Practice & Physician $97,784 9/18
- Texas Practice & Physician $54,860 8/18
- Andalusia, Alabama Physician $505,030 4/18

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OIG/DOJ Year In Review

Rehab and Skilled Nursing

- **Encompass Health Corp**
  - $48 Million FCA settlement (6/19)
  - False diagnosis of “disuse myopathy”.
  - No clinical evidence to support the diagnosis
  - Result of qui tam – whistle blower

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OIG/DOJ Year In Review

Rehab and Skilled Nursing

- Kindred Healthcare legacy
- **Sava Senior Care** (Tenn)
  - DOJ has intervened in Whistleblower case
  - Alleged therapy services that were not medically reasonable and necessary
  - Operates more than 200 Nursing Homes in 23 states
  - Atlanta based
  - $1.4 billion in Medicare reimbursement
  - Government has asked for treble damages
  - Trial Scheduled December 2018- stayed for settlement talks

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OIG/DOJ Year In Review

<u>Rehab and Skilled Nursing</u>

- Kindred Healthcare legacy
- **<u>Eastern Shore Rehab & Health Care</u>** (Daphne, Al)
  - Ultra high RUG levels
  - Assigned all new Medicare patients all 3 types of therapy and extremely long sessions daily
  - Without regard to medical necessity
  - Established unattainable goals to ensure continuing the therapy
  - $10 million settlement
  - Qui tam with government intervention
  - 2 consulting firms and 9 affiliated SNFs in Ala & Fla.

7/2018 Southern SNF Management case S District Alabama

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OIG/DOJ Year In Review

Rehab and Skilled Nursing

- **US vs Esformes, et al (Miami)** (4/19)
  - **$1 Billion dollar** health care fraud case
  - Owns 7 SNFs and 9 Assisted Living Facilities
  - Scheme:
    - Bribe Drs to refer to SNF
    - After maximum 100 days Medicare pays for he would move them to an Assisted Living Facility
    - Then move patients back to Hospital and have Drs sign off on more SNF care starting the cycle over.
  - Also bribed basketball coach at Univ Penn to get son on the team and into Wharton School of Business
  - Jury Found him guilty (money laundering)
  - Sentenced to 20 years (sentenced 9/19)

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OIG/DOJ Year In Review

Rehab and Skilled Nursing

- Kindred Healthcare legacy
  - Beware of aggressive rehab protocols that are similar to the Kindred model
  - Make sure the record provided documentation to support the treatment
- Esformes legacy
  - Don’t be cute
  - Don’t assume you are above the law
  - Avoid black suburbans and plastic bags full of cash

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OIG/DOJ Year In Review

Hospice

- Continue to be a focus
- **Vitas Hospice Services** (10/17)
  - Largest for-profit hospice provider
  - $75 million settlement
  - False claims for patients who were not terminally ill
  - Services that were not necessary, not actually provided, or not performed within Medicare requirements

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OIG/DOJ Year In Review

Hospice

- **Evercare Hospice** (7/16)
  - $18 million settlement
  - False claims for patients who were not terminally ill
  - Practices that discouraged discharge of ineligible patients and failure of nurses to document med record
- **Caris Healthcare** (Knoxville) (6/18)
  - 8.5 million settlement (6/18)
  - False claims for patients who were not terminally ill

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OIG/DOJ Year In Review

Hospice

- **Horizons Hospice** (2/18)
  - $1.24 million settlement
  - False claims for patients who did not qualify (were not terminally ill)
  - Falsified records
  - Also fined the CEO, John C Rezk
- **SouthernCare, Inc** (12/18)
  - $6 million settlement
  - Admitted patients who did not qualify (not terminally ill or lacked medical documentation).

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Hospice

- **AseraCare Hospice** (10/15)
  - Fed District Court in Alabama
  - Alleged false claims for patients not terminally ill
  - Evidence of false claim was based solely on medical expert's disagreement with certifying physician's clinical judgement ($200 million potential)
  - Trial Ct ruled not enough to prove a FCA violation (post jury verdict)

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OIG/DOJ Year In Review

Hospice

- **AseraCare Hospice**
  - 11th Circuit Opinion (9/19)
  - Ruled that a "reasonable difference of opinion among physicians reviewing the med record is not sufficient on its own to suggest that those judgements – or any claim based on them – are false" under the FCA.

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Hospice

- **Hospice Focus:**
  - False certification that a patient is terminally ill – (6 months)
  - Admitting and retaining patients that do not qualify for Hospice
  - Falsifying records indicating patients are eligible
  - Paying bonuses and kickbacks for enrolling patients
  - Discouraging discharge of patients determined not to be terminally ill

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OIG/DOJ Year In Review

Home Health Agencies

- **Renaissance Home Health Services**
  - Illegal kickbacks to patient marketers
  - Sham contracts to cover
  - Company and both owners pled guilty (5/19)
- **Owner of HHA (Michigan)**
  - Pled guilty to paying kickbacks to patient recruiters
  - Medically unnecessary services
  - 84 months in prison and $8.34 million (4/19)
- **TLC Health Services**
  - Owner and unlicensed therapist
  - Kickbacks for referrals
  - Billed for services provided by those not licensed
  - 87 months in prison and $8.6 million (2/19)

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OIG/DOJ Year In Review

Home Health Agencies

- **Amity Home Health Care / Advent Care** (8/19)
  - 2 providers, one CEO, 13 doctors, 5 nurses, social worker
  - $115 Million Medicare kickback scheme
  - Kickbacks disguised as payroll and medical directorships, as well as payment for entertainment, and gifts
  - "elaborate meals, sporting events and purchase of gifts" for Individuals to refer patients.
  - Stay tuned…

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Home Health and Hospice

- **HHA Focus:**
  - Performing medically unnecessary procedures to increase reimbursement
  - Paying patient recruiters
  - Billing for services not actually rendered
  - Billing unskilled services as skilled
  - Falsifying documents to make it appear that patient is home bound when they are not

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Hospitals

- **Health Management Associates, LLC**
  - Headquarters in Naples, Florida (acquired by CHS)
  - "Corporate driven scheme"
  - Unlawfully pressuring and inducing ER admissions – mandatory co wide admission benchmarks (15-20% of all ER patients)
  - Inpatient rather than observation
  - Settlement is for criminal charges and civil claims
  - Entity settled for **$260 Million** 9/18
  - CEO settled for **$3.5 million** (5/19)

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Hospitals

- **Prime Healthcare I**
  - 45 hospitals in 14 states
  - 14 hospitals in California
  - "Corporate-driven scheme"
    - ER patients admitted as inpatients
    - Falsified diagnosis, complications and comorbidities
  - **$65 Million** settlement (8/18)
  - **CEO** to pay $3.25 million

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Hospitals

- **Prime Healthcare II**
  - Prime Healthcare Services, Inc and its CEO
  - Two Pennsylvania hospitals
    - Admitted patients who should have been outpatient or observation
    - Up-coding the diagnosis
  - **$1.25 Million** settlement (2/19)
  - **CEO** to pay

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OIG/DOJ Year In Review

Hospitals

- **Forest Park Medical Center** (Dallas) 4/19
  - $40 million in “bribes and kickbacks”
  - Kickbacks paid thro medical marketing firm
  - Others simply “overpaid”
  - Had proper documents in place
  - Indicted:
    - Hospital, administrator,
    - 21 physicians
    - All but two or were convicted
  - **Sentencing Stage** (4/19)

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Hospitals

- **Union General Hospital** 2/19
  - 45 bed nonprofit facility - Blairsville, Ga
  - Paid more than FMV for sleep lab from Dr
  - More than FMV for
    - Medical directors
    - On-call surgeon
    - Medical staff consultant
  - **$5 Million** settlement
  - Investigated a result of a tip from employee/ opioid arrest

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Hospitals

- **Millcreek Community Hospital** 7/19
  - Hospital in Erie, Pennsylvania
  - Admitted patients to inpatient rehab unit who did not qualify for the service and inadequate documentation to support the services
  - **$2,451,000** settlement
  - OIG investigation

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Hospitals

- **Kentuckiana Medical Center** 6/19
  - Rialto Capital Management owned Center
  - Personal loans to two referring physicians and forbore repayment for two years
  - Violated Anti-kickback and Stark
  - **$3.6 million** settlement
  - OIG investigation

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OIG/DOJ Year In Review

Hospitals

- **Eagleville Hospital** 7/19
  - Hospital level detox treatment
  - Patients were not eligible and lacked documentation to support level of service
  - **$2.85 million** settlement
  - Qui tam case

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OIG/DOJ Year In Review

Hospitals

- **Hospital Focus**
  - Technical compliance with Stark
  - Hospital / physician arrangements
  - Basic kickback schemes
  - Beware of internal decreased focus on Stark compliance
  - Beware of revenue pressure –
    - Upcodes
    - ER admissions
  - They have your DATA

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OIG/DOJ Year In Review

Urgent Care Facilities

- **CareWell Urgent Care Centers** (qui tam 3/19)
  - Owned centers in Massachusetts and Rhode Island
  - Inflated E/M levels
  - Failed to properly identify the providers of E/M
  - Mandated employees examine and document
    - at least 13 body systems for medical histories and
    - at least 9 body systems for physical without regard to patient's complaint/symptoms
    - Encounter plan templates required (built in default)
  - **$2 million** settlement

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OIG/DOJ Year In Review

Physicians

- Issues for physicians:
  - Nuclear stress tests not medically necessary - $1.2 million
  - Referral of unnecessary lab tests - $3.8 million
  - Billing for surgical monitoring not performed and ordering medically unnecessary diagnostic tests - $20 million
  - Point of care cups (to be discussed later)

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OIG/DOJ Year In Review

Physicians

- Southern Cancer Center, PC (Alabama) 9/18
  - 60 Day Rule
  - Allowed accrual of overpayments to Medicare and Medicaid
  - Became aware of the overpayments and failed to return
  - Self disclosed
  - Settlement $538,546

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OIG/DOJ Year In Review

Hiring Excluded Individuals

- 26 settlements in last year
- Ranged from $10,000 to $300,000
- University Chicago Med Center
  - Hired a RN thru a staffing agency
  - $253,671 settlement

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OIG/DOJ Year In Review

EKRA

- **Eliminating Kickbacks in Recovery Act of 2018**

Federal crime to knowingly and willfully:

1. Solicit or receive any remuneration in return for referring a patient to a recovery home, clinical treatment facility, or laboratory;

2. Pay or offer any remuneration either to:

a) induce such a referral, or

b) in exchange for an individual using the services of a recovery home, clinical treatment facility or laboratory.

- Up to $200,000 or 10 years in prison

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OIG/DOJ Year In Review

EKRA

- **Eliminating Kickbacks in Recovery Act of 2018**
  - A number of safe harbors – mostly similar to the AKS
  - Important difference:

    Payments to employees and independent contractors when compensation is not determined by or does not vary with the number of individuals referred, the number of tests or procedures performed or the amount billed or received
  - Applies to ALL referrals even if referral does not involve addiction or recovery treatment
  - Applies to ALL CLIA labs even if they do not do drug testing
  - Applies to All payors – BCBS, United, etc
  - Reevaluate and reassess employed or contracted marketers and sales force

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OIG/DOJ Year In Review

Update: Guidance on Evaluating Corp Compliance Programs

- Revision to 2017 Guidance. (4/19)
- 3 fundamental questions:
  - Is the Program well designed?
  - Is the Program effectively implemented?
  - Does the Program actually work in practice?
- Looks at whether the Program is comprehensive and well integrated into the corp's operations and workforce.
- Excellent guide for compliance officers

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OIG/DOJ Year In Review

Pursuit of Individuals

- **DOJ Yates Memo**
- Seeking accountability from individuals who perpetrated the wrong doing
- **OIG Team 5**
- Focused on owners, executives and physicians

- A **series of memos** from DOJ indicate a "course correction" pointing to a more limited approach to the scope and pursuit of FCA actions.

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OIG/DOJ Year In Review

Course Correction

- Sessions – Guidance Policy (11/16/17)
  - Prohibit DOJ from "issuing guidance" that purport to create rights or obligations binding on persons or entities without rule making
- Brand Memo (1/25/18)
  - Limiting use of other agency "guidance"
  - Non compliance with agency "guidance" may not be violation of law
- Granston Memo (1/10/18)
  - Factors for evaluating dismissal of whistleblower cases
  - Fall out of some of the post Escobar rulings.
- Impact on "implied certification" theory
- Point to a more balanced and moderate approach to enforcement efforts
- More proactive approach to dismissal of relator cases

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OIG/DOJ Year In Review

Major Increase in Civil Money Penalties (CMP)

- Bipartisan Budget Act of 2018
  - Extended CHIP
  - Also dramatically increased CMPs:
    - Civil
      - Violation of AKS increased from $50,000 to $100,000 per violation
      - Knowingly filing an improper claim increased from $10,000 to $20,000 per claim
    - Criminal
      - AKS increased from $25,000 to $100,000 per violation
      - Prison time increased from 5 years to 10 years

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OIG/DOJ Year In Review

HHS Inspector General Resigning

- Daniel Levinson announced his retirement
- Effective May 31st
- 15 years and 3 administrations

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OIG/DOJ Year In Review

Trends to Watch:

1. **Stark and Anti-Kickback Changes**
   - CMS and OIG requested information regarding possible reforms
   - Part of ongoing effort to accelerate shift from fee-for-service to value-based care
2. **Escobar Case and Granston Memo Fallout**
   - DOJ qui tam interventions and dismissals
   - Government wants to dismiss cases that impede objectives
3. **Opioid Crisis**
   - Major governmental focus
   - EKRA
4. **Continued focus on individuals**
5. **Data, Data, Data**

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Annual Health Law Update For Hospitals

OIG/DOJ
YEAR IN REVIEW

September 19, 2019
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Annual Health Law Update for Hospitals

PRIVACY / SECURITY: PRIORITIES FOR 2020

Montgomery, Alabama
September 19, 2019

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PRIVACY / SECURITY: PRIORITIES FOR 2020

Three key priorities for 2020:

1. ***Prioritize*** promoting awareness and demanding accountability.
2. ***Prioritize*** leadership and coordination.
3. ***Prioritize*** strategic partnerships.

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PRIVACY / SECURITY: PRIORITIES FOR 2020

1. Promote awareness and demand accountability.

<u>Awareness</u>:

- Data breaches can have catastrophic effects on hospital finances and operations.
- Risks (far) greater in healthcare vs. other industries.
- Data breaches can threaten ***patient safety***.
- Biggest risk is ***your people***.
- Data breaches can trigger significant legal exposure – if not handled properly.

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PRIVACY / SECURITY: PRIORITIES FOR 2020

Accountability:

- ***No excuse*** for workforce (insiders) not being prepared to identify and (properly) respond to a phishing attack.
- ***No excuse*** for sharing / using others' login credentials.
- ***No excuse*** for "peeping," "snooping."
- ***No excuse*** for not policing remote access.
- ***No excuse*** for not implementing robust backup procedures.
- ***No excuse*** for not addressing third-party risks.

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PRIVACY / SECURITY: PRIORITIES FOR 2020

2. Prioritize leadership and coordination.

- Privacy and cybersecurity are ***not (solely) "IT issues;"*** they are 24/7/365 ***enterprise risk management*** issues.
- ***Technology is not a silver bullet:*** hospitals must have effective systems in place to prevent, detect and respond to privacy and security incidents.
  - Built around ***ongoing*** risk analysis / risk management
  - ***Board-level*** engagement and leadership
  - ***Clearly defined*** lines of responsibility and communication
- Safeguards must be strategically implemented (i.e., risk-based) and "battle tested" (***Test! Test! Test!***).

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PRIVACY / SECURITY: PRIORITIES FOR 2020

3. Establish strategic partnerships.

- ❖ Seek out ***ongoing*** risk analysis relationship
- ❖ Get to know your insurance broker / carrier
- ❖ Engage experienced legal counsel
- ❖ Ensure IT / insurance / legal are in synch.

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PRIVACY / SECURITY: PRIORITIES FOR 2020

QUESTIONS?

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PRIVACY / SECURITY: PRIORITIES FOR 2020

THANK YOU!

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Annual Health Law Update for Hospitals

Hospital Survival Kit:

A Grab Bag of Current Health Care Legal Issues

Montgomery, Alabama
September 19, 2019

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Overview

1. CMS/Administration Updates & Initiatives

2. 340B Updates

3. EMTALA – Select Topics

4. Managing Current Social Norms

5. Your Hospital Telemedicine Program

6. Scope of Practice Update

7. Compliance Corner (Litigation Tidbits)

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CMS/Administration Updates & Initiatives

- Wage Index
- Promoting Interoperability
- Out-of-Network Billing
- ACOs and Risk Tracks
- Direct Primary Care Models and Rural Health Strategy
- CMS Exact Match Program
- New Program Integrity Measures
- Pricing Transparency

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

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CMS/Administration Updates & Initiatives:
2020 IPPS Proposed Rule

Background

- RFI in 2019 IPPS Proposed Rule
  - "[W]e are taking this opportunity to invite the public to submit further comments, suggestions, and recommendations for regulatory and policy changes to the Medicare wage index . . . . If practicable, we are requesting commenters to submit supporting data and specific recommendations in their comments. For any suggestions or recommendations that would involve novel legal questions, we welcome analysis regarding CMS' authority for our consideration."
- 2018 OIG Report
  - Absent misrepresentation or falsification, CMS lacks authority to penalize hospitals that submit inaccurate or incomplete wage data
  - MAC limited reviews do not always identify inaccurate wage data
  - The rural floor decreases wage index accuracy
  - Hold-harmless provisions in federal law and CMS policy relating to geographically reclassified hospitals' wage data decrease wage index accuracy
- Comments of Secretary Azar
  - **June 2018:** urged lawmakers to draft legislation to fix Medicare wage index in House Education and Workforce Committee meeting
    - *Will be difficult* to alter index without taking funds from some hospitals to increase reimbursement for others
  - **March 2019:** acknowledged "absurdity" of wage index to Senate Finance Committee

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CMS/Administration Updates & Initiatives:
2020 IPPS Final Rule

- The Final Rule (84 Fed. Reg. 42044)
  - Hospitals bottom quartile wage index (.8482): increase wage index by ½ the difference between wage index and 25th percentile wage index
    - Alabama Example: Rural hospital with .6663 wage index (.6663 + ½ (.8482-.6663) = .7573)
    - Effective for at least 4 years
  - Decrease in national standardized amount for Budget Neutrality
    - Did not finalize proposal to have corresponding decrease for hospitals with wage index value above 75th percentile
  - Remove wage index data for urban to rural reclassifications from calculation of rural floor
- Industry Backlash and Obstacles
  - As Secretary Azar recognized, there will be winners and losers
  - How to maintain budget neutrality
  - Scope of regulatory authority; need for statutory changes?

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CMS/Administration Updates & Initiatives:
Promoting Interoperability

- **2019 Information Blocking Rule**
  - Information Blocking (21st Century Cures Act, Section 4004):
    - practices that restrict authorized access, exchange, or use of electronic health information for treatment or other permitted purposes
    - implementing HIT in nonstandard ways that are likely to substantially increase complexity or burden of accessing, exchanging, or using electronic health information
    - implementing HIT in ways likely to restrict access, exchange or use of electronic health info with respect to exporting complete info sets or transitioning between HIT systems or likely to lead to fraud, waste, or abuse, or to impede innovations/advancements in health info access, exchange, and use, including care delivery
  - Exceptions: (1) Preventing Harm; (2) Promoting Privacy of EHI; (3) Promoting Security of EHI; (4) Recovering Costs Reasonably Incurred; (5) Responding to Requests That Are Infeasible; (6) Licensing Interoperability Elements on Reasonable and Non-Discriminatory Terms; and (7) Maintaining and Improving HIT Performance
- **2019 Promoting Interoperability Standards**
  - Need at least 50 points from reporting measures to avoid Medicare penalty
  - 2015 Edition CEHRT: any continuous 90-day period
  - Security Risk Analysis measure: no points, but required
- **Promoting Interoperability Proposals for 2020 and Beyond (84 Fed. Reg. 19158, 19554)**
  - CEHRT Reporting Period: any continuous 90-day period for 2021 continues
  - PI Measures
    - Must occur during Reporting Period (Medicare PI Program only)
    - PDMP Query measure (optional); Verify Opioid Treatment Agreement measure (removed)
  - Commentary requested: opioid measures, engaging vendors and clinicians, Hospital Compare, integration of patient-generated data, EHR safety

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CMS/Administration Updates & Initiatives:
Out-of-Network Billing

POTUS Remarks (May 9, 2019)

- No balance billing in emergencies
- Clear transparent bill before scheduled, non-emergency care, including total cost and out-of-pocket expenses
- No surprise bills from out-of-network providers the patient did not choose
- Protect patients without increasing federal expenditures
- Apply requirements to all forms of insurance

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CMS/Administration Updates & Initiatives:
Out-of-Network Billing

Bill No.	Bill	Provisions	Status
H.R. 3630	No Surprises Act (Reps. Frank Pallone and Gregg Walden, May 14, 2019 talking points)		Before House E&C (referred out of Health subcommittee) and Education & Labor
S. 1531	STOP Surprise Bills Act of 2019 (Sen. Bill Cassidy et al., Int. May 16, 2019)		In Senate HELP Committee (since introduction)
H.R. 861	End Surprise Billing Act of 2019 (Rep. Doggett, int. 1/30/2019)		In House Ways and Means and E&C Comm. since introduction
H.R. 4223	Protecting Patients from Surprise Medical Bills Act (Rep. Spano, int. 8/30/2019)		Referred to Education & Labor
S. 1266	Protecting Patients from Surprise Medical Bills Act (Sen. Scott, int. 5/1/2019)		Referred to HELP Comm.
H.R. 3502	Protecting People from Surprise Medical Bills Act (Rep. Ruiz, int. 6/26/2019)		Referred to E&C, Ways & Means, Oversight & Reform, and Education & Labor

CMS/Administration Updates & Initiatives:
ACOs and Risk Tracks

Pathways to Success Rule (Dec. 21, 2018)

- MSSP ACOs required to take on downside risk more quickly
- New Tracks
  - Basic: 5-year performance period; allows 1 year of upside-only risk (2 years for ACOs with no prior experience with downside risk)
    - Glide Path for transition to risk
  - Enhanced: similar to Track 3 of MSSP (most downside risk)
    - Up to 75% of savings based on quality performance, up to 20% of benchmark
    - Losses up to 1 – savings rate (40% < shared loss rate < 75%), up to 15% of benchmark
- Beneficiary incentive programs (two-sided models only)
  - Allow incentive payment up to $20
- New beneficiary assignment rules

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CMS/Administration Updates & Initiatives:
Direct Primary Care and Rural Health Strategy

- "[The] hospital-based, centralized system may no longer be the best option"
- "[C]ommunities will be required to consider value-based payment approaches. Transformation will also require transitioning rural providers to take on meaningful risk for cost and outcomes through alternative payment models"

Comments of CMS Administrator Seema Verma to National Rural Health Association (May 8, 2019)

- Maternal health (CMS pays for approx. ½ the births in the country)
- Prescription drug costs
- Rural Health Strategy
  - QPP and flexibility for rural providers
  - Expanded telehealth opportunities (home dialysis, in-home monitoring, virtual check-ins, Medicare Advantage offerings, Medicaid opportunities, expansion of broadband capabilities through FCC)
  - Wage index disparities
  - Patients Over Paperwork
  - Transformation of rural health care delivery
    - VBP – expanding opportunities that cater to needs of rural areas
    - CMS Primary Care Initiatives
      - Primary Care First
      - Direct Contracting
      - New model to be announced later this year

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CMS/Administration Updates & Initiatives:
CMS Exact Match Program

- Address hospital uses on claims for services provided in off-campus outpatient departments must exactly match the address entered on the Medicare enrollment for that location
  - *e.g.*, "Suite" vs. "Ste." and "Road" vs. "Rd."
- Return-to-provider notice if addresses don't match
- Policy: CMS attempting to prevent creep/expansion of grandfathered off-campus outpatient departments
- Solutions: (1) fix your enrollment info with CMS/MAC (30-45 days)
  (2) fix address in your claims system

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CMS/Administration Updates & Initiatives:
New Program Integrity Measures

- Final Rule (CMS 6058-FC)
  - 3 years in the making (Proposed Rule 81 Fed. Reg. 10720, 3/1/2016)
  - New revocation and denial authorities to stop fraud, waste, and abuse (FWA)
- Purpose and Supporting Figures
  - $51.9 billion paid to 2,097 entities with excludable affiliations
    - New revocation authority would have applied to approximately 40% (839 cases) of identified prior affiliations, which would equate to $20.7 billion 5-year savings
    - Anticipate additional 2,600 new revocations each year ($4.16 billion 10-year savings)
  - 400 cases subject to new reenrollment/reapplication bar authorities ($1.79 billion 10-year savings)

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CMS/Administration Updates & Initiatives:
New Program Integrity Measures

- New "Affiliations" Authority
  - Revocation/denial for authority for affiliations with certain individuals/entities
  - Required disclosures related to affiliations with entities that:
    - Had enrollment denied or revoked
    - Have uncollected debt to Federal Health Care Program
    - Are subject to payment suspension
    - Have been excluded
  - Disclosure obligation applies regardless of whether underlying action is being appealed
  - 5-year lookback period
- Additional Denial/Revocation Authorities
  - Attempting circumvention of program rules by enrollment under different name
  - Billing for items/services from non-compliant locations
  - Exhibiting pattern/practice of abusive ordering/certifying
  - Outstanding debt to CMS referred to Treasury Department
- Reenrollment bar
  - Extend current reenrollment bar from 3 to 10 years
  - Option to add additional 3 years for efforts to circumvent
  - 20-year bar for second-time revocation of billing privileges
- Revocation for failure to report

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CMS/Administration Updates & Initiatives:
Pricing Transparency

- Executive Order (January 24, 2019)
  - increase availability of meaningful price and quality information for patients
  - Requires HHS to propose rule requiring hospitals to publicly post standard charge information
- 2020 OPPS Proposed Rule
  - requirements for making public a list of payer-specific negotiated charges for a limited set of “shoppable” services that are displayed and packaged in a consumer-friendly manner
    - “Shoppable” services: can be scheduled in advance
    - 70 CMS-selected services and 230 hospital-selected services
    - CMPs for noncompliance

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340B Updates

- 2018 and 2019 340B Recap
- A Successful Litigation Challenge
- Policy Developments

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340B Updates:
2018 and 2019 340B Recap

- **2018 Changes**
  - **Methodology:** ASP + 6% → ASP – 22.5%
  - Savings distributed across OPPS
  - Reporting requirements (modifiers)
- **2019 Extensions and Modifications:**
  - Now applies to non-excepted, off-campus provider-based departments of a hospital
  - Biosimilar reimbursement tied to biosimilar's ASP rather than reference drug's ASP
  - Where ASP data not available, reimbursement at WAC + 3% (instead of + 6%)

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340B Updates:
A Successful Litigation Challenge

***American Hospital Association et al. v. Azar* (Case No. 1:18-cv-02084-RC)**

- Permanent injunction previously granted against 2018 rule extended to 2019 rule
  - Average acquisition cost data not available to HHS Secretary, so . . .
    - Reimbursement = average sales price "as calculated and adjusted by the Secretary"
  - HHS Secretary exceeded authority to "adjust the applicable payment rate as necessary"
    - The term "adjustment" does not "encompass the power to make basic and fundamental changes in the [statutory] scheme" and cannot be read to permit "total elimination or severe restructuring of the statutory scheme."
- Remedies
  - Remand to HHS to handle logistics of remediating underpayment

    (1) Budget Neutrality

    (2) savings spread throughout OPPS (approx. 3.2%)

    (3) $25-$30 million dollars in admin costs; impact on cost-sharing

    (4) Retroactive rulemaking

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340B Updates:
2020 OPPS Final Rule

- CMS sticking to its guns on ASP – 22.5% for certain separately payable drugs and biologicals
- Acknowledgement of ongoing litigation
  - Requested final judgment and intend to pursue appeal
- Request for comment on:
  - Alternative payment options for 2020 (ASP + 3%?)
  - Remedies for CY2018 and CY2019 payments
    - ASP + 3% as basis for remedy?
    - Structure of remedy
      - Retrospective vs. Prospective
      - Fairness to non-340B hospitals
      - Budget Neutrality
    - Would apply remedy to 2021 OPPS rule

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340B Updates:
Policy Developments

- PAUSE Act, HELP Act, 340B Optimization Act, etc.
- 340B Protection and Accountability Act of 2019 (HR 1559)
  - New definition of “patient”
  - Required agreements for contracted services
  - Limit of 5 contract pharmacies; low income areas only
  - Audits by Secretary and manufacturers
  - Contract pharmacy moratorium
  - Sliding fee scale for low-income patients
  - Reporting requirements
- Fair Care Act of 2019 (HR 1332)
  - Reporting requirements

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EMTALA – Select Topics

- Overview
- Problem Areas
  - "Comes to the Emergency Department"
  - Physician Call
  - Diversionary Status
  - Specialized Capabilities
  - Reporting Obligations
- Enforcement

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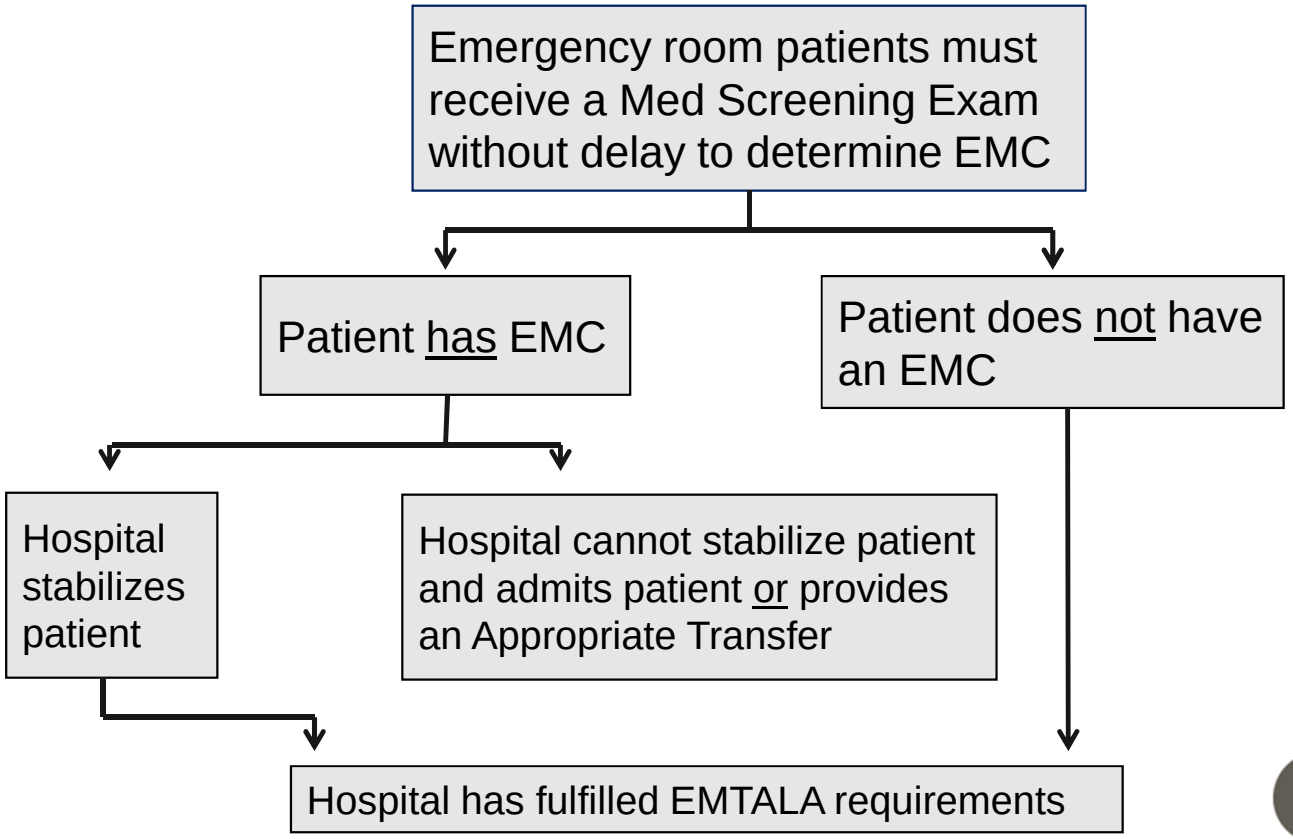
EMTALA – Select Topics: Overview



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EMTALA – Select Topics:
On Campus – "Comes to the Hospital"

- Campus – all contiguous buildings, parking, etc.
- Owned by Hospital and within 250 yards of Main Building
- Excludes physician offices, RHC, SNF
- Provider Based entity on Campus?
  - Entity is not but Hospital may be
- Off Campus hospital department is not subject unless it is a dedicated ER

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EMTALA – Select Topics: Maintain On-Call List

- Hospital must maintain a list of physicians who are on-call to provide treatment necessary to stabilize patient with EMC (§489.20(r)(2))
  - List identifies and "ensures" that ED is "prospectively" aware of which physicians are available.
  - "capacity" of the ED includes the particular specialties available on-call.
  - CMS wants to see all specialties offered to the public represented on the on-call list.
  - On-call list must be by physician – <u>not</u> practice group.

  - CMS does <u>not</u> have rule or require:
    - Frequency of availability of physicians to provide coverage.
    - Pre-determined ratio to identify how many days a hospital must provide coverage in a specialty based on # of physicians on staff. (<u>no</u> rule of 3)

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EMTALA – Select Topics: Availability of On-Call Doctor

- Does the on-call physician have to physically assess the patient?
  - Yes, if the ER physician requests
- May the on-call physician ask that the patient be sent to their office?
  - If an EMC is present, NO.
- Failure to come to the ER when asked or directing that the patient be transferred to another hospital for on-call physician to assess is a violation.

  (Unless a Community Call Arrangement is in place)
- Failure to accept a transfer when hospital has capacity and capability is a violation by the physician. (new)

(§489.24(j))

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EMTALA – Select Topics: Availability of On-Call Doctor

- If a physician is on-call
  - Has been requested by the treating physician to appear at the ER, and
  - fails or refuses to appear within a "reasonable time",
  - then the hospital and the physician have violated EMTALA and are subject to sanctions.

- What is "reasonable time"?
  - Based on medical staff bylaws, rules and regulations, but should not be more than 30 minutes.

- Refusal to take on-call coverage but seeing his own patients in ER may be a violation of EMTALA.

(§489.24(j))

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EMTALA – Select Topics: Availability of On-Call Doctor

- Simultaneous call at two hospitals?
  - Only if the hospitals have written policies for back-up
- On-call physician allowed to perform elective surgery?
  - Only if the hospital has written policies providing for situation where physician is unable to respond. (i.e., a back-up call designee)
  - Example: Verdict against Dr. Bradley Bilton, DCH Health Care Authority, et al.
- Community Call Plans
  - Clear delineation of coverage
  - Description of geographic area affected
  - Signed written agreement
  - EMS protocols include the arrangement
  - Annual assessment
  - Initial hospital still must conduct MSE and appropriate transfer

(§489.24(j))

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EMTALA – Select Topics: Diversionary Status

- "Diversionary status" or "diversion" are not specifically defined. Context of ambulances.
- "Diversionary status" – Hospital does not have the staff or facilities to accept any additional emergency patients. (§489.24(b)(4))
- Tied to "capacity"
- Encompasses all situations when a hospital cannot accept individuals due to lack of staff and facilities.

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EMTALA – Select Topics: Diversionary Status

- Diversion Criteria
  - Some have used:
    - # of beds available (i.e., 110% capacity)
    - ICU beds available
    - Beds staffed
  - ER Capacity – ability to handle additional emergency patients is what the regs refer to
- Guidelines imply that other departments might impact ER capacity
- Room for the spouse of the Chairman?
- Who decides if on "Diversion"?
- How is the decision made – what objective criteria?

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EMTALA – Select Topics:
Problem Areas: Specialized Capabilities

- Park Royal Hospital (FL) - $52,414 Settlement
  - Failure to accept transfer of patient with unstabilized psychiatric EMC
  - Park Royal has specialized psychiatric capabilities (114-bed psych hospital)
  - Refused to accept transfer because patient insurance was out of network
- Interpretive Guidelines 7/16/10

  "…if an individual is found to have an EMC that requires specialized psychiatric capabilities, a psychiatric hospital that participates in Medicare and has capacity is obligated to accept an appropriate transfer of that individual….(even) if the psychiatric hospital does not have a dedicated ER."

  §489.24(f)(2)
- Takeaways:
  - Must accept transfer if you have specialized capability (regardless of whether you operate a dedicated emergency department
  - Economic/insurance screening not permitted

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EMTALA – Select Topics: Obligation to Report

- Hospitals and Physicians obligated to report suspected violations
  - failure to report is a violation
  - 72 hours to report
- If you suspect improper transfer reach out for full story
- Be prepared – <u>both</u> will get a survey
- Who decides if you report? Policy?

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EMTALA – Selected Topics: Enforcement

- CMS (through arrangement with ADPH) investigates complaints.
- CMS 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

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EMTALA – Selected Topics: Enforcement

- AQAF (QIO) hearing if medical opinion is necessary.
- QIO report delivered to CMS and OIG
- OIG then determines whether to assess a CMP
  - $100,000+ per violation ($50,000+ under 100 beds)
    - Seriousness of condition of the individual
    - Culpability of hospital or doctor
    - Evidence of other noncompliance with EMTALA
    - Financial condition
    - Nature and circumstances of violation

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EMTALA – Selected Topics: Enforcement

- Also reports to
  - Office of Civil Rights
  - Department of Justice
  - Internal Revenue Service
  - Joint Commission
- Issues in CMP reported cases
  - 43% failed to provide MSE
  - 36% failed to provide stabilizing treatment
  - 20% improper or failure to accept transfers

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Managing Current Social Norms

- A Real Scenario
- One Clinical Perspective
- Applicable Laws
- Possible Approaches

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Managing Current Social Norms:
A Real Scenario

Sam, the 32-year-old pregnant man (N. Engl. J. Med. 2019; 380: 1885-1888 (May 16, 2019))

- 32-year-old man brought to the ED by his boyfriend
- Reported 8-hour history of severe (8 out of 10) intermittent lower abdominal pain
- Triage:
  - BP = 185/84; Heart Rate = 67 bpm
  - Nurse noted obesity
  - Sam told the nurse he was a transgender man; EHR reflected that he was male
    - Previous use of testosterone and hypertensives; several years since last menstruation; positive home pregnancy test
- Triage Assessment: man with abdominal pain who had not taken prescribed blood pressure meds; condition stable, so nonurgent
  - Fortunately, the nurse did order an hCG test

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Managing Current Social Norms:
A Real Scenario

Sam, the 32-year-old pregnant man **(N. Engl. J. Med. 2019; 380: 1885-1888 (May 16, 2019))**

- Outcome:
  - Several hours later, emergency physician evaluated Sam and noticed positive hCG results
  - Physician took more detailed history and began to consider possible early pregnancy complications
  - Ultrasonography confirmed advanced pregnancy with unclear presence of fetal cardiac activity
  - Emergency caesarean delivery
  - No fetal heartbeat detected
  - Stillborn delivery

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Managing Current Social Norms:
One Clinical Perspective

Dr. Daphna Strousma, *et al.* (N. Engl. J. Med. 2019; 380: 1885-1888 (May 16, 2019))

- Sometimes the binary system doesn't cover "rich information" about sex
  - Rightly classified as man (identity, legal sex)
  - Elevated blood pressure treated as related to untreated essential hypertension instead of hypertensive disorder of pregnancy
  - Other examples: missed diagnosis of cystic fibrosis based on race in multiracial child; failure to diagnose STIs in elderly patients
- Proposal to create appropriate classifications for transgender individuals
  - Recognize that our system has failed transgender patients
  - treat *individual* transgender people
  - Change in language: "pregnant people" instead of "pregnant women"
- Meaningful steps for physicians
  - Recognize how we use classification in order to identify the cracks/gaps
  - Use procedural and structural safeguards
    - More flexibility in EHR systems (legal sex, sex assigned at birth, organ inventory, etc.)
    - Updated ER algorithms to address this type of situation
    - Training programs

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Managing Current Social Norms:
Applicable Laws

Section 1557, Affordable Care Act

- Prohibits discrimination on the basis of race, color, national origin, *sex*, age, or disability
  - Extends Title IX prohibition against discriminating on the basis of "sex" to the health care industry
  - Regulations define "gender identity" as "an individual's internal sense of gender, which may be male, female, neither, or a combination of male and female, and which may be different from an individual's sex assigned at birth" (45 C.F.R. 92.4)
- Applies to:
  - Individuals participating in any health program or activity any part of which receives funding by HHS or is administered by HHS
  - Marketplace and any plan listed on the Marketplace (reaches private insurers)
- However, *see Franciscan Alliance, Inc. et al. v. Burwell* (N.D. Tex. 2016)
  - Enjoined Section 1557 prohibition against discrimination on basis of gender identity and termination of pregnancy on a nationwide basis
  - "the meaning of sex in Title IX [incorporated into Section 1557] unambiguously refers to the biological and anatomical differences between male and female students as determined at their birth"

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Managing Current Social Norms:
Applicable Laws

Section 1557 Fallout

- **Section 1557 Amended Rule Proposal (June 14, 2019)**
  - Removes gender identity and termination of pregnancy from scope of sex discrimination (response to *Franciscan Alliance* ruling)
  - Eliminate provisions that are redundant or inconsistent with existing Civil Rights statutes and regulations
    - Taglines for LEP individuals, language access plans, notices of nondiscrimination
    - Allow comparably effective audio interpretation services in place of video interpretation services
  - Retains requirement for covered entities to submit assurances of compliance
  - Retains certain provisions for language access for LEP individuals
    - meaningful language access to healthcare
    - qualification standards for translators and interpreters
    - limitations on the use of minors and family members as translators in healthcare settings
  - Retains certain provisions ensuring access and communications for individuals with disabilities
- **Equality Act (H.R. 5)**
  - Amend Section 201 of the Civil Rights Act of 1964 (42 U.S.C. 2000a):
    - Include discrimination based on "sex (including sexual orientation and gender identity)"
    - New section with "establishment that provides health care, accounting, or legal services" under definition of "public accommodation"

Managing Current Social Norms:
Applicable Laws

- **Conscience Rule (84 Fed. Reg. 23170)**
  - Expand scope from 3 conscience laws to 25
  - Revised/clarified enforcement mechanisms (*e.g.*, complaints, certifications, etc.)
  - HHS/OCR declined to clarify how this rule interacts with anti-discrimination statutes and rules, including Section 1557
  - However, reiterated position that stabilization/treatment requirements in EMTALA do not conflict with conscience and anti-discrimination laws
  - Trump Administration announced delay in enforcement. However . . .
- **University of Vermont Medical Center Enforcement Action**
  - Conduct: requiring nurse to perform elective abortion
    - Scheduled nurse to participate although she had previously registered moral/religious objection
    - Loss of funding from HRSA at stake (Medicare and Medicaid not mentioned)
    - First case since Conscience and Religious Freedom Division formed within OCR

Managing Current Social Norms:
Possible Approaches

Options

- Re-tooling the medical screening examination
- Physician, practitioner, and staff education and training
- EHR adjustments

Precautions

- Questions about race, gender identity, etc. – the appearance of discrimination?
- Mindfulness of faults in diagnostic and other classification systems

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Your Hospital Telemedicine Program

- Why It Matters…Expanding Coverage
- Medical Staff Credentialing
- Operational Issues

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Your Hospital Telemedicine Program:
Why It Matters…Expanding Coverage

- Medicare Coverage
  - Stroke telemedicine coverage expanded beyond rural areas
  - Expanded coverage and capabilities for ESRD/dialysis
  - Medicare Advantage plans can include delivery of telemedicine services in a plan's basic benefits starting in 2020
  - Rural restrictions eliminated and patient home added as a qualifying originating site for certain in 2020
- Other Insurers
  - Frequently follow Medicare policies after implementation
  - Continued drive toward delivering quality health care at lower costs

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Your Hospital Telemedicine Program:
Medical Staff Credentialing

General

- "The medical staff must examine the credentials of all eligible candidates for medical staff membership and make recommendations to the governing body on the appointment of these candidates . . . .";
- Periodic appraisal of medical staff members
- Medical Staff Bylaws
  - Approved by the governing body of the hospital
  - Statement of duties and privileges
  - Organization of medical staff
  - Qualifications for candidates to be recommended for appointment by governing body
  - Criteria for determining privileges and procedure for applying criteria

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Your Hospital Telemedicine Program:
Medical Staff Credentialing

Telemedicine

- Two Options: (a) direct credentialing; (b) credentialing by proxy
- Credentialing by Proxy:
  - Rely on credentialing and privileging decisions of distant-site hospital/telemedicine entity "when making *recommendations* on privileges for the individual distant site physicians and practitioners providing such services"
  - Written agreement with distant-site hospital/telemedicine entity
    - Distant-site hospital/telemedicine entity participates in Medicare and credentialing/privileging standards at least satisfy Medicare requirements
    - Individual physicians/practitioners privileged at distant site
    - List of current physicians/practitioners provided by distant site
    - Distant-site practitioner holds license recognized in AL (or other state where patient is receiving telemedicine services)
    - Internal review of performance by distant-site physician/practitioner; shared with distant-site

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Your Hospital Telemedicine Program:
Operational Issues

- Credentialing methodology
- Who purchases the equipment?
- Who is responsible for maintaining the equipment?
- Policies and Procedures:
  - Appropriate use of the equipment
    - Understanding functionality
    - Appropriate circumstances
  - Quality and reporting matters

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Scope of Practice Update – APPs in the ED

- Statutory/Regulatory Authority
- Interpretive Guidelines
- Alabama Applications

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Scope of Practice Update – APPs in the ED
Statutory/Regulatory Authority

Definition of "Hospital" (SSA, § 1861(e)):

- primarily engaged in providing, *by or under the supervision of physicians*…diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons..."
- Medicare hospital patients must be *under the care of a physician*
- 24/7 nursing service with LPN or RN on duty at all times
  - 24/7 physician service not required or explicitly referenced
- **CoPs (42 CFR Part 482):**
  - Every patient is under the care of a physician
  - An MD or DO is on duty *or on call* at all times (*cf.* LPN or RN *on duty* 24/7)
  - Medical staff *must* be composed of MDs and DOs; *may* include NPPs determined eligible for appointment by the governing body

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Scope of Practice Update – APPs in the ED:
Statutory/Regulatory Authority

CoPs (42 CFR Part 482):

- Every patient is under the care of a physician
- An MD or DO is on duty *or on call* at all times (*cf.* LPN or RN *on duty* 24/7)
- Medical staff *must* be composed of MDs and DOs; *may* include NPPs determined eligible for appointment by the governing body
- Medical staff bylaws must:
  - Describe qualifications for a candidate to be recommended for appointment
  - Include criteria for determining privileges to be granted and procedure for applying the criteria
- Emergency services must be organized under the *direction* of and *supervised by* a *qualified member of the medical staff*

EMTALA (42 CFR § 489.24):

- MSE provided by someone determined qualified by the hospital bylaws, rules, and regs and who meets requirements of § 482.55 ("Qualified Medical Person" or "QMP")
- QMP may arrange "appropriate transfer" in consultation/agreement with physician

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Scope of Practice Update – APPs in the ED:
Interpretive Guidelines

- **SOM, App'x A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals (rev. 10-12-2018)**
  - "All hospital patients must be under the care of a physician *or under the care of a practitioner who is directly under the supervision of a member of the medical staff.*"
  - Emergency services must be "organized under the *direction* of a qualified member of the medical staff"; qualified member of the medical staff must supervise the provision of emergency services
    - "supervision" implies a more immediate form of oversight by a qualified member of the medical staff during all times emergency services are available
    - Supervisor may be briefly absent from emergency department, but "expected to be in the hospital and immediately available to provide direction and/or direct care"
    - Medical staff must establish criteria for delineating qualifications of medical staff member for supervision of emergency care services
  - Emergency department must be staffed with appropriate numbers and types of professionals to meet anticipated needs of the facility

- **SOM, App'x V – Responsibilities of Medicare Participating Hospitals in Emergency Cases (rev. 7-6-2010)**
  - A hospital must formally determine who is qualified to perform the initial MSE (the QMP)
  - It is permissible for hospital to designate an NPP as the QMP
    - Designation must be set forth in document approved by governing body of the hospital and identified in bylaws, rules, and regs

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Scope of Practice Update – APPs in the ED:
Alabama Applications

- APPs approved by Joint Committee (BME/BON) for practice in the ED, under limited circumstances
  - Rural hospital
  - Low volume (<10,000 ED visits)
  - Low acuity (≥85% discharge home or otherwise low acuity)
  - APP qualifications (Family Practice NP, life support certifications, experience, etc.)
  - Collaborative practice with emergency department physician
- Process
  - Submit collaborative practice agreement to Joint Committee
  - Appoint/privilege APP through medical staff bylaws
    - Statement of duties and privileges
    - Qualifications for medical staff membership and specific privileges
    - Criteria to be applied to determine membership/privileges and procedure for application
  - Submit documentation to ADPH for waiver/approval

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Scope of Practice Update – APPs in the ED:
Alabama Applications

CMS Response

- Based on AL proposal, “a NP could theoretically be granted privileges for the supervision of emergency care services if the grant was consistent with state law and met the criteria in the SOM”
- Emphasis on scope of practice and grant of privileges to supervise provision of emergency care
- Supervisor must be present but for occasional brief absences
- Conclusive decisions based on surveys rather than hypotheticals

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Compliance Corner (Litigation Tidbits)

- *United States v. Beauchamp*
- *Cochise Consultancy v. U.S. ex rel Hunt*
- *Azar v. Allina Health Services*

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Compliance Corner (Litigation Tidbits):
United States v. Beauchamp

The Scheme(s)

- Promised in-network and billed out-of-network (substantially higher) rates
- Did not collect cost-sharing amounts from patients
- Bribes and kickbacks for referring patients to ASC or the surgeons who operated there
  - Tracked surgeries and referrals to "credit" kickbacks and bribes indirectly through shell companies created under sham marketing arrangements
  - In-kind kickbacks: advertising services, sporting event tickets, meals, discounts on diamonds and investment opportunities
  - Cash for referrals of patients with "lower-reimbursing insurance coverage" to other facilities
- 21 Defendants, 20 Counts, $40 million in bribes and kickbacks, and over $200 million in reimbursement ($500 million in billings) from 2009 to 2013

Key Takeaways:

- Paper Compliance ≠ Compliance
  - Attorneys reviewed the agreements
  - Gov't conceded that the documents were legal on their face, BUT "there was a sinister underbelly to them: They were just wads of paper used to make bribes and kickbacks look like legitimate payments."
- Traveler's Act
  - Illegal to use a facility in interstate commerce with the intent to distribute the proceeds of "unlawful activity"
  - State bribery laws serve as the basis for the "unlawful activity"

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Compliance Corner (Litigation Tidbits):
Cochise Consultancy v. U.S. ex rel Hunt

- FCA case (non-health care)
  - Relator sued Cochise Consultancy in November 2013, alleging that they had submitted false claims for security services in Iraq from sometime prior to January 2006 until early 2007
  - Suit filed 7 years after the alleged fraud occurred, but no more than 3 years after alerting FBI agents
- FCA Limitations Period
  - The latter of:
    - 6 years after the date on which the violation was committed; or
    - 3 years after the date when facts material to the action are known or reasonably should have known by the official of the U.S. charged with responsibility to act in the circumstances (not to exceed 10 years after the date of the violation)
- Practical Impact
  - 89% of FCA settlements last year were in the healthcare industry
  - Relators may wait longer to file an FCA action (larger damages)
  - Keep records for at least 10 years

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Questions?

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ALABAMA UPDATE

September 19, 2019
Gregg B. Everett, Esq.
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CASES:

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A) WORKERS' COMPENSATION:

1. City of Gadsden v. Billingsley
Alabama Court of Civil Appeals
December 21, 2018
Case No. 2170873

This case was originally remanded to the trial court to determine the extent to which the employee's shoulder injury has affected the employee's ability to earn income. The appellate court noted that the employee could not recover for back pain and mental suffering. On remand however, the trail court found that the employee had suffered a back injury and mental suffering. However, the Court of Appeals reversed this finding because the mandate on remand was for the trial court to determine the effect of the employee's shoulder injury, and it was error for the trial court to change the Court of Appeal's original decision.

2. ***Ex parte*** **Mercedes-Benz U.S. International, Inc. (Nix v. Mercedes-Benz U.S. International, Inc.)**
Supreme Court of Alabama
January 4, 2019
Case No. 1170623

This case pertains to the interpretation of a venue statute. An employee bringing a worker's compensation claim argued that venue was proper because the employer "conducted business by an agent" in Jefferson County. The Supreme Court held that the purchasing of parts from a supplier, by itself, does not constitute doing business by an agent in that county and therefore, venue was improper in this case. This decision overruled a previous case from 2002 (*Ex parte Scott Bridge Co.*, 834 So.2d 79).

3. Enterprise Leasing Company-South Central, LLC v. Drake
Alabama Court of Civil Appeals
January 4, 2019
Case No. 2170870

The Court of Civil Appeals reversed and remanded a trial court decision due to the application of an incorrect evidentiary standard. To prove that an injury arose from work-related conduct, an employee must present "clear and convincing" evidence of legal and medical causation.

4. Ex parte RM Logistics, Inc. (Elliot v. RM Logistics, Inc.)
Alabama Court of Civil Appeals
January 11, 2019
Case No. 2180137

Elliot filed a workers' compensation claim against his employer, RM Logistics, Inc. RM Logistics responded by filing a motion to transfer venue. The hearing for the motion to transfer venue had been postponed several times for a period of almost two years. Finally, RM Logistics filed a petition for writ of mandamus. The court granted the writ of mandamus reasoning that venue is a threshold matter which should be ruled upon as expeditiously as possible.

5. Georgia Pacific Consumer Products LP v. Gamble
Alabama Court of Civil Appeals
February 15, 2019
Case No. 2170750

The Appellate court affirmed the trial court decision by holding that Plaintiff was permanently and totaling disabled. The court noted that the proper test is one's inability to perform one's trade and the inability to find gainful employment. Further, the court noted that a claimant reaches MMI when there is no further medical care or treatment that could be reasonably anticipated to lessen the claimant's disability.

6. Merchants FoodService v. Rice

Supreme Court of Alabama
March 1, 2019
Case No. 1170282

The Supreme Court affirmed an award in favor of Employee because, following termination, Employee received less pay per hour at their new job, employer failed to determine each basis for the compensatory damages award, and the punitive damages to compensatory damages ratio was not unreasonable.

7. Ex parte Trusswalk, Inc. (Price v. Trusswalk, Inc.)

Alabama Court of Civil Appeals

March 29, 2019

Case No. 2180266

Employee filed a motion to compel medical treatment. Alabama Code § 25-5-77 provides that an employer shall pay for reasonably necessary medical treatment. The employee presented medical records as evidence of his injury but the records did not contain any recommendation that the employee receive pain management treatment. Therefore, the trial court could not have reasonably inferred that such treatments was medically necessary.

8. Tuscaloosa County v. Beville
Alabama Court of Civil Appeals
April 19, 2019
Case No. 2171022

Plaintiff was injured on the job and brought a workers' compensation claim against Tuscaloosa County. At the beginning of trial, the parties stipulated that Plaintiff had suffered a 4% impairment. At trial, the court ruled in favor of Plaintiff finding that Plaintiff had suffered a 60% injury. The Court of Appeals held that the trial court was free to assign an impairment based on the evidence and that Tuscaloosa County failed to object to this at trial.

9. Ex parte Farley (Farley v. Transport America, Inc.)
Alabama Court of Appeals
June 29, 2019
Case No. 2180513

Following a worker's compensation claim, the company asked the employee to execute releases of certain disability records regarding worker's compensation and unemployment benefits. The employee maintained that Alabama law did not require the execution of those releases. The court rejected this argument holding that the signed releases would allow the company to obtain information which was discoverable under the Alabama Rules of Civil Procedure. Further, the court held that the employee demonstrated no legal right to relief in relation to his request. As a result, the employee was ordered to execute the releases for records.

"We mostly handle injury, but we're looking to expand into insult."

B) MEDICAL MALPRACICE:

1. Ex parte Estate of Elliot (In re: Estate of Elliot v. Brookwood Baptist Health 1, LLC)
Supreme Court of Alabama
September 7, 2018
Case No. 1170564

The plaintiffs brought a wrongful death claim against Baptist Health System, Inc. and Courtney Johnson. After Plaintiffs requested employment, training, and disciplinary records, the defendants asserted privilege. However, the defendants did not present any evidence to support their assertion that the documents were privileged. As a result, the Supreme Court held that the defendants had not met their burden for establishing privilege protection for the records in question.

2. HealthSouth Rehabilitation Hospital of Gadsden, LLC v. Honts
Supreme Court of Alabama
September, 28, 2018
Case No. 1170592

Honts, a personal representative of Green's estate, brought suit for medical malpractice after Green tested positive for opiates after transfer to a second hospital, where Green ultimately died. A plaintiff in a medical malpractice case must establish the appropriate standard of care, a breach of that care, and a causal connection between the breach and injury. Here, Plaintiff's expert witness testified to the appropriate nursing standard of care, but the court charged the jury on the hospital standard of care. Thus, the Supreme Court held that the trial court's jury instruction was clear error and the decision denying a motion for new trial on that basis must be reversed.

3. Shadrick v. Grana
Supreme Court of Alabama
October 26, 2018
Case No. 1170513

A personal representative of Shadrick's estate brought a medical malpractice claim against a cardiologist and an internist after Shadrick died from chest complications. Shadrick's estate planned to call a cardiologist for expert testimony. However, the internist argued that this would be improper because the cardiologist was not a similarly situated healthcare provider in relation to the internist. The Court concluded that expert testimony would be necessary but that the testimony must be provided by a "similarly situated medical provider."

4. Ex parte Mobile Infirmary Association
Supreme Court of Alabama
December 14, 2018
Case No. 1170567

Personal representative of deceased patient's estate brought a wrongful death action against Hospital, alleging that patient died as a result of medical malpractice. Plaintiff served interrogatories and requests for production on the hospital, and the hospital filed a motion for protective order alleging that plaintiff could use the information obtained in other cases against the hospital. The Supreme Court held that Alabama Code § 6-5-551 prohibits a party from conducting discovery with regard to "any other act or omission." Therefore, the Court held that the paragraph allowing evidence obtained to be used in any other action was a clear abuse of discretion.

5. Hamilton v. Scott
Supreme Court of Alabama
January 11, 2019
Case No. 1150377

The trial court refused to permit plaintiff to give her "better position" charge to the jury. Plaintiff's argument was that if the doctor had followed the correct standard of care, the effects of the infection would have been ameliorated. The Supreme Court reversed the trial court's decision and stated that the plaintiff must produce evidence to show that her condition was adversely affected by the alleged negligence. Therefore, the trial court committed reversible error by refusing to allow Plaintiff to make her "better position" charge.

6. Stephan v. Millennium Nursing and Rehab Center, Inc.
Supreme Court of Alabama
October 5, 2018
Case No. 1170524

Deceased resident's daughter brought a wrongful death claim against nursing and rehab center. Prior to being transferred from the hospital to the nursing home, the daughter signed an arbitration agreement on behalf of the father, though the father had not signed a power of attorney nor was there evidence that the father lacked mental capacity. Based on the evidence at trial, the Supreme Court held that the father lacked mental capacity, but the daughter signed the arbitration solely as a family member and not on the father's behalf. Therefore, the order compelling arbitration was reversed.

C) OTHER:

1. Cooley et al. v. HMR of Alabama
Eleventh Circuit
September 6, 2018
Case No. 18-10657

The plaintiffs, forty-four nurses employed by HMR of Alabama, brought suit under the Fair Labor Standards Act and under state theories of quasi-contract and quantum meruit alleging that they had worked in excess of forty-hours per week and had worked without compensation during lunch breaks in which they attended to patients. In order to recover under the FLSA, a plaintiff must allege he or she worked more than a forty-hour workweek. (*Cont'd on next page.*)

1. (CONT'D) - Cooley et al. v. HMR of Alabama

A meal period is not included in the work-week calculation if an employee is "completely relieved from duty." The plaintiffs alleged that they were not relieved because they had to tend to patients during their breaks. The Eleventh Circuit held that it was reasonable to assume that tending to patients is a principal activity of a nursing home and that the district court erred by dismissing the FMLA claim. However, the Eleventh Circuit held that the plaintiffs could not recover under state claims of quasi-contract and quantum meruit because the plaintiffs failed to allege that they reasonably expected to be compensated for their work.

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2. Wright v. Harris
Supreme Court of Alabama
February 15, 2019
Case No. 1171031

Plaintiff filed claims against Hospital Board (which operated a nursing home) and four nurses under the Alabama Medical Liability Act for injuries Plaintiff sustained from a fall. The trial court granted a motion for summary judgment in favor of the nurses on July 9, 2018, and included a certificate of finality. That same day, the Hospital Board filed a motion partially joining the nurses' summary judgment motion. The trial court granted an appeal on the nurses' portion of the case, and stayed the hospital board's portion. The Supreme Court noted that the issue was still pending and that the trial court exceeded its discretion in entering the Rule 54(b) certificate of finality.

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3. Alabama State Board of Pharmacy v. Parks, et al.
Alabama Court of Civil Appeals
July 26, 2019 (*Original opinion withdrawn and this one substituted*.)
Case No. 2180227

This opinion represents the third appeal on this case. The Board suspended the license of a pharmacist for failing to comply with licensure requirements, and put two of her pharmacy permits on probation for five (5) years. The pharmacist brought suit in circuit court for judicial review of the Board's decision. The court noted that pursuant to statute, the agency had authority to impose sanctions against the pharmacist and the pharmacies. Further, the Court noted that the sanctions were not unreasonable, arbitrary, or capricious.

4. The Health Care Authority for Baptist Health v. Central Alabama Radiation Oncology
Supreme Court of Alabama
June 28, 2019
Case No. 1171030

Central Alabama Radiation Oncology, LLC ("CARO") and The Health Care Authority for Baptist Health ("the Authority") executed a noncompetition agreement in 2012 in which the authority agreed not to employ physicians within 150 miles of Montgomery. In February 2018, the authority submitted a CON application seeking to offer radiation-oncology services in Prattville. In April 2018, CARO opposed the CON and submitted an action alleging breach of the noncompetition agreement. Subsequently, and pursuant to the Alabama Open Records Act ("ORA"), CARO requested all documents and records relating to radiation-oncology.

4. (Cont'd) - **The Health Care Authority for Baptist Health v. Central Alabama Radiation Oncology**

The Authority permitted CARO to review certain documents in Camera and then submitted numerous redacted documents to CARO in June 2018.
After a hearing, the circuit court ordered the Authority to produce unredacted versions of all previously disclosed documents. The Court noted that the Authority chose to partner with the University of Alabama and received several governmental benefits thus making the Authority a governmental entity subject to the ORA. Further, after determining that the Authority was subject to the ORA, the Court held that the requested documents did not fall within any exceptions to the ORA. Specifically, due to the fact that the Authority permitted an in camera review of the documents, the documents were not privileged, confidential, or detrimental to the best interests of the public. Ultimately, the Court held that the circuit court's order of disclosure did not exceed the scope of the ORA.

"Looks like another killer app."

5. **May v. Azar**, 28 ALW 32-3
Alabama Court of Civil Appeals
August 2, 2019
Case Nos: 2180004, 2180033

This opinion contains an analysis of the interplay between Federal and State law in a case involving an 83-year-old woman going into a nursing home and seeking to become eligible for Medicaid Benefits.

6. **Alabama Department of Labor v. Griggs**, 28 ALW 31
Alabama Court of Appeals
July 26, 2019
Case No. 2180449

This was an unemployment compensation case. An ambulance driver was discharged after parking in a handicapped space and being confronted by a "little old lady" for parking in the space, without a patient in the ambulance. He had previously been warned for a speeding ticket and was discharged. Section 25-4-78 was held to be applicable and he was ruled ineligible for unemployment benefits.

7. **Arnold v. Hyundai Motor Manufacturing Alabama**, 28 ALW 29 Alabama Court of Civil Appeals
July 12, 2019
Case No. 1170974

The employment agreement required repayment of moving expenses if the Plaintiff resigned within twenty-four (24) months. The Plaintiff resigned after sixteen (16) months because of "intolerable working conditions." The Court found in favor of Hyundai.


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"Wait, it's September *already*?! Wow, time flies, huh?
OK, then you only have *two* months to live."

LEGISLATION:


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ANDERSON

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1. **Act 2019-52, HB289 (Economic Development Professionals)** – This Act adds a new section to the Alabama Ethics Law to exclude economic development professionals from the definition of a lobbyist. Effective: April 19, 2019.

2. **Act 2019-55, HB115 (Board of Occupational Therapy)** – This Act is the requisite action under the Alabama Sunset Law to continue the existence of the Alabama Board of Occupational Therapy until October 1, 2023. Effective: April 23, 2019

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3. **Act 2019-57, HB117 (Board of Dental Examiners)** – This Act is the requisite action under the Alabama Sunset Law to continue the existence of the Alabama Board of Dental Examiners until October 1, 2021. Effective: April 23, 2019.

4. **Act 2019-58, HB118 (Board of Massage Therapy)** – This Act is the requisite action under the Alabama Sunset Law to continue the existence of the Alabama Board of Massage Therapy until October 1, 2023. Effective: April 23, 2019.

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5. **Act 2019-60, HB121 (Board of Pharmacy)** – This Act is the requisite action under the Alabama Sunset Law to continue the existence of the Alabama Board of Pharmacy until October 1, 2021. Effective: April 23, 2019.

6. **Act 2019-64, HB232 (St. Clair County Ad Valorem Tax)** – This act edits the local constitution to permit the county to levy an ad valorem tax of up to 2% to support the county school district for a period not to exceed 30 years. Effective: April 23, 2019.

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7. **Act 2019-82, SB80 -** Amends Section 29-2-40, Code of Alabama 1975, to: (1) increase the membership of the Contract Review Permanent Legislative Oversight Committee from five to seven members; (2) specify that the Chairs of the Senate Finance and Taxation General Fund and Senate Finance and Taxation Education Committees and the Chairs of the House Ways and Means General Fund and House Ways and Means Education Committees are included within the membership of the Contract Review Permanent Legislative Oversight Committee; and (3) authorize a member of the committee who is a member by virtue of office, if elected to the same house without a break in service, to continue to serve until his or her successor is appointed. Effective: July 1, 2019.

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8. **Act 2019-88, HB129 (City of Madison Ad Valorem Tax)** – This act enables the city to increase the rate of its ad valorem tax by 1.2%. Effective: April 30, 2019.
9. **Act 2019-91, HB299 (Montgomery County Rental Tax)** – This act enables the county to levy and collect a rental tax against the lessees/renters of tangible personal property (.75% on vehicles and 2% on all other property subject to the tax). Effective: May 1, 2019.
10. **Act 2019-92, HB164 (Chilton County Sale and Use Tax)** – This act enables the county to levy and collect a sales and use tax. The taxes collected under this act will be used for the construction, maintenance, and operation of hospital facilities in the county. Effective: May 1, 2019.

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11. **Act 2019-94, HB250 (Alabama Business Corporations Law)** – This act adds a new chapter to Title 10A of the *Code of Alabama*, 1975 and amends select chapters within the same title. Change in the law reflects the Model Business Corporations Act of 2016 and Delaware Corporate Law in an attempt to reflect national standards in Alabama's state corporate law. Effective: January 1, 2020.
12. **Act 2019-98, SB54**, is the Insurance Data Security Law. The act requires insurers and other entities licensed by the Department of Insurance to develop, implement, and maintain an information security program based on the risk assessment of the licensee that contains administrative, technical, and physical safeguards for the protection of nonpublic information and of the information system of the licensee from cybersecurity events, as defined, and requires notification of the commission of insurance when a cybersecurity event occurs. Effective: May 1, 2019.

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"Really? Everyone says it hurts when I do that.
Let me try again..."

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13. **Act 2019-102, SB38 (Nurse Licensure)** – This act allows the Alabama Board of Nursing to enter into the Enhanced Nurse Licensure Compact to provide uniformity in licensing requirements and interstate practice throughout party states. Effective: August 1, 2019.
14. **Act 2019-128, HB34 (Pharmacy Technicians Registration)** – This act amends Section 34-23-131 of the *Code of Alabama*, 1975 to delete the time limit for reinstatement of the lapsed reinstatement of a pharmacy technician without examination by the Board of Pharmacy and limit the penalties and late fees required to be paid to five years. Effective: May 8, 2019.

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15. **Act 2019-133, SB228**, amends Sections 14-6-40, 14-6-42, 14-6-47, 14-6-48, and 36-22-17 of, and repeals Section 14-6-43 of, the Code of Alabama 1975, to: (1) increase the allowance paid by the state for the feeding of prisoners in the custody of the sheriff from a daily amount of $1.75 per prisoner to $2.25 per prisoner; (2) provide that under no circumstances may the sheriff be personally responsible for the cost of feeding prisoners in the event of any shortage of funds; (3) establish a Prisoner Feeding Fund in each county sheriff's office and require all payments made by the state to be deposited into each account; (4) require each sheriff to maintain records of all payments received and all expenditures made from the Prisoner Feeding Fund and subject the fund to a regular audit by the Department of Examiners and Public Accounts;

15. (CONT'D) - Act 2019-133, SB228,

(5) provide that at the end of each fiscal year, the sheriff may expend not more than 25 percent of the fund for the operation of the jail or for law enforcement purposes, and that the remaining balance must be carried over to the following fiscal year; and (6) commencing September 30, 2019, make an appropriation of $500,000 each year from the State General Fund to the Emergency Prisoner Feeding Fund, which shall not exceed a total accumulated amount of $1,000,000, to be used by counties in the case of an unforeseeable emergency cost overrun that fully depletes the Prisoner Feeding Fund in the county treasury. Effective: August 1, 2019.

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16. **Act 2019-170, HB367 (Chilton County Sale and Use Tax)** – This act enables the county to levy an additional sales tax up to 2% of gross receipts/gross proceeds from sales. Effective: May 15, 2019.
17. **Act 2019-189, HB314 (Human Life Protection Act)** – This act makes abortion and attempted abortion felony offenses except in cases where abortion is necessary in order to prevent a serious health risk to the unborn child's mother; to provide that a woman who receives an abortion will not be held criminally culpable or civilly liable for receiving the abortion; and in connection therewith would have as its purpose or effect the requirement of a new or increased expenditure of local funds within the meaning of Amendment 621 of the *Constitution of Alabama* of 1901, now appearing as Section 111.05 of the Official Recompilation of the *Constitution of Alabama* of 1901, as amended. Effective: November 15, 2019.

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18. **Act 2019-202, SB176 (Hoover Ad Valorem Tax)** – This act authorizes the City Council of the City of Hoover in Jefferson and Shelby Counties, pursuant to Amendment No. 373 of the *Constitution of Alabama* 1901, to increase the rate of ad valorem tax levied and collected on all taxable property in the city. Authorized pursuant to the *Constitution of Alabama* of 1901, by an additional .24% of assessed value to be used exclusively for public school purposes. Effective: May 21, 2019.

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19. **Act 2019-203, SB177 (Mountain Brook Ad Valorem Tax)** – Authorizes the governing body of the City of Mountain Brook, Alabama, pursuant to Amendment No. 373 to the *Constitution of Alabama* of 1901, to increase the rate at which there is levied and collected by the city, on all taxable property situated within the city, the special ad valorem tax for public school purposes authorized in Amendment No. 56 to the *Constitution of Alabama* of 1901, to a maximum rate, for any tax year of the city, of 2.06% of assessed value. Effective: May 21, 2019.

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20. **Act 2019-221, SB57**, amends Sections 12-18-156, 16-25-14, and 36-27-16, Code of Alabama 1975, to authorize a member of the Retirement Systems of Alabama to designate a portion of his or her retirement benefits to be paid to a special needs trust for the benefit of a dependent child. Effective: August 1, 2019.

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21. **Act 2019-224, SB213 (Board of Genetic Counseling)** – This act creates the Alabama Genetic Counselor Act; to establish the Alabama Board of Genetic Counseling; to provide for the powers and authority of the board; to provide qualifications for licensure as a genetic counselor and requirements for license renewal and restoration of inactive licenses; to make the practice of genetic counseling without a license a criminal offense; to exempt physicians and other licensed professionals from licensure by the

21. (Cont'd) Act 2019-224, SB213 –

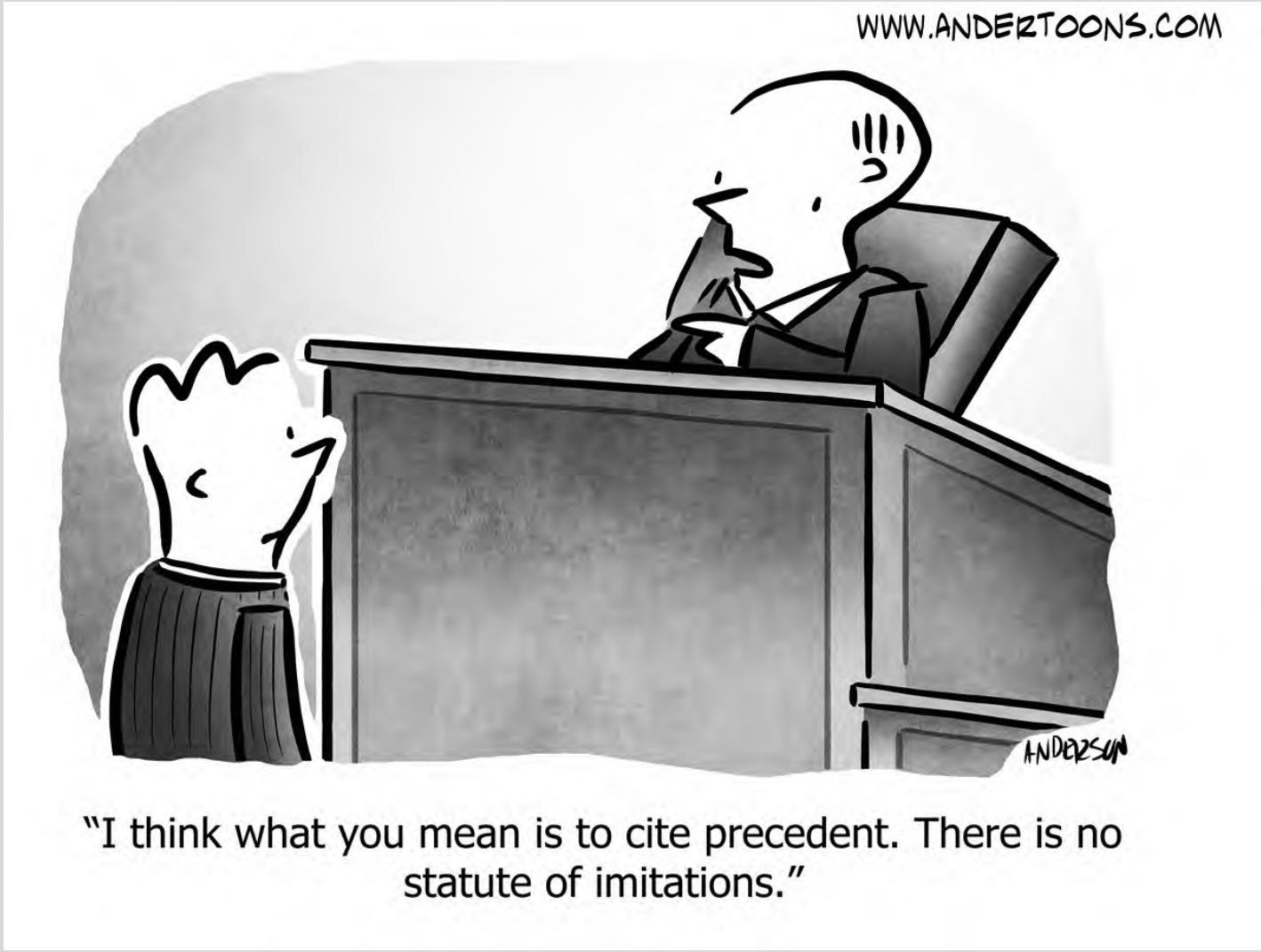
board; to clarify that genetic counselors are not authorized to practice medicine; to establish the Genetic Counseling Fund in the State Treasury; to subject the board to review pursuant to the Alabama Sunset Law; and in connection therewith would have as its purpose or effect the requirement of a new or increased expenditure of local funds within the meaning of Amendment 621 of the *Constitution of Alabama* of 1901, now appearing as Section 111.05 of the Official Recompilation of the *Constitution of Alabama* of 1901, as amended. Effective: May 21, 2019.

22. **Act 2019-264, HB572 (Huntsville Ad Valorem Tax)** – This act authorizes the City Council of the City of Huntsville, to equalize the level of ad valorem taxation collected for public school purposes throughout the city; to modify, pursuant to the procedures provided for in Amendment 373 to the *Constitution of Alabama* of 1901, including a favorable vote of the qualified electors of the city who vote on the proposed modification at an election thereon to be called and held pursuant to the provisions of Amendment 373, and contingent upon a corresponding reduction in the levy of

22. (Cont'd) Act 2019-264, HB572:

certain ad valorem taxes heretofore authorized to be levied in the school district of the city for public school purposes, the maximum rate of the ad valorem tax on all taxable property in the city presently levied and collected for public school purposes in the city pursuant to Amendment 8 to the *Constitution of Alabama* of 1901, to a rate not in excess of 2.2%, the amounts collected from the levy of such tax to continue to be used exclusively for public school purposes in the city. Effective: May 23, 2019.

23. **Act 2019-273, HB11 (Perfection of Lien)** – This act amends Sections 35–11–371 and 35–11–372, *Code of Alabama* 1975, to require a hospital that provides medical treatment to an injured person to seek compensation solely from that person's health insurance provider, with the exception of approved copayments and deductibles, unless certain circumstances apply; and to allow a hospital to perfect a hospital lien against any recovery the injured person may be awarded for injuries by way of settlement or judgment in certain circumstances. Effective: August 1, 2019.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24. **Act 2019-276, HB157**, appropriates $39,885,565 from the Children First Trust Fund to be distributed in specified amounts, and in quarterly allotments, to the following agencies: (1) Alcoholic Beverage Control Board; (2) Children's Trust Fund; (3) Department of Forensic Sciences; (4) Alabama Department of Human Resources; (5) Juvenile Probation Services Fund; (6) Alabama Medicaid Agency; (7) Alabama Department of Mental Health; (8) State Multiple Needs Children's Fund; (9) Department of Public Health; (10) Department of Rehabilitation Services; and (11) Department of Youth Services. The act provides for the deposit of tobacco settlement revenues into the Children First Trust Fund within 30 days of receipt, and conditions allocations of the appropriated funds to each agency upon the receipt of tobacco revenues that have been earmarked for that Agency.

24. (Cont'd) Act 2019-276, HB157 –

The Act also requires that the portion of Children First Trust Fund receipts currently allocated for the State Board of Education shall be transferred to the State General Fund during the fiscal year ending September 30, 2020. The act also requires an appropriation from additional tobacco settlement funds of $48,901,593 for the fiscal year ending September 30, 2020, to be distributed in specified amounts to the following entities: (1) Department of Early Childhood Education; (2) 21st Century Debt Service; (3) Senior Services Trust Fund; (4) Alabama Medicaid Agency; and (5) Department of Senior Services – Medicaid Waiver. Any remaining tobacco revenues available shall be conditionally appropriated on the recommendation of the Director of Finance, the Chairman of the House Ways and Means General Fund Committee, and the Chairman of the Senate Finance and Taxation-General Fund Committee when approved by the Governor.
Effective: May 28, 2019.

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25. **Act 2019-278, HB176 (Hospital Funding Program Extended)** – This act amends Sections 40–26B–71, 40–26B–73, 40–26B–77.1, 40–26B–79, 40–26B–80, 40–26B–81, 40–26B–82, 40–26B–84, 40–26B–85, and 40–26B–88, *Code of Alabama* 1975, to extend the private hospital assessment and Medicaid funding program for fiscal years 2020, 2021, and 2022. Effective: October 1, 2019.

26. **Act 2019-279, HB177 (Privilege Assessment on Nursing Facilities Extended)** – This act amends Section 40–26B–21, *Code of Alabama* 1975, relating to the privilege assessment, the supplemental privilege assessment, and monthly surcharge on nursing facilities; to extend the current supplemental privilege assessment and monthly surcharge to August 31, 2022. Effective: May 28, 2019.

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27. **Act 2019-280, HB245 (Certified Registered Nurse Anesthetist Defined for Insurance)** – This act amends Section 27–46–3 of the *Code of Alabama* 1975, providing for direct reimbursement for the services of a certified registered nurse anesthetist by insurers, to further provide for the definition of a certified registered nurse anesthetist for the purposes of the law. Effective: May 28, 2019.

28. **Act 2019-301, SB37 (Loan Repayment for Advanced-Practice Nurses)** – This act amends Section 34–21–96, *Code of Alabama* 1975, relating to the loan repayment program for advanced-practice nursing administered by the Board of Nursing; to authorize the board to provide loans to currently certified nurse practitioners, certified nurse midwives, and certified registered nurse anesthetists who contract with the board to practice in medically underserved areas of the state. Effective: August 1, 2019.

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29. **Act 2019-302, SB59 (Reporting Notifiable Diseases)** – This act amends Sections 22–11A–4 and 22–11A–40, *Code of Alabama* 1975, to require laboratories to submit isolates or additional clinical materials to the Department of Public Health in certain cases of suspected disease; and to add Section 22–11A–42 to the *Code of Alabama* 1975, to authorize the State Board of Health to set a reasonable schedule of fees for services rendered by the Bureau of Clinical Laboratories. Effective: August 1, 2019.

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30. **Act 2019-303, SB277**, amends Sections 38-13-2 and 38-13-4, Code of Alabama 1975, to: (1) require criminal background checks for any adult working in a child care institution, group home, maternity center, or transitional living facility; and (2) expand the list of violent crimes for which a conviction would make an individual unsuitable for employment, volunteer work, approval, or licensure regarding a child care institution, group home, maternity center, or transitional living facility. Effective: May 29, 2019.

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31. **Act 2019-304, HB251 (Right of Inspection by Governing Persons)** – This act amends Section 10A–1–3.33, *Code of Alabama* 1975, as amended by Act 2018–125 of the 2018 Regular Session, Section 10A–5A–1.01, *Code of Alabama* 1975, and Sections 10A–8A–1.02 and 10A–8A–4.11, as added to the *Code of Alabama* 1975, by Act 2018–125 of the 2018 Regular Session, relating to business corporations; to specify which law governs the right of inspection and access by governing persons under existing and proposed law; to make certain technical corrections regarding the name of the Alabama Limited Liability Company Law, the ability of a partnership to continue as an entity for a brief period of time under the law with one partner or no partners, and the duty of a partner in a general partnership to not compete with the partnership before the partnership is dissolved; and to provide for a retroactive effective date. Effective: Retroactive to January 1, 2019.

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32. **Act 2019-315, HB20 (Electronic Meeting of State Health Officer Board)** – This act amends Section 22–21–27, *Code of Alabama* 1975; to authorize the advisory board to meet by electronic means and require the advisory board to establish rules of procedure for its meetings. Effective: May 29, 2019.
33. **Act 2019-332, HB553 (Bibb County Sales and Use Tax)** – This act authorizes the county commission to levy an additional sales and use tax; providing for the collection, distribution, and use of the proceeds of the tax; and prescribing penalties and fixing punishment for violations of this act. Effective: May 23, 2019.

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34. **Act 2019-337, SB401 (Macon County Sales and Use Tax)** – This act authorizes the county commission to levy a temporary additional sales and use tax (.5%); to provide for the collection of the tax and for the distribution and use of the proceeds of the tax to fund only ambulance service for the citizens of the county; and to prescribe penalties and fix punishment for violation of this act. Effective: May 23, 2019.

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35. **Act 2019-340, SB69**, amends Sections 22-9A-17, 30-1-5, 30-1-12, and 30-1-16, Code of Alabama 1975, to: (1) abolish the requirement of a marriage license for marriages performed in this state; (2) establish requirements for a marriage document to be completed and signed by the parties to the marriage; (3) require the payment of a recording fee to the judge of probate for each marriage recorded; (4) establish that there is no requirement for a marriage ceremony in order to legitimize a marriage; and (5) repeal Sections 30-1-9, 30-1-10, 30-1-11, 30-1-13, and 30-1-14, Code of Alabama 1975, relating to marriage. Effective: August 29, 2019.

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36. **Act 2019-355, HB381 (Persons Physically/Mentally Unable to Consent)** – This act amends Section 22–8–1, *Code of Alabama* 1975, to further provide for the provision of medical or mental health services to a person who is physically or mentally unable to consent under certain conditions. Effective: June 4, 2019.
37. **Act 2019-357, HB7 (Persons Physically/Mentally Unable to Consent)** – This act amends Section 34–23–94 of the *Code of Alabama* 1975, relating to judicial review of orders of the State Board of Pharmacy; to provide that appeals of orders of the board may be filed in the county where the board maintains its headquarters. Effective: June 4, 2019.

38. **Act 2019-368, HB35 (Pharmacy Collaborative Practice Agreements)** – This act authorizes a pharmacist licensed by the Board of Pharmacy and a physician licensed by the State Board of Medical Examiners to enter into a collaborative practice agreement; and to authorize the Board of Pharmacy and Board of Medical Examiners to adopt certain fees. Effective: June 4, 2019.

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39. **Act 2019-392, HB540 (Alabama Incentives Modernization Act)** – This act amends Sections 27–4A–3, 40–18–376, 40–18–376.1, 40–18–410, 40–18–411, 40–18–412, 40–18–413, and 40–18–414, *Code of Alabama* 1975; to add new Sections 40–18–6.1, 40–18–8.1 and 40–18–376.3, Code of Alabama 1975; to add a new Article 2C to Chapter 10 of Title 41, *Code of Alabama* 1975; to add new tools for the attraction of new and expanding businesses in rural Alabama; to attract high-tech companies to Alabama; to add new tools for the attraction of new and expanding technology companies to Alabama; to make various enhancements to Alabama's incentives laws; to enhance Alabama's participation in the opportunity zone program; to provide for the repeal of conflicting laws; to provide further for the distribution of proceeds from the insurance premium tax; and to provide for an effective date. Effective: August 5, 2019.

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40. **Act 2019-396, HB498**, requires: (1) state two-year and four-year colleges and universities to adopt and enforce policies that protect and uphold free speech rights for students, faculty, and staff; (2) the boards of trustees of each public institution of higher education to submit to the Governor and the Legislature a report detailing the course of action implemented to ensure compliance with the act within 90 days after its effective date and any changes or updates to the chosen course of action within 30 days after the changes; and (3) the boards of trustees to publish annual reports detailing violations of the policies, describing how the violations were handled, describing difficulties and successes in maintaining institutional neutrality, and including any other assessments, criticism, commendations, or recommendations the boards see fit to include. Effective: July 1, 2020.

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41. **Act 2019-398, SB246**, (1) amends Sections 22-52-10.2 and 22-52-10.3, Code of Alabama 1975, to provide that a probate court may issue a renewal of an involuntary commitment order for treatment for a mentally ill person if it finds, after a hearing, that the person is in need of further care; and (2) adds a new Section 22-52-10.10, Code of Alabama 1975, to provide procedural requirements for petitioning for such a renewal. Effective: September 1, 2019.

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42. **Act 2019-404, SB78 (Alabama Innovation Act)** – This act allows a research and development enhancement grant for qualified research expenses in Alabama; to provide that the research and development enhancement grants be subject to the appropriations of the Legislature; no eligible research entity can be awarded more than 20% of the maximum amount awarded in a single fiscal year; to require that the grant only apply to research falling within certain industries; to direct the Alabama Department of Economic and Community Affairs to develop rules to administer the program; to establish the Alabama Research and Development Enhancement Fund; to provide the fund to receive appropriations from the legislature, or from the receipt of gifts, grants, or federal funds to be expended for the purpose of the program; to provide for the criteria under which grants are to be given; and to require an annual report on the progress of the program. Effective: June 6, 2019.

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43. **Act 2019-406, SB245 (Interchangeable Biological Products)** – This act amends Section 34–23–1, *Code of Alabama* 1975, relating to the Alabama State Board of Pharmacy; to define biological products and interchangeable biological products; to add Section 34–23–8.1 to the *Code of Alabama* 1975, to authorize licensed pharmacists to dispense substitutes for certain biological products under certain conditions; to provide for certain notice provisions; and to further provide that this act is intended and shall be construed to apply only to biological drug products. Effective: September 1, 2019.

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44. **Act 2019-437, SB312**, amends Section 32-1-1.1, Code of Alabama 1975, to provide for the definition of scooter, shared micromobility device, and shared micromobility device system. The act also adds Section 32-19-2 to the Code of Alabama 1975, to: (1) prohibit the operation or deployment of shared micromobility devices on the public highways or bikeways of the state without prior authorization from the county or municipality in which the system will be operated; (2) exempt shared micromobility devices from the insurance, licensing, and registration requirements required of motor vehicles; (3) require the owner of a shared micromobility device system to obtain commercial liability insurance in the amount of $1,000,000 per occurrence; and (4) authorize counties and municipalities to regulate the operation of shared micromobility devices. Effective: September 1, 2019.

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45. **Act 2019-441, HB69 (Substitution of Drugs/Brand of Drugs)** – This act amends Section 34–23–8, *Code of Alabama* 1975, to provide that an electronic prescription from a practitioner specify whether a generic product may be dispensed. Effective: September 1, 2019.
46. **Act 2019-445, HB187 (Law Enforcement Worker's Compensation)** – This act amends Sections 25–5–60, 25–5–66, 25–5–68, 25–5–69, and 36–29A–9, *Code of Alabama* 1975, as added to the *Code of Alabama* 1975, by Act 2018–523, 2018 Regular Session, relating to workers' compensation; to provide retroactive effect for the surviving spouse and dependents of a law enforcement officer or firefighter who dies on or after January 1, 2018, as a result of injuries received while engaged in the performance of his or her duties. Effective: September 1, 2019.

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47. **Act 2019-447, HB349**, amends Sections 12-15-102, 16-28-3, 22-52-16, 26-1-1, and 26-14-1, Code of Alabama 1975, to: (1) provide the juvenile court with jurisdiction over individuals who are under 19 years of age and before the court for any of the following: a child in need of supervision matter; commitment to the State Department of Mental Health; or for a proceeding where it is alleged that the rights of the individual are improperly denied or infringed in proceedings resulting in suspension, expulsion, or exclusion from a public school; (2) provide that a person under the age of 19 years who is on track to graduate from public school may not be denied admission to the school solely on account of his or her age; (3) authorize unemancipated minors who are 18 years of age to enter into binding contracts; and (4) require the Department of Human Resources to provide services to an individual under the age of 19 years who is in need of protective services when the individual does not qualify for adult protective services. Effective: September 1, 2019.

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48. **Act 2019-450, HB138 (Health Care Good Samaritan Law)** – This act provides civil immunity to persons who provide transportation to a health care facility or health care provider in certain circumstances. Effective: September 1, 2019.
49. **Act 2019-453, HB549 (Alabama Alzheimer's and Dementia Education, Care, and Training Act)** – This act authorizes the Department of Public Health to provide education and services regarding care for individuals with Alzheimer's disease, dementia, or related diseases to those individuals, their families, and the general public; to repeal Sections 22–50–70, 22–50–71, 22–50–72, 22–50–73, and 22–50–74, *Code of Alabama* 1975, in order to remove the responsibility and authority to do so from the Department of Mental Health; and to provide for funding. Effective: October 1, 2019.

50. **Act 2019-455, HB79 (Alabama Network of Children's Advocacy Centers - Membership)** – This act amends Section 26–16–70, *Code of Alabama* 1975, to expand and clarify the existing requirements for full membership in the Alabama Network of Children's Advocacy Centers for child advocacy centers that wish to apply; and to update defined terms. Effective: September 1, 2019* (contingent on another HB passing?)

51. **Act 2019-456, HB32 (Administration of Medication on School Grounds)** – This act amends Sections 16–1–39 and 16–1–48, *Code of Alabama* 1975, relating to the administration of medications on K–12 school campuses; to name the code sections together as the Kyle Graddy Act; to allow the possession and self-administration of single dose autoinjectable epinephrine by students; and to provide further for the definition of single dose autoinjectable epinephrine. Effective: June 7, 2019.

52. **Act 2019-457, SB73 (Alabama Pharmacy Benefits Manager Licensure and Regulation)** – This act prohibits pharmacy benefit managers from preventing pharmacies and pharmacists from disclosing information on the amount an individual would pay for a prescription drug if he or she does not have an insurance plan, benefits, discounts, or if an individual paid for a prescription without using their pharmacy benefits; and to require pharmacy benefit managers to register with the Department of Insurance. Effective: June 7, 2019.

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53. **Act 2019-461, HB288 (Health Care Professionals Duty to Report Gunshot Injury)** – This act requires any member or employee of the medical profession to immediately report to law enforcement any injury resulting from a gunshot and to provide that the person making the report would be immune from any criminal or civil liability. Effective: September 1, 2019.
54. **Act 2019-464, SB163**, (1) prohibits an occupational licensing board from automatically denying an application for a license or from revoking an existing license because of a criminal conviction when a valid Order of Limited Relief has been issued for the otherwise disqualifying conviction or convictions in question; (2) authorizes an individual who has been convicted in this state of a misdemeanor or felony to file a petition in the circuit court for an Order of Limited Relief; (3) establishes the grounds and procedure for the granting of an Order of Limited Relief; and (4) requires an administrative fee with the petition. Effective: September 1, 2019.

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55. **Act 2019-465, SB320**, amends Sections 13A-5-6, 13A-6-60 to 13A-6-65, inclusive, 13A-6-65.1, 13A-6-66, 13A-6-67, 13A-6-68, 13A-6-70, 13A-6-71, 13A-6-81,13A-6-82, 13A-6-122, 13A-6241, 13A-6-243, 13A-11-9, 13A-11-32.1, 13A-12-120, 13A-12-121, 13A-12-190, 13A-12-192, 15-3-5, 15-20A-5, 15-20A-44, 15-23-101, and 15-23-102, Code of Alabama 1975, to: (1) redefine deviate sexual intercourse as sodomy; (2) include mental defectiveness, mental incapacitation, and physical helplessness in a broad definition of incapacitation; (3) redefine sexual contact to include touching that occurs through clothing without regard to martial relationship; (4) expand the definition of forcible compulsion; (5) provide that certain sexual contact can be an offense under sexual misconduct; (6) include additional offenses within the crime of sexual torture;

55. Act 2019-465, SB320 (*CONT'D*)

and (7) create a presumption that juveniles adjudicated delinquent of certain sex offenses are not subjected to the state sex offender registration requirements if the juvenile has been counseled on the dangers of the conduct for which he or she was adjudicated delinquent unless the sentencing court makes a determination that the juvenile sex offender is to be subjected to those sex offender registration requirements. Effective: September 1, 2019.

56. Act 2019-475, SB207 (Children/Incapacitated Persons Unattended in Motor Vehicle) – This act prohibits any person from leaving a child or an incapacitated person in a motor vehicle unattended in a manner that creates an unreasonable risk of injury or harm; to provide criminal immunity to a person who rescues a child or incapacitated person from an unattended motor vehicle; and to provide civil and criminal immunity to a public safety official who rescues a child or incapacitated person from an unattended motor vehicle. Effective: September 1, 2019.

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57. **Act 2019-478, SB10**, amends Sections 21-7-1 to 21-7-9, inclusive, Code of Alabama 1975, to: (1) provide an individual with a disability with the full and equal accommodations, advantages, facilities, and privileges in every public accommodation; (2) require a public accommodation to modify its policies, practices, and procedures to permit the use of a service animal by an individual with a disability; (3) provide that an individual with a disability has the right to be accompanied by a service animal in all areas of a public accommodation; (4) require a service animal to be under the control of its handler and have a harness, collar, lease, or other tether, with exceptions; (5) provide the trainer of a service animal with the same rights as an individual with a disability; (6) authorize a public accommodation to ask for certain information to

57. (Cont'd) Act 2019-478, SB10 -

ascertain whether an animal is a service animal or a pet; (7) authorize a public accommodation to remove an animal, including a service animal, from its premises if the animal is out of control and the handler does not take control of the animal, the animal is not housebroken, or the animal poses a direct threat to the health and safety of others; (8) provide criminal penalties to a person who knowingly misrepresents himself or herself as using a service animal and as being qualified to use a service animal or as a trainer of a service animal; and (9) prohibit a housing accommodation for rent or lease to discriminate against an individual with a disability and that individual's service animal, if any. Effective: September 1, 2019.

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58. **Act 2019-489, SB76**, requires the personal representative filing to initiate a proceeding under the Alabama Small Estates Act to give notice of his or her appointment to the Alabama Medicaid Agency and provides requirements for the contents of the notice. The act also: (1) prohibits certain debts against the estate of the decedent from being paid until the notice has been filed in the probate court and 30 days have passed since the agency received the notice; (2) authorizes the agency to petition to open the probate estate of a Medicaid recipient by filing a petition to appoint a third party administrator and issue letters of administration; and (3) authorizes the agency to file a claim against the estate of the Medicaid recipient for the amount of any medical assistance payments made on behalf of the recipient, with exceptions. Effective: September 1, 2019.

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59. **Act 2019-491, SB396** amends Sections 41-9-1021, 41-9-1023, 41-9-1024, 41-9-1027, 41-9-1028, 41-9-1030, 41-9-1031, 41-9-1032, 41-9-1033, 41-9-1034, 41-9-1035, 41-9-1036, 41-9-1037, and 41-9-1038, Code of Alabama 1975, to: (1) provide for the regulation of professional bare knuckle boxing by the Alabama Athletic Commission in the same manner as boxing and mixed martial arts; (2) provide that drug tests are required to be conducted in accordance with the most recent list of prohibited substances and methods outlined by the World Anti-Doping Agency; and (3) provide that a violation of the drug testing policy is punishable by a suspension of licensure and a civil fine of up to $25,000, together with a percentage of the purse not to exceed 15 percent, for each violation. Effective: September 1, 2019.

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60. **Act 2019-493, HB58 (EMS Personnel)** – This act amends Sections 22–18–4 and 22–18–6, *Code of Alabama* 1975; to authorize the State Board of Health to establish by rule, licensure fees for EMS personnel; to revise course requirements for ground ambulance drivers; to authorize a process that provides for conducting criminal background checks on EMS personnel seeking licensure; to provide penalties for unauthorized disclosure of records generated from a criminal background check; and in connection therewith to have as its purpose or effect the requirement of a new or increased expenditure of local funds within the meaning of Amendment 621 of the *Constitution of Alabama* of 1901, now appearing as Section 111.05 of the Official Recompilation of the *Constitution of Alabama* of 1901, as amended. Effective: September 1, 2019.

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61. **Act 2019-498, SB204**, amends Sections 41-22-2, 41-22-3, 41-22-5, 41-22-5.l, 41-22-5.2, 41-226, 41-22-7, 41-22-8, 41-22-22, 41-22-22.l, 41-22-23, and 41-22-27, Code of Alabama 1975, to: (1) specify when an agency is required to prepare a business impact analysis; (2) require filing of the business impact analysis with the Legislative Services Agency, Legal Division; (3) specify that failure to file as required invalidates the action; (4) provide that a rule may not become effective until at least 45 days after notice is published in the Alabama Administrative Monthly that the certified rule was filed with the Legislative Services Agency; and (5) change the name of the Joint Committee on Administrative Regulation Review to the Joint Committee on Administrative Rule Review and establish what is a quorum for purposes of conducting business. Effective: September 1, 2019.

62. **Act 2019-499, SB330**, is the Alabama Alzheimer's and Dementia Education, Care, and Training Act. The act authorizes the Department of Public Health to develop educational programs concerning Alzheimer's disease, dementia, or related diseases, and to offer those programs to individuals with those diseases, their families, and the general public. The act also repeals Sections 22-50-70, 22-50-71, 22-50-72, 22-50-73, and 22-50-74, Code of Alabama 1975, in order to remove the responsibility and authority of providing such educational programs from the Department of Mental Health. Effective: October 1, 2019.

63. **Act 2019-500, SB425 (Buprenorphine in Nonresidential Treatment Programs)** – This act establishes guidelines for the use of buprenorphine in nonresidential treatment programs; and to provide for the adoption of rules to further implement and enforce the provisions of the act. Effective: June 10, 2019.
64. **Act 2019-511, SB236 (CBD and Medical Cannabis)** – This act amends Section 13A–12–214.2, Code of Alabama 1975; to establish a Medical Cannabis Study Commission and provide for its membership and duties; and to extend Carly's Law. Effective: June 10, 2019.

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65. **Act 2019-514, HB59**, is the William Buechner Act. The act amends Sections 13A-5-40 and 13A-5-49, Code of Alabama 1975, to: (1) provide that murder of a first responder is a capital offense if committed while the first responder is operating in an official capacity; and (2) add to the list of aggravating circumstances to be considered in sentencing for a capital offense circumstances where the victim was a law enforcement officer, a prison or jail guard, or a first responder, and where the victim was operating in his or her official capacity. Effective: September 1, 2019.

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66. **Act 2019-515, HB212**, is the Anti-Road Rage Act. The act amends Section 32-5A-80, Code of Alabama 1975, to: (1) provide that a vehicle may not travel in the left lane of an interstate highway for more than 1.5 consecutive miles unless the vehicle completely passes at least one other vehicle, unless doing so is necessary due to: traffic conditions; inclement weather, obstructions, or hazards; compliance with a law, rule, ordinance or traffic control device; exiting a roadway to the left; paying a toll or user fee at a toll collection facility; operation of an authorized emergency vehicle in the course of duty; or operation of a vehicle in the course of highway maintenance or construction or through a construction zone; and (2) provide that law enforcement may issue only a warning citation for a violation for 60 days following the effective date of the act. Effective: September 1, 2019.

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67. **Act 2019-519, HB225 (Equal Pay Act)** – This act prohibits an employer from paying any of its employees at wage rates less than those paid to employees of another sex or race for equal work unless a wage differential is based upon one or more specified factors. Effective: September 1, 2019.
68. **Act 2019-522, HB379 (Chemical Castration)** – This act provides chemical castration treatment conditions for the parole of persons convicted of a sex offense under certain conditions; to require the Department of Public Health to administer the treatment; and to require the cost of the treatment to be paid for by the offender, with exception. Effective: September 1, 2019.

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Annual Health Law Update for Hospitals - 2019

69. **Act 2019-536, HB471 (Pike County-Treatment of Mental Illness)** – This act authorizes an attending physician, nurse practitioner, or physician assistant at a hospital licensed in this state to detain and provide emergency treatment to an individual with a mental illness for up to 72 hours under certain conditions and to provide protection from civil or criminal liability when acting in good faith for actions taken related to the admission or discharge of the patient; to authorize a law enforcement officer from a designated law enforcement agency to take an individual whom the officer believes has a mental illness into protective custody under certain conditions; to provide for the transportation of the individual to a hospital or other facility for evaluation and treatment; and to provide protection from civil liability to law enforcement officers who, in good faith, place individuals with mental illness into protective custody. Effective: September 1, 2019.

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70. **Act 2019-537, HB76 (Dispensing Controlled Substances)** – This act provides that a practitioner or pharmacist may not knowingly prescribe, administer, or dispense a controlled substance enumerated in Schedules I through V except for a legitimate medical purpose in the practitioner's regular practice of his or her profession; to provide further for the crime of unlawfully distributing or dispensing a controlled substance; and in connection therewith would have as its purpose or effect the requirement of a new or increased expenditure of local funds within the meaning of Amendment 621 of the *Constitution of Alabama* of 1901, now appearing as Section 111.05 of the Official Recompilation of the *Constitution of Alabama* of 1901, as amended. Effective: June 10, 2019.

Annual Health Law Update for Hospitals

ALABAMA UPDATE

September 19, 2019
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OPIOID FALLOUT UPDATE

Feeling the Pain

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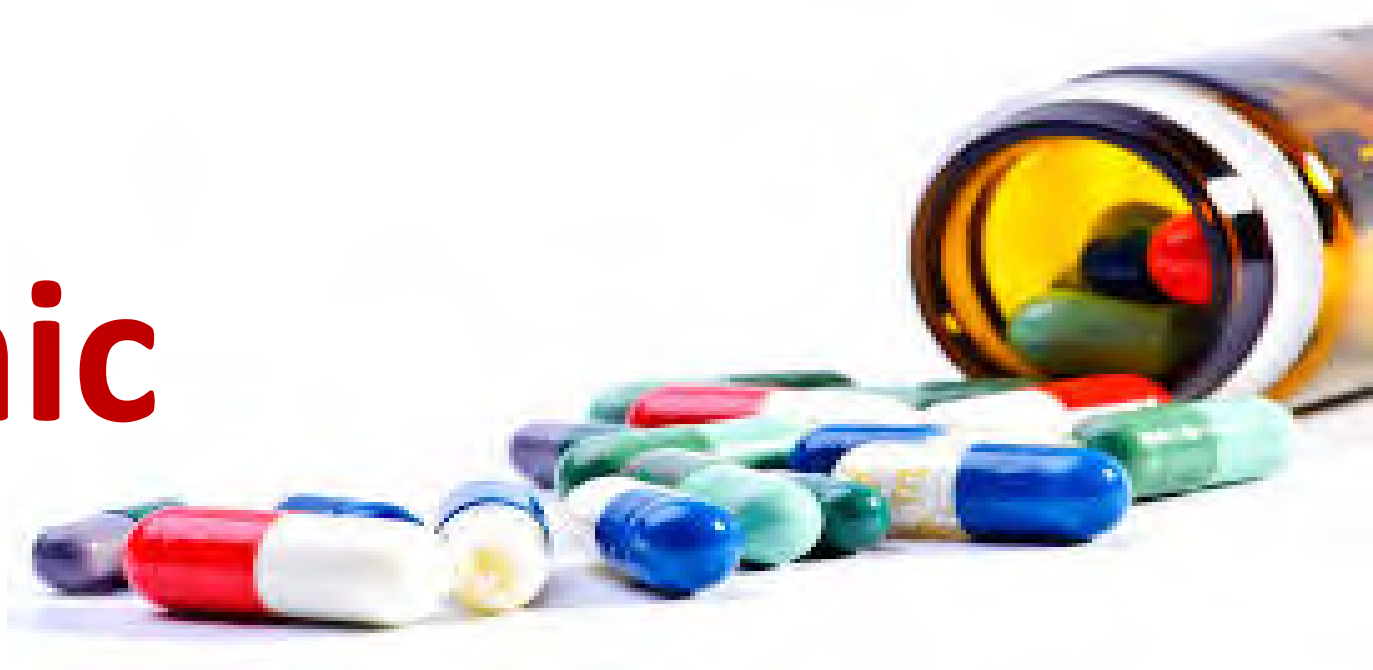
Opioid Epidemic



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OIG/DOJ Year In Review

Opioid Fallout

- July 2017 – Largest ever health fraud enforcement effort (to date).
  - 412 charged defendants in 41 districts
  - 120+ related to prescribing or distributing opioids
- August 2017 – DOJ- Opioid Fraud & Abuse Detection Unit (Data Analytics)
  - Focus on opioid related health care fraud using data to identify and prosecute
  - 12 Federal districts participating (including ND Alabama)

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OIG/DOJ Year In Review

Opioid Fallout

- June 2018 – National Health Care Fraud Takedown. (new largest enforcement)
  - 601 charged defendants in 58 districts
  - Over $2 Billion in false billing
  - Over 13 million illegal doses of opioids
  - 76 doctors charged for their roles in prescribing and distributing opioids
  - In last year 587 providers excluded for conduct related to opioids out of a total of 2,700 individuals excluded last year
  - N & S districts Alabama: 15 defendants charged re role in 8 schemes re compounding pharmacies and controlled substances

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OIG/DOJ Year In Review

Opioid Fallout

- April 2019 – Appalachian Regional Prescription Opioid Strike Force.
  - 60 charged defendants in 11 fed districts
  - Over 350 Thousand improper scripts
  - Over 32 million illegal doses of opioids
  - 31 doctors charged for their roles in prescribing and distributing opioids
  - In last year 650 providers excluded for conduct related to opioids out of a total of 2,000 individuals excluded last year
  - N District Alabama: 4 physicians charged in 5 cases.

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OIG/DOJ Year In Review

Opioid Fallout

- Jan 1, 2018– New TJC standards for Hospitals.
  - Pain assessment and management identified as an organizational priority
  - Actively involve med staff in activities to improve quality of care, treatment, and safety
  - Collect data to monitor performance

    (TJC R3 Report, Issue 11, 8/29/17)
- CMS – removed pain management questions from HCAHPS survey
  - Did you need medicine for pain?
  - Was pain well controlled?
  - Did staff do everything they could to help with pain?

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OIG/DOJ Year In Review

Opioid Fallout

- Feb 27, 2018– DOJ announced new task force
  - Prescription Interdiction & Litigation (PIL) Task Force
  - Charged with bringing Fed law enforcement resources to bear on opioid producers
  - Focus is big pharma and illicit production and distribution

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OIG/DOJ Year In Review

Opioid Fallout

- CMS 2019 Opioid Epidemic Roadmap
  - Aligning monitoring of "systemic inappropriate prescribing" with CDC guidelines for opioid prescribing by primary care practitioners
- 2020 Budget proposal (over 30 references)
  - $60 million community facilities grants
  - $1.5 billion State Opioid Response grants
  - $1 billion NIH opioid and pain research
  - $221 million for behavioral health work force
  - $476 million for CDC to track overdose deaths
  - $55 million to strengthen FDA response to Opioids
  - $3 billion for DOJ efforts

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OIG/DOJ Year In Review

<u>Opioid Fallout</u>

Alabama is at the Epicenter

- 42% of all Medicare Part D enrollees received an opioid prescription in 2016
- 1.2 opioid prescriptions per-capita

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OIG/DOJ Year In Review

Opioid Fallout

Alabama is at the Epicenter

- Harvard University Study (2016 data):
  - Alabama's Fourth Congressional District (Franklin, Colbert, Marion, Lamar, Fayette, Walker, Winston, Cullman, Lawrence, Marshall, Etowah, DeKalb Counties plus parts of Jackson, Tuscaloosa, and Cherokee County): **highest rate of opioid prescriptions in the nation**
    - 166 prescriptions per 100 people (more than twice the national average)
    - In 2016, this district had a population of 683,273 which would amount to 1,134,233 prescriptions.
  - Alabama's First Congressional District (Washington, Mobile, Baldwin, Escambia, Monroe Counties plus parts of Clark County): **5th highest prescription rate in the nation**
    - 131 prescriptions per 100 people
    - In 2016, this district had a population of 704,457 which would amount to 922,839 prescriptions.

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OIG/DOJ Year In Review

<u>Opioid Fallout</u>

Alabama is at the Epicenter

- Dr Aggarwal (#1 prescriber in 2012)
  - 15 years in prison plus $9.5 million
- Dr Couch (houses, cars and stocks)
  - 2 years in Prison plus $14 million
- Dr Sanchez (14 others in office)
  - Sanchez pled guilty, >12 years in prison
  - Judge rejected 10 year plea bargain

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OIG/DOJ Year In Review

<u>Opioid Fallout</u>

Broader Impact

- Hospitals/providers potential FCA liability if employed physicians' opioid prescribing violates the law
- Theoretically, hospital & clinic compliance programs should have been monitoring opioid prescriptions
- Does your compliance program monitor opioid prescribing patterns?

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OIG/DOJ Year In Review

More Opioid Fallout – Liquid Gold

- Dominion Diagnostics (Vermont)
  - $815,000 settlement
  - Urine drug screens and routine clinic blood testing – specimen validity
  - Standing orders for validity testing
- Kentucky Pain Management (1/24/19)
  - Submitted claims to Medicare for specimen validity testing
  - $126,799 settlement
- Ohio Practice and Owner (2/6/2019)
  - Submitted claims to Medicare for specimen validity testing
  - $111,706 settlement
- Kentucky Lab (3/13/19)
  - Submitted SVT claims to Medicare, $125,983 settlement
- Kentucky Medical Practice (3/13/19)
  - Submitted SVT claims to Medicare, $69,776 settlement

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OIG/DOJ Year In Review

More Opioid Fallout – Liquid Gold

More Specimen Validity Testing

- Kentucky Lab (5/31/19)
  - Submitted claims for Specimen Validity Testing (SVT)
  - $88,214.88
- Florida Physician Group (6/6/19)
  - Submitted claims for SVT
  - $62,727.88 settlement
- Kentucky Lab (6/28/2019)
  - Submitted claims for SVT
  - $1,345,959.74 settlement
- Tennessee Lab (8/7/19)
  - Submitted SVT claims to Medicare
  - $95,882.36 settlement

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OIG/DOJ Year In Review

More Opioid Fallout – Liquid Gold

- Other Lab Schemes
  - Acacia Mental Health Clinic (Wisconsin)
    - Mental health/drug dependency clinic
    - Conducted simple $5 "cup" test and charged for sophisticated tests (did not have equipment to run the tests) $200 per test
    - Duplicative and medically unnecessary urine drug tests – required every Medicaid patient to receive a "cup" test and additional tests
    - Also submitted claims to Medicaid for telemedicine services rendered by psychiatrists located outside the US
    - **$4.1** million settlement by clinic and its owner

3/2019

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OIG/DOJ Year In Review

More Opioid Fallout – Liquid Gold

- Other Lab Schemes
  - In and Out of Network deals
    - Labs contract with the hospital- hospital bills as HOPD and test performed by lab. Parties "split" the payment.
    - Frequently there is a "management" company in the middle that pays "inducements, kickbacks or bribes" to get the physicians to order tests which are "unnecessary, clinically inappropriate or have no clinical utility."
    - CBS Special Reports

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OIG/DOJ Year In Review

More Opioid Fallout – Liquid Gold

- Other Lab Schemes
  - In and Out of Network deals
    - BCBS Miss V. Sharkey-Issaquena Com Hospital
    - BCBS of Ga v. DL Investment Holdings
      - Alleges Georgia hospitals billed lab tests "as if they had been performed in a hospital".
      - Outside lab actually performed the tests
      - Toxicology testing
      - Now in arbitration
    - United Healthcare vs Next Health
      - Sued 4 Texas hospitals for over $100 million in out-of-network testing (toxicology and genetic testing)

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OIG/DOJ Year In Review

More Opioid Fallout – Liquid Gold

- Other Lab Schemes
  - In and Out of Network deals
    - Kyle Marcotte Case
      - Arrangement between reference labs and treatment facilities for 40% or reimbursement
      - The arranged for urine screens to run through rural hospitals
        - Campbellton-Graceville Hospital (FL)
        - Regional General Hospital Williston (FL)
        - Chestatee Hospital (Ga)
        - Other rural hospitals
      - Pled guilty (7/19) –awaiting sentencing
      - $57 million dollar fraud and money laundering scheme

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OIG/DOJ Year In Review

More Opioid Fallout – Liquid Gold

- Remuneration
  - Cups provided by Millennium Laboratories
  - Free point of care test cups constitute remuneration – gives rise to Stark violations and Kickbacks
  - Caused a financial relationship with physicians that did not meet an exception under Stark
    - Ameritox Vs Millennium Labs: $15 Million

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OIG/DOJ Year In Review

More Opioid Fallout – Liquid Gold

Millennium Cups (Fraud & Abuse/Stark):

- Massachusetts Practice $87,650 6/19
- Michigan Practice $44,900 7/19
- Space Coast Pain Institute $95,302.50 2/18
- Addiction Medical Care (Ohio) $79,880.50
- Opp, Alabama Dr (Kevin Diel) $40,500.50 4/18
- Michigan Rehab Center $64,555 5/18
- Florida Pediatric Practice and Physician $58,370 9/18
- Arizona Physician $75,409.15 10/18
- Oklahoma Pain Management Practice $98,942.50 12/18 (and Physician)

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OIG/DOJ Year In Review

More Opioid Fallout – Liquid Gold

- Close to Home (9/18)
  - East Alabama Medical Center owned lab
  - Settlement: $4.3 million
  - Alleged payments to marketing entity based on % of revenue
  - Also point of care cups provided

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Annual Health Law Update For Hospitals

OPIOID FALLOUT UPDATE

September 19, 2019
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OIG WORK PLAN FOR 2019

2019 WORK PLAN

September 19, 2019

Gregg Brantley Everett

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OIG/DOJ Year In Review

OIG WORK PLAN FOR 2019

2019 WORK PLAN

- Updated monthly now – need to check on a monthly basis.
- New and ongoing reviews are summarized.
- Office of Audit Services.
- Office of Evaluation and Inspections.
- Office of Investigations.
- Office of Counsel to the Inspector General
- Executive Management.

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OIG/DOJ Year In Review

2019 WORK PLAN

- CMS Medicare and Medicaid Services (CMS).
- Completed Studies: Oversight of Provider Based Facilities. (Note there are still problems.)
- Adverse events in rehabilitation hospitals – New: Adverse events in general acute care hospitals.
- Nationwide analysis of common characteristics in-home health fraud cases.

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OIG/DOJ Year In Review

- Vulnerabilities related to the provider enrollment and ownership disclosure.
- Drug coverage issues.
- Outpatient Services provided to Inpatients: should be "under arrangements" and one bill.

2019 WORK PLAN

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OIG/DOJ Year In Review

New Studies and those which are Still Open (HHS.OIG.GOV):

- DME infusion drugs (compounding pharmacies).
- Hospice certifications of terminal illness.
- Laboratory billing.
- Non-Invasive Ventilator usage (Non-invasive at home ventilators).
- Medicaid and Medicare incentive payments for adopting electronic health records.
- Hospital electronic health record contingency plans; looking at security of EHR's.

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OIG/DOJ Year In Review

New Studies and those which are Still Open (HHS.OIG.GOV) (Cont'd):

- Payment for CPAP Devices when no diagnosis of obstructive sleep apnea.
- Medicare DRG window policy.
- Use of telehealth in Medicaid behavioral health services.
- Outpatient Services to inpatients: Involves two hospitals.
- High Severity DRGS.
- Inpatient Claims paid as Outliers.
- IRF Claims.
- Outpatient Medical Devices.

2019 WORK PLAN

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OIG/DOJ Year In Review

New Studies and those which are Still Open (HHS.OIG.GOV) (Cont'd):

- "Discharge" of patient to HHA and seen within three days – not a discharge, but a transfer.
- Medicare Part B services to beneficiaries in nursing homes.
- Medicare Facet Joint Procedures – Back Pain.
- Medicare payments for clinical diagnosis Laboratory Tests.
- Involuntary transfers and discharges from nursing homes.

2019 WORK PLAN

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OIG/DOJ Year In Review

New Studies and those which are Still Open (HHS.OIG.GOV) (Cont'd):

- National Background check program.
- Access to buprenorphine – waivered providers – opioid treatment.
- Hyperbaric oxygen therapy services: provider reimbursement; national coverage determinations manual, Chapter 20 and Section 20.29; treatments for non-covered conditions, etc. Must be in a chamber, not masks.
- Provider Based vs. Free-Standing Clinics.

2019 WORK PLAN

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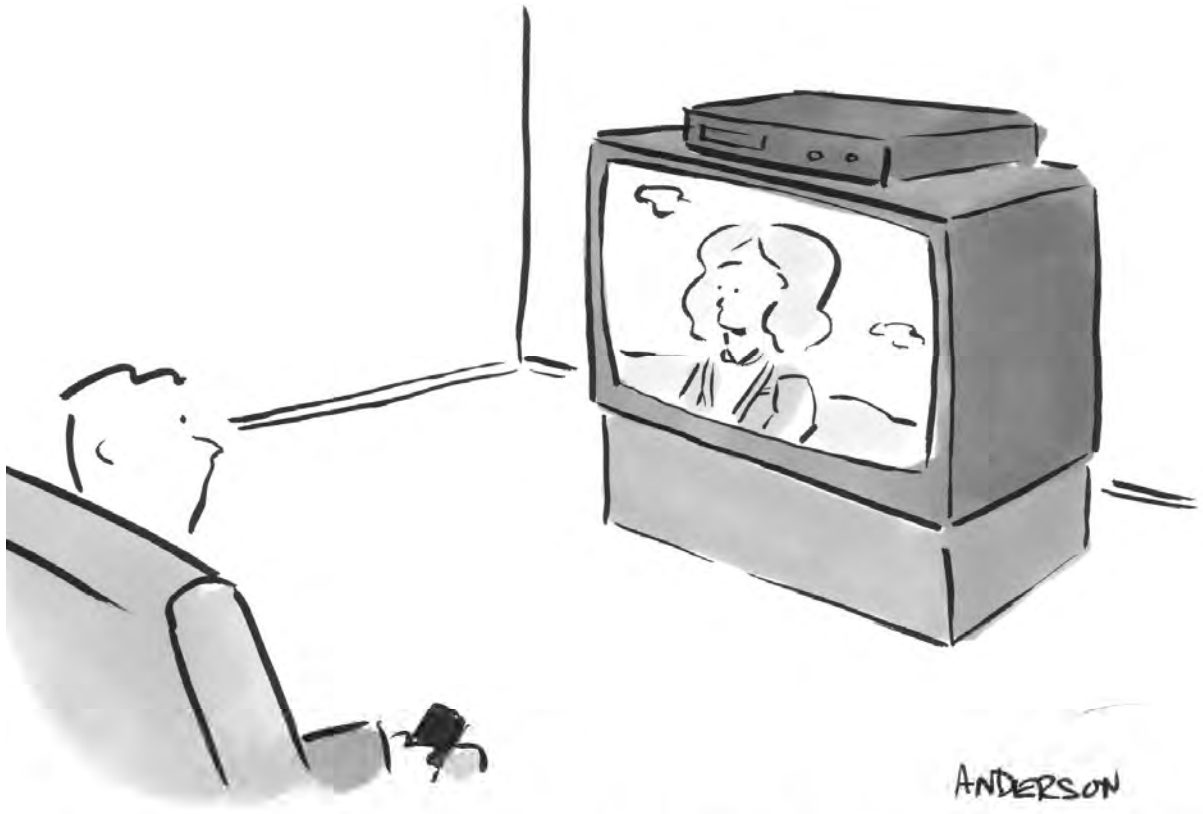

"If you think you might be a hypochondriac, talk to your doctor about Plexium, Nicotor, Plaxix, Incotrim, Fasitor..."

OIG/DOJ Year In Review

Completed Studies:

- Medical assistance days claimed by hospitals: calculation of disproportionate share payments; Medicaid covered days.

- Case review of inpatient rehabilitation hospital patients not suited for intensive therapy: freestanding hospitals and units; determining whether patients benefit from intensive therapy provided in a rehabilitation hospital or unit.

2019 WORK PLAN

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OIG/DOJ Year In Review

Completed Studies (Cont'd):

- Nursing home complaint investigations: nursing home complaints categorized as immediate jeopardy and actual harm to be investigated within a two or ten-day timeframe.
- Skilled nursing facilities-unreported incidents of potential abuse and neglect: audit of state survey agencies.

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OIG/DOJ Year In Review

Completed Studies (Cont'd):

- Skilled nursing facility reimbursement: periodic assessment of patients using minimum data set.
- Skilled nursing facility adverse event screening tool: OIG developed this tool.
- Medicare hospice benefit issues: issues around payment, compliance, and oversight, as well as quality of care.
- Outpatient physical therapy services.

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OIG/DOJ Year In Review

Completed Studies (Cont'd):

- Further review of hospice compliance with Medicare requirements.
- Hospice home care: frequency and number of nurse on-site visits.
- Comparison of home health agency survey documents to Medicare claims data; unqualified providers providing services and provision of services to beneficiaries who were not homebound or did not require skilled nursing services.

2019 WORK PLAN

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OIG/DOJ Year In Review

Completed Studies (Cont'd):

- Part B services during Non-Part A nursing home stays: DME/where a beneficiary continues to reside in a skilled nursing facility after 100 days, Medicare Part B may provide coverage for certain therapy and supplies (DME, prosthetics, orthotics and supplies) – starting again!
- Psychotherapy services – Coding for testing & therapy.
- Mail order diabetic testing strips: follow-up review of portion of the market that Medicare is paying for.

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OIG/DOJ Year In Review

Completed Studies (Cont'd):

- CPAP device supplies: Are providers automatically providing supplies when there are no physician orders for refills – goes along with in-home ventilation.
- Now looking at CPAP devices where no formal diagnosis of Obstructive Sleep Apnea.

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"We caught it early, but your insurance wants to let it go for a while and see what happens."

OIG/DOJ Year In Review

Completed and Ongoing Studies:

- Medicare payments for clinical diagnostic laboratory tests: calculation of new laboratory payments. Statutory changes still being implemented.
- Medicare payments for clinical diagnostic laboratory tests: calculation of new laboratory payments. (BC/BS).

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OIG/DOJ Year In Review

Completed and Ongoing Studies (Cont'd):

- Chronic care management: defined as non-face-to-face services provided to beneficiaries who have multiple significant chronic conditions that placed the patient at significant risk of death, acute exacerbation or functional decline. The services cannot be billed during the same time as transitional care management, home health care supervision/hospice care, and certain end-stage renal disease services.
- Stay tuned for Medicaid changes.

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OIG/DOJ Year In Review

Completed and Ongoing Studies (Cont'd):

- Open payments program: physician payment Sunshine Act and manufacturers' disclosure of payments made to physicians and teaching hospitals.

- Power mobility devices: compilation of prior studies and development of recommendations to reduce Medicare vulnerabilities.

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OIG/DOJ Year In Review

Ongoing Studies:

- Drug waste of single use vial drugs: the FDA approves vial sizes for single use submitted by manufacturer, but does not control the vial sizes submitted for approval. There have been times when a provider would use a single dose vial on multiple patients.

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OIG/DOJ Year In Review

Completed Studies:

- Potential savings from inflation-based rebates in Medicare Part B: Medicare spending on prescription drugs.
- Payments for service dates after recipient death; pretty simple review: Was the patient dead when the billed service was supposedly provided.

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OIG/DOJ Year In Review

Completed and Ongoing Studies:

- Quality payment program: new program for physician payment.
- Medicare Part C payment for services after individual's date of death: again checking to see if the date of service billed is after the date of death.
- Extent of denied care in Medicare advantage plans: comparison of rates of denials, appeals, and overturns across Medicare advantage plans.
- Selected Inpatient and Outpatient billing: Hospitals (specifically use term "upcoding" in description of project!)

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OIG/DOJ Year In Review

Completed Studies:

- Medicare Part D rebates related to drugs dispensed by 340B pharmacies: manufacturers frequently do not pay rebates for Part D prescriptions filled at 340B-covered entities, since they are already providing a discount on the purchase of the drug. The OIG has expressed many concerns about 340B programs over the years.
- Questionable billing for compounded topical drugs.

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OIG/DOJ Year In Review

Ongoing Studies:

- Medicare Part D payments for services after date of death: Medicare contractors are supposed to dis-enroll an individual on the first day of the calendar month following their month of death.
- Hospital reliance on drug compounding pharmacies. Many hospitals have in-house compounding capability.
- Inpatient psychiatric facility outlier payments: freestanding and units. There has been a steady increase in outlier payments for these types of cases. Documentation is key.

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OIG/DOJ Year In Review

Revised and Ongoing Studies:

- Intensity-modulated radiation therapy: these services are divided into treatment phases: planning and deliveries – can't bill both at the same time. Confused with another radiation therapy.

- National background checks for employees who have direct contact with patients.

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"How much exercise would you say you skip each week?"

OIG/DOJ Year In Review

Completed Studies:

- Ambulance services compliance: review of advanced life support emergency service billing.

- Inpatient rehab facility payment: review of medical record documentation at the time of admission, which supports a reasonable expectation that the patient needs multiple intensive therapies, one of which must be physical and/or occupational therapy.

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OIG/DOJ Year In Review

Completed Studies:

- Histocompatibility laboratories: Claims for bone marrow and solid organ transplantation services.
- Outpatient outlier payments for short stay claims: OIG thinks too much payment is made.
- Hospital use of outpatient and inpatient stays under Medicare's two midnight rule.

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OIG/DOJ Year In Review

Completed and Revised Studies:

- Payment credit for replaced medical devices that have been implanted: Overpayments.
- Improper use of Modifier 59 in cardiac catheterizations and endomyocardial biopsies: Not supposed to be billed together – should be an exception, and not the rule.

2019 WORK PLAN

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OIG/DOJ Year In Review

Revised Studies:

- Review of anesthesia claims to determine if anesthesia was billed at the time of another Medicare service: appropriate anesthesia modifier code to be personally performed or medically directed by an anesthesiologist.
- Chiropractic services: Part B only pays for chiropractors' manual manipulation of the spine to correct a subluxation. Over 70% of chiropractic claims are paid improperly?
- Medicare incentive payments for adopting electronic health records. Now security of EHR.
- Added podiatric treatment recently.

2019 WORK PLAN

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OIG/DOJ Year In Review

Completed Studies:

- Security of certified electronic health record technology under meaningful use.
- OIG will continue investigative activities for controlled and non-controlled prescription drugs, home health personal care and home and community-based services, ambulance transportation, DME, diagnostic radiology and laboratory testing.

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OIG/DOJ Year In Review

Removed Studies:

- Diabetes testing supplies: Blood glucose test strips and lancets – mail order sampling.
- Power mobility devices.
- CMS management of ICD 10 implementation.
- Hospital cost reports and Medicare reimbursement.

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Medicaid Reviews:

- New Reviews:
- Medicaid payments for multiuse vials of Herceptin: many vials contain much more medicine than is needed for one dose.
- Home health services and other community-based care: home health and community case care are susceptible to fraud.
- Checking Exclusion List monthly for new employees and current employees and independent contractors.

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Medicaid Reviews (Cont'd):

- Delivery system reform incentive payments for hospitals and nursing homes: CMS will, in particular, be looking at payments that supposedly enhance access to healthcare, increase the quality and cost-effectiveness of care, and increase the health of patients and families served. (Language aligned with ICN Legislation.)

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Updated Medicaid Reviews:

- Third-party collections by Medicaid agencies: Medicaid is supposed to be a payer of last resort.
- Medicaid managed care.
- Medicaid overpayment reporting and collections: If a federal audit indicates that the state has failed to identify an overpayment the office of Inspector General will endeavor to take back the federal share of those payments, and not the provider's payment yet.

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Revised Medicaid Reviews:

- Health care related taxes and Medicaid managed care organization compliance with hold harmless requirements: Alabama uses provider taxes and IGT's to fund the Medicaid hospital program.

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Existing Revised Reviews:

- Physician administered drugs: cancer treatment.
- Home and community based waiver costs.
- Transportation services: compliance with federal and state requirements.
- Healthcare acquired conditions: prohibition on federal reimbursement.

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Existing Reviews:

- Medicaid beneficiary transfers from group homes and nursing facilities to hospital emergency rooms: concerns about care provided in nursing homes and group homes.
- Federal certified public expenditure (CPE) regulations and provider taxes used to generate federal funding: the OIG has never liked Alabama's program.

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Existing Reviews (Cont'd):

- Medicaid managed care: The OIG will be looking at such things as healthcare acquired conditions payments and payments for services after beneficiary dies.
- Managed care organizations' identification of fraud and abuse: The OIG reports that over a quarter of managed care organizations surveyed in prior years did not report a single case of suspected fraud and abuse in 2009; will be looking at ICN's.

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Nursing Homes:

- State Agency Verification of Deficiency Corrections.
- Use of Atypical Anti-Psychotic Drugs.
- Minimum Data Sets Submitted by Nursing Homes.
- Medicare Part A Billing.
- Medicare Part B Billing.
- National Background Checks for Employees.
- Transfers to Hospitals when Unnecessary.
- Nursing Home Prospective Payment System Requirements.
- Nursing Home Discharges.

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Hospices:

- Length of service and outside payments to other providers.
- GIP Services.

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Home Health:

- Home Health Face-to-Face Requirement.
- Employment of Aides with Criminal Records.
- Prospective Payment Requirements.
- New Rule.

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Medical Equipment and Supplies:

- Accreditation.
- Policies & Practices.
- Wheelchairs – Rent vs. Own.
- Diabetes Testing Supplies.
- Billing & Payments.
- Prosthetics & Orthotics.

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Medical Equipment and Supplies (Cont'd):

- Nebulizers & Drugs.
- Orthotic Braces – Looking at "off the shelf" in particular.
- Osteogenesis Stimulators.
- Nebulizers: Rent or own?
- Diabetes Testing Supplies.
- Ventilators.

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Comments & Suggestions

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OIG WORK PLAN FOR 2019

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