

# Health Law Update For Hospitals

Alabama Hospital Association

Presented by:

Gilpin Givhan, PC

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# Health Law Update For Hospitals

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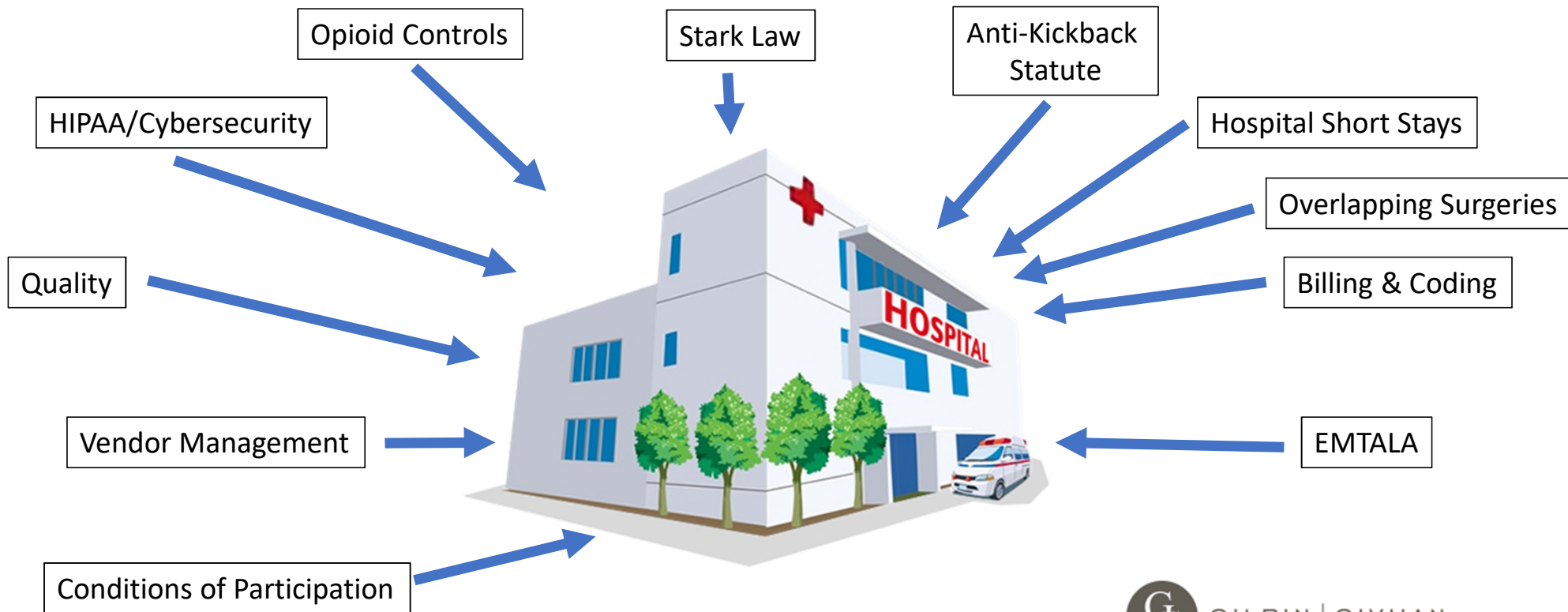
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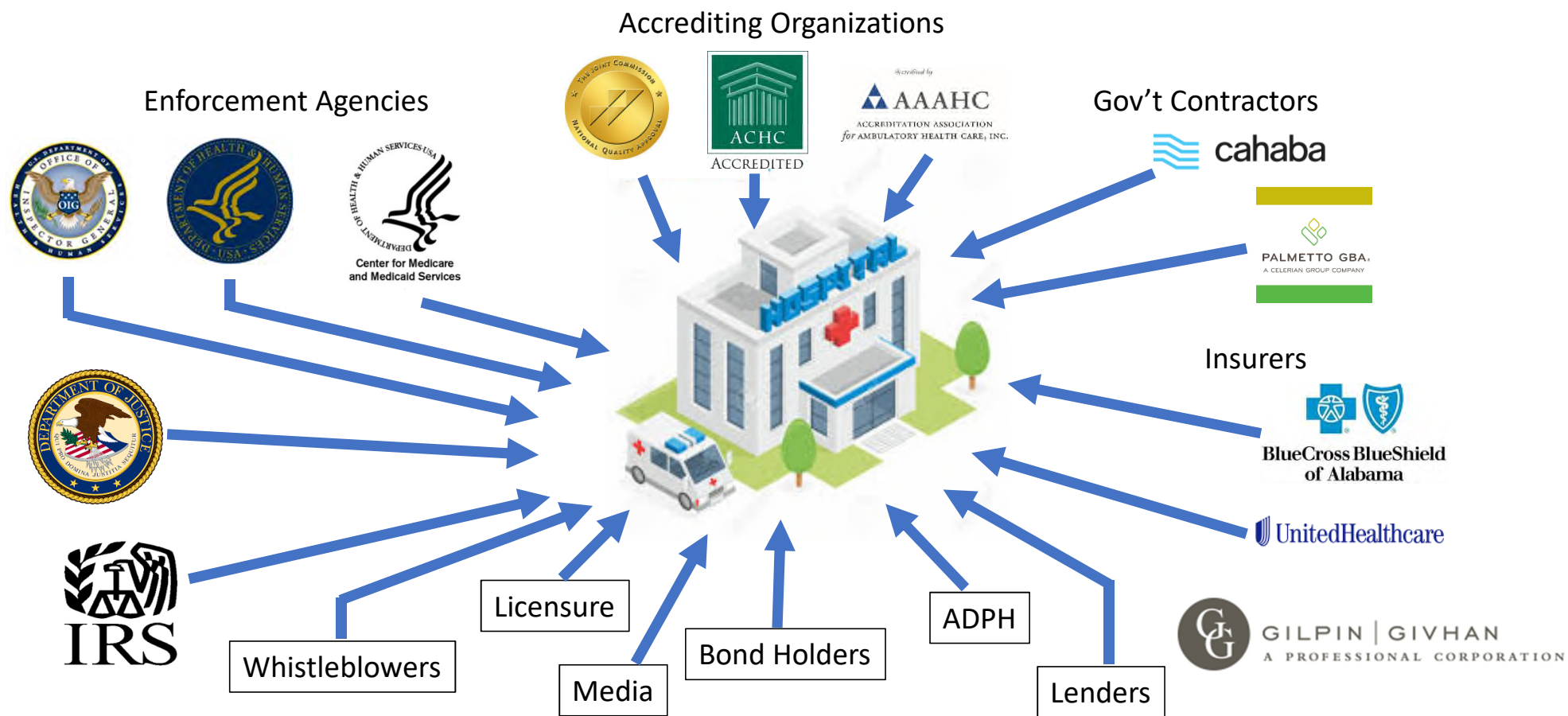




# Health Law Update For Hospitals



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# Health Law Update For Hospitals

- OIG/DOJ Update
- COVID Waivers and What Is Next?
- Alabama Update
- HIPAA - Privacy and Security Update
- OIG Work Plan
- Questions

Annual Health Law Update For Hospitals

# OIG/DOJ YEAR IN REVIEW

(Patterns and Trends)



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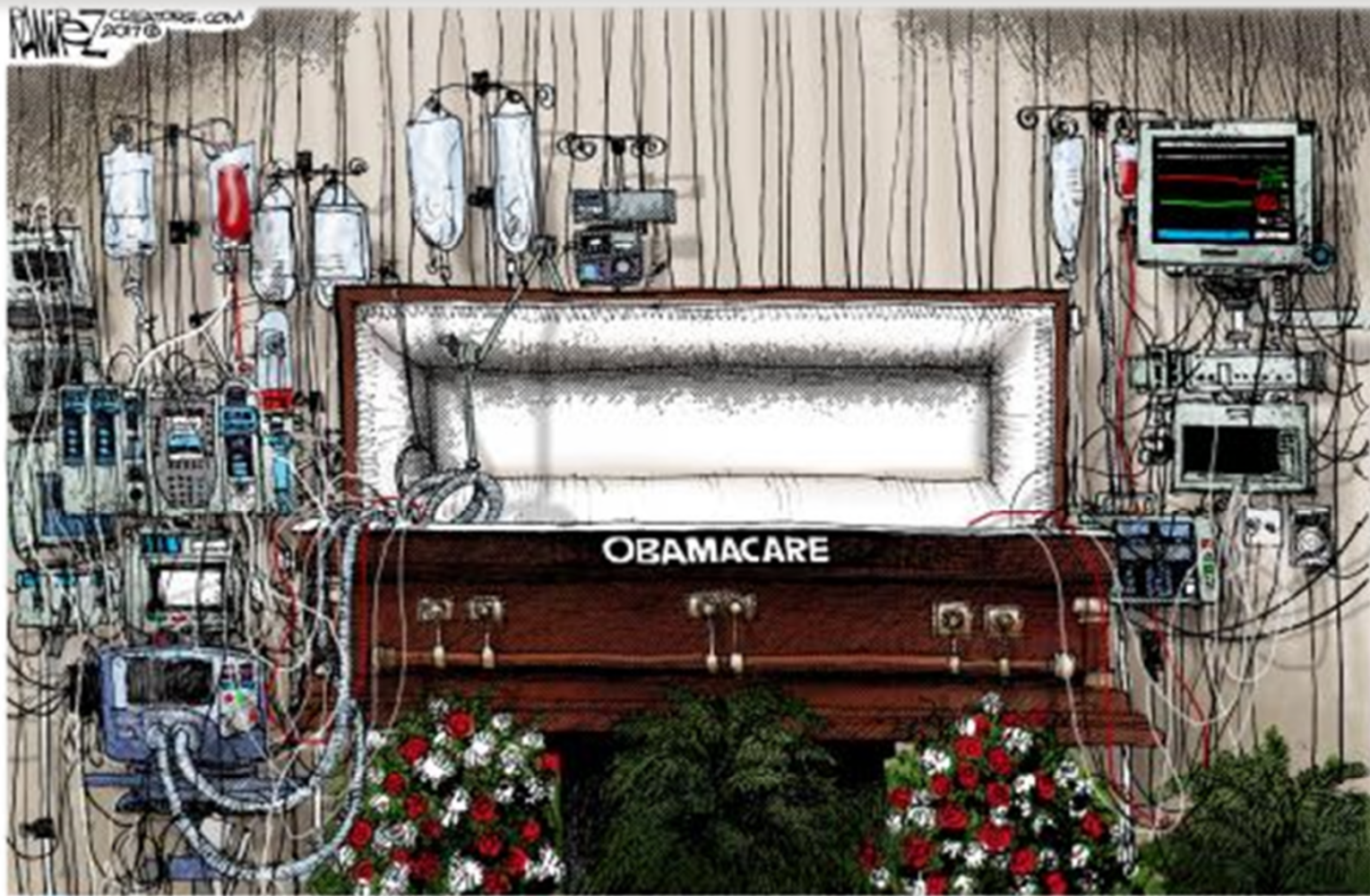


# OIG/DOJ Year In Review

- FY 2019 Government Summary
- DOJ/OIG Cases and Settlements
- Other Developments







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Ten Years and Counting.....





# OIG/DOJ Year In Review

- 2019 Another One in the Record Books

Health Care Fraud Recoveries		
Fiscal Year	Total Fraud Recoveries	Health Care Fraud Recoveries
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
2019*	\$3.6 Billion	\$2.6 Billion

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

# OIG/DOJ Year In Review

- **2019 Another One in the Record Books**
  - **DOJ**
    - 1,060 Criminal fraud convictions ('18 - 1,503)
    - 1,112 Civil settlements/judgements ('18 - 810)
  - **OIG**
    - 2,640 Individuals and entities excluded ('18 - 974)
    - 747 Criminal actions against individuals and entities
  - **Return on Investment**
    - 2017-2019 return of \$4.20 for each enforcement \$1 spent



# OIG/DOJ Year In Review

## Continuing Trends:

- 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





# OIG/DOJ Year In Review

## 3 Major Cases:

### US ex rel Bookwalter v. UPMC

Stark Law compensation issues

- 3<sup>rd</sup> Circuit Court of Appeals (Second Opinion 12/20/20)
  - 1<sup>st</sup> Opinion –
    - Adopted “correlation” theory – physician’s compensation varies with volume and value of referrals if physician is paid based on his personally performed services (ie w/RVU) and there is correlation between physician referrals and the personally performed services.
  - 2<sup>nd</sup> Opinion – eliminated “correlation” but still held that compensation took into account surgeons referrals.



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# OIG/DOJ Year In Review

## **Azar v. Allina Health Services** (Sup Ct 11/21/19)

Any Medicare issuance that establishes or changes a “substantive legal standard” governing the scope of benefits, payment for services, eligibility, etc., must go through notice and comment rulemaking.

- CMS Internal Memo 10/31/19
  - To extent IOMs or other guidance set forth payment rules that are not “tied to statutory or regulatory standards” the government cannot use violations of that guidance in enforcement efforts.

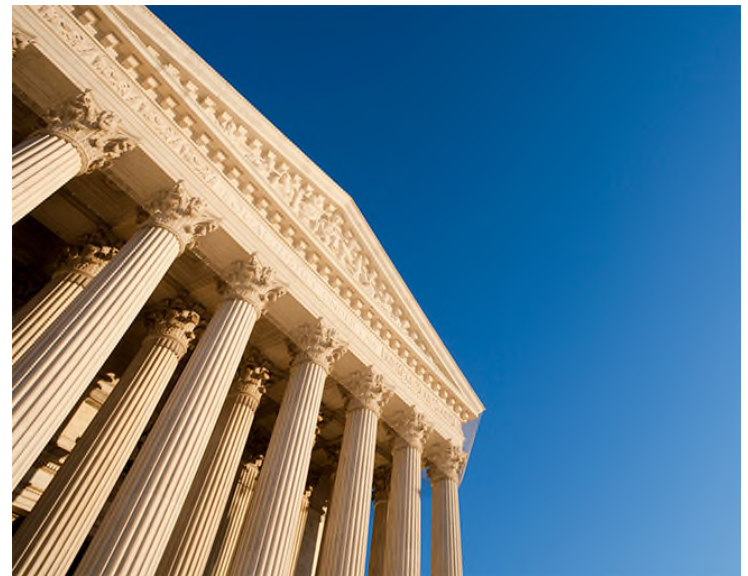




# OIG/DOJ Year In Review

## AseraCare

- 11<sup>th</sup> 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.
  - Also held judge erred and sent it back to trial court.
- Settled for \$1 Million (2/2020)
  - Original claims had been for over \$200 million





# OIG/DOJ Year In Review

## Telemedicine Schemes

- Covid -19 has had a drastic impact on Telemedicine
- Beware however.....



# OIG/DOJ Year In Review



## NATIONWIDE BRACE SCAM

Scammers are contacting Medicare beneficiaries to offer “free or low-cost” orthotic braces. These fraudsters bill Medicare for medically unnecessary equipment using beneficiaries’ information. All beneficiaries across the country are potential targets in this scheme.

Learn More: [oig.hhs.gov/bracescam](https://oig.hhs.gov/bracescam)

Report Fraud: **1-800-HHS-TIPS** or  
[oig.hhs.gov/fraud/hotline](https://oig.hhs.gov/fraud/hotline)

U.S. Department of Health and Human Services  
**Office of Inspector General**



## The **Alleged Scheme** and **Key Players**



### Conspirators

They own a call center that airs television and radio advertisements for orthotic braces paid for by Medicare. Telemarketers call beneficiaries directly to offer “free or low-cost” orthotic braces.

- ! They are the masterminds of this scheme.



### Call Center

The call center confirms that the beneficiaries are on Medicare and transfers beneficiaries to a telemedicine firm for a doctor’s consultation.

- ! The call center pays the telemedicine firm and its doctor for the prescriptions.



### Doctor & Telemedicine Company

Regardless of medical necessity, the doctor prescribes an orthotic brace. The telemedicine company submits the brace prescription to the call center.

- ! The telemedicine company and doctor generate prescriptions to keep this scheme running—not because the beneficiary needs the brace.



### Call Center

The call center collects the prescriptions and sells them to the medical equipment company.

- ! Providers should send prescriptions to a medical equipment company because beneficiaries have medical needs for products. **Prescriptions should never be sold.**



### Medical Equipment Company

After the medical equipment company buys the prescriptions, the medical equipment company sends the brace, or multiple braces, to beneficiaries. The company bills Medicare and pays a kickback to the conspirators.

- ! The medical equipment company receives \$500-\$900 per brace from Medicare and pays the conspirators a kickback of almost \$300 per brace.

\* This alleged scheme is current as of April 2019.



# OIG/DOJ Year In Review

## “Operation Brace Yourself”

- National Investigation (17 Federal Districts)
  - Multi billion dollar scheme
- One District in So Georgia 7/2020
  - \$480 million in fraudulent telemedicine patient orders (So Ga)
  - Kickbacks paid for signed orders for orthotic braces from physicians and nurse practitioners which were then sold to DME companies and billed to Medicare Part B and Part C.
  - 26 Defendants – Criminal Charges - in So Georgia
    - 8 Physicians,
    - 2 nurse practitioners,
    - 3 telemedicine company operators,
    - 3 brokers of patient data and
    - Multiple DME owners
  - Nationally, Coordinated - FBI, OIG, IRS, etc





# OIG/DOJ Year In Review

## Similar Lab Scheme

- Genetic Testing Scheme
  - “Operation Double Helix”
  - Similar structure with telemarketing companies and cancer genetic labs
  - Labs paid kickbacks to physicians in exchange for Medicare referrals for medically unnecessary genetic cancer tests
  - Physicians did not see patients or had “brief telephonic” conversations.
  - Tests frequently not provided to the treating physician
  - 35 individuals charged across 5 districts
  - \$2.1 billion in fraudulent claims



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# OIG/DOJ Year In Review

## Latest Takedown – September 30

- Joint effort: DOJ, OIG, FBI, DEA
- 345 charged defendants/ 51 Fed Districts
- \$6 billion in alleged false claims
- More than 100 doctors, nurses and licensed med professionals
- Telemedicine schemes
  - DME, Genetic testing, pain medication
  - 256 additional medical professionals excluded from Medicare for telemedicine
- “Sober Homes”
  - Claims for tests and treatments for patients seeking treatment for drug and alcohol
  - EKRA?



# OIG/DOJ Year In Review

## Are you asking?

- In physician practice acquisitions/employment
  - Are you contracted to provide Telemedicine?
  - Do you have contractual arrangement with any device manufacturers or distributors?
  - List on exhibit or otherwise disclosure.



# OIG/DOJ Year In Review

## “National Nursing Home Initiative” (3/2020)

- Task Force with focus beyond basic fraud:
  - Targeting “grossly substandard care”
  - Understaffing
  - Insufficient infection control practices
  - Patient mistreatment (eg. adequate food)
  - Withholding medication or overmedicating



# OIG/DOJ Year In Review

## Rehab and Skilled Nursing

- Kindred Healthcare legacy
- **Guardian Elder Care Holdings** (2/2020)
  - 52 facilities
  - \$15.4 million settlement
  - FCA allegation re high levels of rehab without regard to medical necessity
    - Therapists required to:
      - Spend designated amount time regardless of patient's health
      - Patients with dementia who refused care
      - Patients unable to leave their bed
      - Patients who were allegedly dying (in hospice)



# OIG/DOJ Year In Review

## Rehab and Skilled Nursing

- Kindred Healthcare legacy
- **Longwood Management Corp.** (7/2020)
  - 27 facilities
  - \$16.7 million settlement
  - Systematic effort to increase Medicare billings
    - Submitted claims for medically unreasonable and unnecessary Ultra High rehab levels.
    - Therapists pressured to provide care to meet pre-planned targets for Medicare revenue without regard to patient therapy needs





# OIG/DOJ Year In Review

## Rehab and Skilled Nursing

- **Saber Healthcare Group, LLC** (4/2020)
  - 9 facilities
  - \$10 million settlement
- **Encore Rehabilitation Services, LLC** (4/2020)
  - Contracted with 3 nursing home facilities
  - \$4 million settlement
- **Diversicare Health Services, Inc.** (2/2020)
  - 74 facilities
  - \$9.5 million settlement



# 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





# OIG/DOJ Year In Review

## Hospice

- Continues to be a focus
- **Hope Hospice** (8/2020)
  - \$3.2 million settlement
  - False claims for patients who were not terminally ill (did not qualify) (1 patient for 4 yrs)
  - Services that were not medically necessary, high levels
- **Healthcare of Atlanta** (3/2020)
  - \$1.75 million settlement
  - Claims for patients who were not eligible for hospice
  - Aggressive enrollment goals and failure to supervise admission practices





# OIG/DOJ Year In Review

## Hospitals

- **Universal Health Services, Inc.**

- Owns or manages over 200 psych hospitals
- Facility in Moultrie, Ga.
- Admitted inpatients who did not qualify for inpatient care
- Failed to properly discharge inpatients when inpatient care was no longer needed.
- Failed to provide adequate staff, to develop or update individual assessments/treatment plans, to provide adequate discharge planning, to provide individual and group therapy services
- Entity settled for **\$122 Million** 7/20



# OIG/DOJ Year In Review

## Hospitals

- **Centra Health Inc and Blue Ridge ENTs**
  - Virginia hospital system
  - Recruitment arrangement with income guarantee for physician joining ENT
  - Group claimed payment for expenses in Excess of “actual additional incremental costs”
  - Plus: >Physicians already relocated
    - >Compensation taking into account value of in-office labs
    - >Arrangements not in writing for call
  - **\$10 Million** settlement (4/20)





# OIG/DOJ Year In Review

## Hospitals

- **Piedmont Healthcare**

- Pacemakers/ defibrillators
- Billed for inpatient care despite physician recommendation for outpatient / observation
- Alleged to have inflated physicians' pay to induce referrals
- “Physician churning” multiple consults with host of unnecessary tests
- Purchased Cath Lab from physician practice for “commercially unreasonable” and excess of FMV
- **\$16 Million** settlement (6/20)



# OIG/DOJ Year In Review

## Hospitals

- **SpineFrontier Case** 3/20
  - Dr Chin – CEO of SpineFrontier  
Spine implant/device manufacturer
  - Also owns, through series of entities, IME, a  
“consulting company
  - IME paid “consulting fee” to surgeons, but only  
When they used SpineFrontier products
  - IME did not use feedback and paid even if  
surgeon provided no feedback
  - DOJ intervened in March....stay tuned.



# OIG/DOJ Year In Review

## Hospitals

- **Wheeling Hospital** 9/9/20
  - Alleged payments to employed physicians in excess of FMV and not commercially reasonable:
    - OB/GYN \$1.2 million
    - 2 Rad Oncs \$1.2 million
    - Cardiologist \$780,000 plus 6 months vacation
  - Knew practice would operate at a loss
  - Hospital tracked referral volume and revenue generated
  - Settled: \$50 Million



# OIG/DOJ Year In Review

## Hospitals

- **Reverse EMTALA** <sub>12/19</sub>
  - AnMed Health Med Center (Greenville, SC)
  - Hospital put “moaning in pain” “too weak to walk” patient in car and told Uber driver the destination was up to him
  - Hospital says patient’s care is under review.



# 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**





# 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

## “Sprint” Regulation Proposals

- **October 2019**
- Proposed revisions to Stark and Anti-kickback statute regulations
- Designed to remove “barriers” and create clarity
- **Stark**
  - Value Based Care §411.357(aa)
  - Indirect Compensation §411.357(c)(4)
  - Clarification of compensation arrangements §411.354(e)
  - Tweaking rental arrangements (§411.357(a&b), Physician recruitment (§411.357(e), Provision of electronic health records (§411.357(w), Nonphysician recruitment (§411.357(x), and others
  - Flexibility for nonabusive business practices (§411.357(z)
  - Some very helpful discussion in the commentary





# OIG/DOJ Year In Review

## “Sprint” Regulation Proposals

- **Anti-Kickback**

- New Proposed Safe Harbors
  - 3 new value based safe harbors
  - Tools and supports furnished to improve outcomes
  - New safe harbor for CMS sponsored models
  - Donation of cybersecurity tech and service

- **Modifications**

- EHR (cybersecurity, interoperability and remove sunset date)
  - PSA and management contracts – flex for outcomes-based payment and part-time arrangements
  - Local transportation
- Tweak definition of “remuneration” re ACOs



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# OIG/DOJ Year In Review

## Update: Guidance on Evaluating Corp Compliance Programs

- Latest Revision to 2017 Guidance. (6/2020)
- 3 fundamental questions in 2017:
  - Is the Program well designed?
  - Is the Program effectively implemented?
  - Does the Program actually work in practice?
- Changed second question to: is the program **“adequately resourced and empowered to function effectively.”**
- Excellent guide for compliance officers







# OIG/DOJ Year In Review

## Update: Guidance on Evaluating Corp Compliance Programs

- Other 2020 changes include whether:
  - Risk assessments are continuous or just snapshots?
  - Past issues of company considered in risk assessments and program improvements?
  - Policies and procedures are available in searchable manner and common searches are identified?
  - Training programs include: (i) shorter, targeted training (ii) allow employee questions, (iii) evaluate training and employee behavior?
  - Employee awareness of and comfort with reporting system is tested?
  - Reporting system is publicized to 3<sup>rd</sup> parties?
  - Culture of compliance exist at all levels?
  - Invests in training and development of compliance personnel?
  - Monitor investigations and resulting discipline to ensure consistency?





# OIG/DOJ Year In Review

## Trends to Watch:

### 1. Stark and Anti-Kickback Changes

- CMS and OIG proposed “Sprint Regulations”
- 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

### 4. Continued focus on individuals

### 5. Remember EKRA



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# OIG/DOJ Year In Review

## Trends to Watch:

- 6. Telemedicine abuses
- 7. Don't forget "they" have your

# DATA



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# Questions?

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Annual Health Law Update for Hospitals

# There and Back Again:

## A COVID-19 Tale



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# Overview





# Telehealth

## Existing Law

- Services otherwise reimbursable under Medicare when provided in person
- Real-time audio-visual communication technology
- Secure platforms in compliance with HIPAA
- Patients located in rural areas, some expanded access for Medicare Advantage enrollees and dialysis and stroke patients
- Services furnished in limited subset of locations (hospitals, skilled nursing facilities physician offices, etc.)
- Physicians, PAs, NPs, clinical psychologists, licensed social workers, etc.
- Pre-existing relationship with patient required

## Current Flexibilities

- Services otherwise reimbursable under Medicare when provided in person
- Broader technology options available (real-time audio-visual, FaceTime, simple telephone call, etc.)
- OCR statement of enforcement discretion for security of telehealth platform
- Urban or rural areas
- Services may be furnished in beneficiary home and any facility
- **Note:** does not apply where patient and remote practitioner are located in the same facility (these services are billed as in-person services)
- OIG offering flexibility to reduce or waive co-insurance
- CMS not auditing for prior relationship with patient
- Additional services eligible to be provided via telehealth



# EMTALA

## Existing Law (SSA § 1867, 42 C.F.R. § 489.24)

- If a patient “comes to the emergency department...”
- Medical Screening Examination (MSE)
  - And either . . . .
- Stabilizing treatment; or
- Appropriate transfer; or
- Inpatient admission

## Current Flexibilities

- EMTALA still applies during the PHE!!!
- Certain portions waived under Section 1135 of the Social Security Act
  - Individuals (regardless of whether suspected for COVID-19) may be directed or relocated to another location to receive MSE
  - An individual who has not been stabilized may be transferred to another facility if necessitated by the circumstances
- Alternate Testing Sites
  - not subject to EMTALA, even if run by hospital
  - Includes drive-thru testing sites
  - May be established collaboratively between providers, but each provider must have its own distinct space within the alternate testing site
  - Confusion about ability to redirect patient for MSE
  - Patients should be logged into the central log regardless of where they receive the MSE



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# Verbal Orders

## **Existing Law (42 C.F.R. §§ 482.23; 482.24; 485.635)**

- Except for a few exceptions, “orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders in accordance with State law and hospital policy, and who is responsible for the care of the patient.
- Verbal orders to be used “infrequently”
- Must be accepted by persons who are authorized to do so by hospital P&P consistent with Federal and State law
- All orders (including verbal orders) must be dated, timed, and authenticated promptly

## **Current Flexibilities**

- Verbal orders may be used more than “infrequently”
- Authentication may occur later than 48 hours after verbal order entered
- Procedural/administrative requirements for standing orders waived
- CAHs may use verbal orders, even though regulation requires medication administration to be based on written, signed orders (must be authenticated as soon as possible after the fact)



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# Patient Rights

## Existing Law (42 C.F.R. § 482.13)

- **Medical Records:** Patient right to access medical record upon request and within a reasonable timeframe (“as quickly as the record system permits”)
- **Visitation:** Hospital must have written P&P on visitation rights, including any clinically necessary or reasonable restrictions and reasons
- **Seclusion:** limited to management of violent or self-destructive behavior
  - Only used when less restrictive interventions determined ineffective
  - Least restrictive intervention
  - In accordance with order of physician or other licensed practitioner
  - Never as standing order or on PRN basis
  - Limits on renewability
  - Face-to-face visit required within 1 hour

## Current Flexibilities

- Only in areas impacted by “widespread outbreak” (low bar = 51+ cases)
- Additional time to provide copy of medical record
- Flexibility on visitation policies to promote infection control
  - However, ADA still applies
- Seclusion not limited to management of violent or self-destructive behavior (unclear whether other seclusion requirements waived)



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# Reporting Deaths in Relation to Restraint/Seclusion

## Existing Law (42 C.F.R. § 482.13(g))

- Hospitals must report to CMS by COB on the next business day any death that occurs while a patient is in restraint or seclusion, within 24 hours after patient removed from restraint/seclusion, or within 1 week of removal if it is “reasonable to assume” that the restraint/seclusion contributed directly or indirectly to patient death
- Hospital must keep internal log for deaths where no seclusion was used and only restraint is soft wrist restraint to prevent pulling tubes/IVs
  - Must be made within 7 days after death of patient
- Documentation in medical record required

## Current Flexibilities

- Waiving requirement to report patients in ICU whose death is caused by their disease, but who required soft wrist restraints to prevent pulling tubes/IVs no later than COB on next business day
- Where restraint may have contributed to death, hospital must still report within *standard* time limits (*i.e.*, COB on the next business day)
- Purpose is to ensure hospitals can focus on increased patient care demands and patient census



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# Medical Staff Renewals

## **Existing Law (42 C.F.R. § 482.22)**

- Periodic appraisals of medical staff members required
- Examination of credentials of eligible candidates
- Recommendation to the governing body for appointment in accordance with State law, including scope-of-practice laws, and medical staff bylaws, rules, and regulations
- Special requirements for telemedicine credentialing

## **Current Flexibilities**

- Physicians whose privileges will expire may continue practicing
- Physicians who have not yet received full medical staff/governing body approval may start practicing
- Formal procedural requirements for credentialing and privileging process are waived



# Completion of Medical Records

## Existing Law (42 C.F.R. § 482.24)

- Organization of medical record service appropriate to size and complexity of services performed
- Medical record for each inpatient and outpatient
- Medical record accurately written, promptly completed, properly filed and retained, and accessible
- System of author identification that ensures integrity of authentication and protects security of record entries
- H&P no more than 30 days before or 24 hours after admission or registration
- Final diagnosis with completion of medical records within 30 days following discharge

## Current Flexibilities

- Requirements for organization and staffing of medical records department waived
- Requirements for form and content of medical record waived
- Record retention requirements waived
- Flexibilities may be implemented as long as consistent with state emergency preparedness/pandemic plan
- Flexibility to complete medical records within 30 days following discharge
- Allow clinicians to focus on patient care



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# Physical Environment

## Existing Law (42 C.F.R. §§ 482.41; 485.623)

- Overall hospital environment must be developed and maintained to assure the safety and well-being of patients
- Life safety from fire
  - *E.g.*, outside window or door required in every sleeping room, and for buildings constructed after 7/5/2016, window sill height must not exceed 36 in above floor
- Facilities
  - Diagnostic and therapeutic facilities located for safety of patients
  - Facilities, supplies, and equipment maintained to ensure acceptable level of safety and quality
  - Extent and complexity of facilities determined by scope of services offered
  - Proper ventilation, light, and temperature controls in pharmaceutical, food prep, and other appropriate areas

## Current Flexibilities

- Increased flexibility for surge capacity and patient quarantine
- Facility and non-facility space not normally used for patient care can be used for patient care or quarantine
- Location must be approved by the state (ensuring safety and comfort for patients and staff are sufficiently addressed)
- Consistent with state emergency preparedness/pandemic plan
- *See also* ADPH requirements for Alternate Care Sites (ACSs)



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# Use of Distinct Part Units

## Current Flexibilities

- Housing Acute Care Patients in the Inpatient Rehab Facility (IRF) or Inpatient Psychiatric Facility (IPF) Excluded Distinct Part Units
  - Continue to bill as general acute care
  - Notate patient is in excluded unit and document necessity
- Care for Excluded IRF or IPF Patients in the Acute Care Unit of a Hospital
  - Confirm bed is appropriate for IRF or IPF patient, staff and environment conducive to safe care
  - Continue to bill under appropriate PPS for excluded IRF or IPF unit
  - Notate patient is IRF or IPF patient in acute care bed and document necessity
  - IRF patients must continue to receive intensive rehab services
- Reasons: Capacity and other exigent circumstances related to state of emergency (*e.g.*, patient cohorting, bed shortages, etc.)
- Flexibility for Inpatient Rehabilitation Facilities Regarding the “60 Percent Rule”
- Waiver of Inpatient Rehabilitation Facility “3-Hour Rule”



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# Temporary Expansion Locations (Alternate Care Sites)

- For the duration of PHE
- Waiver of physical environment requirements at 42 C.F.R. §§ 482.41; 485.623 and provider-based requirements at 42 C.F.R. § 413.65
- Allow hospitals to establish and operate as part of hospital any location meeting CoPs that continue to apply during the PHE
- Hospitals can change status of current provider-based department locations as necessary to meet needs of hospital and patients
- *E.g.*, ASC enrolling as a hospital; hospital establishing new location
- Enrollment flexibility
  - Enrollment hotline
  - Waived application fees and criminal background checks
  - Waiver of site visits



# CAHs

## Existing Law

- **Personnel:**
  - **CNS:** must hold master's/doctoral level degree in a defined clinical area of nursing
  - **NPs and PAs:** certifications and educational program requirements
- **Status/Location:** located in rural area/area treated as being rural; located at least 35 miles (15 miles for mountainous terrain/secondary roads) from any other hospital; Off-Campus/Co-Location Requirements
- **Beds/LOS:** limited to 25 beds and average 96-hour LOS
- **Physicians:** required to be present for medical direction, consultation, and supervision for the services provided;

## Current Flexibilities

- **Personnel:** educational and certification requirements waived
- **Status/Location:** rural area and distance requirements waived to allow flexibility to establish surge site locations; Off-Campus/Co-Location Requirements waived
- **Beds/LOS:** CAH permitted to have more than 25 beds and greater than 96-hour average LOS
- **Physicians:** require to be available by direct radio/telephone/electronic communication but not required to be physically present



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# Stark Waivers

## Existing Law (SSA § 1877, 42 C.F.R. § 411.350 et seq.)

- Referral by a physician to an entity (DHS entity) with which the physician or an immediate family member has a financial relationship (ownership/investment interest or compensation arrangement)
- DHS:
  - Inpatient and outpatient hospital services
  - DMEPOS
  - Laboratory
  - Outpatient pharmaceuticals
  - PT/OT/ST
  - Radiology/Imaging
  - Radiation Therapy
  - Home Health, etc.
  - Parenteral and enteral nutrients, equipment, supplies
- DHS entity prohibited from billing for DHS pursuant to prohibited referral
- Exceptions for leases, personal service agreements, employment, and other relationships deemed to be low risk of fraud and abuse

## Current Flexibilities

- **Purposes:**
  - Diagnosis/medically necessary treatment of COVID-19
  - Securing services of physicians and other practitioners in response to COVID-19 outbreak
  - Ensuring ability of health care providers to address patient and community needs
  - Expanding capacity to address patient and community needs
  - Shifting diagnosis and care of patients to appropriate alternative settings
  - Addressing medical practice or business interruption to maintain availability of medical care and related services for patients and community
- **Waivers:**
  - Above/below FMV rental, lease, and other payments
  - Medical staff incidental benefits in excess of limits
  - Nonmonetary compensation in excess of limits
  - Certain loans between physicians and DHS entities
  - Expansion of physician-owned hospitals
  - Waiver of “same building” and “centralized building” requirements for group practices
  - Arrangements not meeting the writing requirement but otherwise complying with an exception
- Must satisfy all conditions of blanket waiver
- Must make records available to Secretary upon request (parties encouraged to develop and maintain records in a timely manner as a best practice)
- Expires with expiration of Secretary’s authority to grant waivers related to the COVID-19 PHE under § 1135 of the Social Security Act



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# Medical Necessity

- Circumstances:
  - Private room for patients that need to be quarantined/isolated
  - Extended inpatient stay for patients who no longer need acute care, but need post-acute care, and there are not available post-acute care beds in the area
- Medicare will pay the Diagnostic Related Group (DRG) rate and any outlier costs for the entire stay until the patient is discharged  
(<https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf>)
- Similarly, Alabama Medicaid covering extended stays pending post-acute placement ([https://medicaid.alabama.gov/alert\\_detail.aspx?ID=13808](https://medicaid.alabama.gov/alert_detail.aspx?ID=13808))
- May not charge cost differential for private room if medically necessary



# Post-Acute Care

## Existing Law (42 C.F.R. Part 483)

- 3-day prior hospitalization required for coverage of a SNF stay
- PASARR screening required
- **Nurse Aide Training/Certs:** nurse aides cannot be employed longer than 4 months without nurse aide meeting training/cert requirements in §483.35(d)
- **Physician/NPP Visits:** required to be performed personally, in-person in many circumstances

## Current Flexibilities

- 3-day prior hospitalization requirement waived
- Level 1 PASARR screening may be performed post-admission, and patients should be referred for Level 2 screening ASAP
- CMS waiving some physical environment requirements to allow SNF care to be provided in non-SNF building (SNFs Without Walls)
- **Nurse Aide Training/Certs:** flexibility granted, but SNF still required to verify competency to provide nursing and nursing-related services
- **Physician/NPP Visits:** physician may delegate to other qualified practitioners, provided physician still supervises and delegation is consistent with state law and facility policies, and visits allowed to be provided via telehealth



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# Swing Beds

## Existing Law (42 C.F.R. § 482.58)

- Hospital:
  - has fewer than 100 beds (some exclusions apply);
  - is located in a rural area;
  - does not have in effect a 24-hour nursing waiver under 42 C.F.R. § 482.58
  - has not had a swing bed approval terminated within the two years prior to the application for swing bed approval
- Hospital must provide skilled nursing facility (SNF) services substantially in compliance with SNF Requirements:
  - Resident rights
  - Admission, transfer, discharge rights
  - Freedom from abuse, neglect, exploitation
  - Social services
  - Discharge summary
  - Special rehab services,
  - Dental services
- Admission subject to 3-day prior hospitalization requirement (just like SNF admissions)

## Current Flexibilities

- Hospitals in urban areas and/or with more than 100 beds qualify to offer swing bed services
- To qualify, hospitals must:
  - Not use SNF swing beds for acute level care
  - Comply with all other hospital CoPs and SNF requirements to the extent not waived
  - Be consistent with state emergency preparedness/pandemic plan
- Enrollment through MAC hotline:
  - Good faith effort to exhaust all other options
  - No SNFs within hospital catchment area that under normal circumstances would have accepted SNF transfers but are unable to because of COVID-19
  - Waiver eligibility requirements met
  - Plan to discharge patients as soon as practicable when SNF bed becomes available or PHE ends
- 3-day prior hospitalization requirement waived during PHE (just like for SNF admissions)



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# RHC Flexibility

## Existing Law (42 C.F.R. Part 491)

- **Staffing:**
  - At least one NP or PA must be an employee of the RHC
  - A physician, NP, PA, CNM, CSW, or CP must be available to furnish patient care services at all times the RHC operates
  - An NP, PA, or CNM must be available to furnish patient care services at least 50% of the time the RHC operates
- **Supervision:**
  - Must have physician medical direction for RHC health care activities
  - Must have consultation for, and medical supervision of, health care staff, including NPs
- **Location:**
  - Separate locations must be individually considered and enrolled
  - Must be located in rural area
  - Must be located in shortage area

## Current Flexibilities

- **Staffing:** NP, PA, or CNM not required to be available to furnish patient care services at least 50% of time the RHC operates (physician, NP, PA, CNM, CSW, or CP must be available at all times though)
- **Supervision:** Expanded flexibility for NP to practice to fullest extent permitted under state law; physician continues to be responsible for overall medical direction of RHC, consultation for health care staff, and medical supervision of remaining staff (other than NPs)
- **Temporary Expansion Locations:** RHCs may expand to additional locations without separate enrollment to meet patient needs during PHE (including locations outside of rural areas designated as shortage areas)



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# After the Pandemic

## The Good

- **Telehealth After COVID-19...Expansion Probably Here to Stay**
  - President Trump's Executive Order (August 3, 2020)
    - Directs HHS to propose regulation (extend the flexibility under the pandemic and maintain telehealth flexibility beyond the existing pandemic)
  - HHS Proposed Rule
    - Expand telehealth to cover additional services
  - Many of these proposals likely to require legislative action
- **Expanded Scope of Practice**
  - 2021 Physician Fee Schedule proposed rule (85 Fed. Reg. 50139)
    - Open-ended questions about scope of practice for various NPPs under state law
    - Proposal to allow certain NPPs to supervise diagnostic tests
    - Proposal to allow pharmacists to provide medication management services incident to physician or NPP services
    - Proposal to allow PTAs and OTAs to provide maintenance therapy services as part of maintenance program established by a PT or OT under Part B (*cf.* preexisting policy for Part A SNF policy)



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# After the Pandemic . . .

## **The Bad / The Ugly (OIG Work Plan Items)**

- Audit of Medicare Payments for Inpatient Discharges Billed by Hospitals for Beneficiaries Diagnosed With COVID-19
- Audit of CARES Act Provider Relief Funds—General and Targeted Distributions to Hospitals
- A Review of Medicare Data To Understand Hospital Utilization During COVID-19
- Use of Medicare Telehealth Services During the COVID-19 Pandemic
  - Two Reviews: (i) usage; and (ii) program integrity risks
- Several Work Plan items related to Nursing Homes (infection control, reporting requirements, COVID-19 challenges, etc.)



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# Questions?

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## Annual Health Law Update For Hospitals

# Alabama Update 2020



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## Alabama Update 2020

# HEALTH LEGISLATION OF INTEREST (2020)



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# Alabama Update 2020

## **Act 2020-14, HB 147**

- This act prohibits a City from imposing an occupational tax, unless it already has such a tax, without legislative approval.
- Effective: March 3, 2020.



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# Alabama Update 2020

## **Act 2020-73, HB 202 (Public Benefit Corporations)**

- This Act significantly amends Title 10A of the Code of Alabama 1975 to: (1) allow business corporations to elect to become benefit corporations; (2) allow electronic filing of all entity filings; (3) update definitions to include terms applicable to the allowance of electronic and digital transactions and transmissions of filings, notices, and data; (4) to establish certain basic standards for all filing instruments; (5) provide a mechanism to allow the Secretary of State to reject certain filing instruments which are not accompanied by full payment; (6) clarify the requirements of existence for entities; (7) remove outdated definitions and matters; (8) clarify that volunteer partners, managers, members, governing persons, and other members of a governing authority are considered officers of a qualifying nonprofit entity, thereby recognizing that there are nonprofit partnerships, nonprofit limited partnerships, and non-profit limited liability companies.
- Effective: May 18, 2020.



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# Alabama Update 2020



## **Act 2020-147, HB 401 (Nursing Home Tax)**

- This act amends Sections 40-26B-21, 40-26B-26, and 40-26B-27 of the Code of Alabama 1975 to increase the privilege assessment on the business activities of every nursing facility in Alabama from \$1,890.96 for each bed in the facility, to \$2,218.44 per annum. Furthermore, the act provides the methodology for recalculation of current asset value as it relates to nursing facility rates, creates a Medicaid quality incentive program for nursing facilities, and provides that if federal financial participation is not available to the Alabama Medicaid program, then Section 40-26B-27 is intended to be severable.
- Effective: May 18, 2020.

# Alabama Update 2020

## **Act 2020-195, HB 484 (Macon County - Tax for Ambulance Service)**

- This Act amends Sections 45-44-247.02 and 45-44-247.08 of the Code of Alabama 1975 to authorize the Macon County Commission to levy an additional sales and use tax for ambulance service, and extend the period the tax may be levied until from November 30, 2020 to January 30, 2022.
- Effective: May 19, 2020.



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# Alabama Update 2020

## **Act 2020-40, SB 12 (Missing and Endangered Persons Alert Act)**

- This act amends Sections 26-19-A-1, 26-19A-2, 26-19A-3, 26-19A-4, and 26-19A-5 of the Code of Alabama 1975, to expand existing law relating to missing senior citizens to also include missing and endangered persons living with a mental or physical disability who are at risk of bodily harm or health.
- Effective: March 30, 2020.

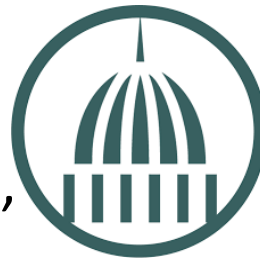




# Alabama Update 2020

## **Act 2020-84, SB 111 (Synthetic Urine Prohibited)**

- This act prohibits persons from knowingly manufacturing, marketing, selling, distributing, using, or possessing synthetic urine or urine additives (with exceptions if the use of the urine, synthetic urine, or urine additive is solely for educational, medical, or scientific research). It further provides that on the first conviction of subsection (b) of the act, the violator is guilty of a Class B misdemeanor, with each subsequent conviction being a Class A misdemeanor. Approved: March 31, 2020.
- Effective: June 1, 2020.



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# Alabama Update 2020

## **Act 2020-115, SB 129 (General Fund Budget Reserve Fund)**

- This act creates within the State Treasury the “General Fund Budget Reserve Fund.” Beginning on October 1, 2020 and on October 1 of each fiscal year thereafter, twenty percent (20%) of the ending balance in the General Fund from the previous fiscal year that was unanticipated and unappropriated by the Legislature from the previous fiscal year will be transferred into the General Fund Budget Reserve Fund.
- Effective: May 18, 2020.



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# Alabama Update 2020

## **Act 2020-85, SB 140 (Statewide Emergency Notification System)**

- This act amends Sections 31-9-80 and 31-9-81 of the Code of Alabama 1975 to add Section 31-9-87, to create and fund a Statewide Emergency Notification System pursuant to cooperation between the Emergency Management Agency and the Alabama Disaster Recovery Program Committee.
- Effective: March 31, 2020.



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# Alabama Update 2020



## **Act 2020-168, SB 157 (General Fund Budget)**

- This bill makes appropriations for the ordinary expenses of the executive, legislative, and judicial agencies of the State, for other functions of government, for debt service, and for capital outlay for the fiscal year ending September 30, 2021. For healthcare purposes, the bill appropriates a total of \$7,743,305,796 to the Alabama Medicaid Agency, \$501,503,915 to the Department of Mental Health, \$118,000 to the Board of Examiners of Nursing Home Administrators, and \$306,748 to the Alabama State Board of Occupational Therapy.
- Effective: October 1, 2020.

# Alabama Update 2020



## **Act 2020-116, SB 158 (Tobacco Settlement Revenues)**

- This act (1) makes an appropriation of \$40,427,150 from the Children First Trust Fund for the fiscal year ending September 30, 2021, to the entities and for the purposes designated in Section 41-15B-2.2 of the Code of Alabama 1975; (2) provides for the deposit of tobacco settlement revenues into the Children First Trust Fund; (3) requires written notification of anticipated agency allocations by the State Director of Finance; (4) requires quarterly allocations; (5) conditions allocations on receipt of tobacco revenues; (6) provides for the transfer to the State General Fund during fiscal year 2021 that portion of Children First Trust Fund receipts currently allocated for the State Board of Education; (7) makes an appropriation of \$53,148,004 from other tobacco settlement funds for the fiscal year ending September 30, 2021; and (8) makes a conditional appropriation and allocation of additional tobacco revenues upon 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, and the approval of the Governor.
- Effective: May 18, 2020



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# Alabama Update 2020

## **Act 2020-167, SB 242 (Investing in Alabama's Future Act)**

- This Act (1) authorizes the Alabama Public School and College Authority to sell and issue \$1,250,000,000 in aggregate principal amount of additional bonds for capital improvements for the support of public education and to use such funds for repayment of certain debt incurred for capital improvements; (2) provides funds for capital improvements for public schools, the Alabama Community College System, and public institutions of higher education; (3) makes an appropriation and pledge for the payment of the principal of and premium, if any, and interest on the bonds from specific taxes necessary to pay the principal and interest at their respective maturities and authorizes the Authority to pledge for payment of the principal of and premium, if any, and interest on the bonds the funds that are appropriated and pledged; (5) provides that the bonds shall not constitute a debt of the state but shall be limited obligations payable out of the funds appropriated and pledged therefor; (6) provides that the bonds and income therefrom shall be exempt from all taxation in Alabama; (7) authorizes the Authority to issue refunding bonds and give details of such refunding; and (8) authorizes the Authority to allocate bond proceeds.
- Effective: May 18, 2020.



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# Alabama Update 2020

- **Act 2020-206, HJR 69 –**
- Resolution for Alabama Department of Mental Health to create Crisis Diversion Centers. (Mental Health has asked for RFP's for eight Crisis Centers in different regions of the state.)



## Alabama Update 2020

# ALABAMA CASES OF INTEREST (2020)



# Alabama Update 2020

## WORKERS' COMPENSATION CASES:

### 1. *Ex parte Warrior Met Coal, Inc.*

- Alabama Court of Civil Appeals
- September 6, 2019
- Case No. 2180740



Claimant, an electrician brought a claim against his employer for hearing loss in both ears as a result of his employment. The employer filed for a writ of mandamus, saying the trial court lacked subject-matter jurisdiction because employee's claim was not ripe. Alabama Code § 25-5-117 states that "the date of injury" for an occupational disease is "the date of the last exposure to the hazards of the disease." Employer argued that the employee's "last date of injury" had yet to occur, because he was still on the job. The Court of Appeals upheld the trial court's denial of summary judgment and denied the writ of mandamus, holding that ability to continue working does not in and of itself preclude compensation. Furthermore, just because an injured employee may again be exposed to conditions that created the injury, does not present an issue of ripeness.

# Alabama Update 2020

## WORKERS' COMPENSATION CASES:

### 2. Billingsley v. City of Gadsden

- Alabama Court of Civil Appeals
- September 27, 2019
- Case No. 2180621
- This case involved the appeal of a trial court's dismissal with prejudice of an injured claimant's workers' compensation claim, after the claimant had died while the case was in that court on remand. Afterwards, claimant's counsel filed an appeal with claimant named as the sole plaintiff. The Court of Appeals held that this appeal was a nullity, and they lacked appellate jurisdiction to hear the case following the claimant's death.



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# Alabama Update 2020

## WORKERS' COMPENSATION CASES:

### 3. Enterprise Leasing Company-South Central, LLC v. Drake

- Alabama Court of Civil Appeals
- October, 11 2019
- Case No. 2180627



This was the second time the Court of Appeals heard this case, after initially reversing and remanding a trial court judgment 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. The Court of Appeals initially remanded with instruction for the trial court to determine whether the employee’s right-knee injury was a direct and natural consequence of his left-knee injury. The trial court concluded under the “clear and convincing” standard that employee had suffered permanent partial impairment in both knees, and the Court of Appeals affirmed.



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# Alabama Update 2020

## WORKERS' COMPENSATION CASES:

### 4. Swain v. AIG Claims, Inc.

- Alabama Court of Civil Appeals
- October 18, 2019
- Case No. 2180336



Employee filed a workers' compensation claim after being injured at work when a large electrical circuit breaker exploded. He claimed both physical and mental injuries, including PTSD, as well as additional tort claims based on the defendants' post-accident handling of his workers' compensation claim. The Court of Appeals stated that the trial court's grant of a motion to dismiss under Alabama Code § 25-5-77(a) was not appropriate here, because the employee had to prove that his injury fell outside the coverage of the Act, and that determination required a proximate-cause analysis which could not have been made on a motion to dismiss.

# Alabama Update 2020

## WORKERS' COMPENSATION CASES:

### 5. *Ex parte Ultratec Special Effects, Inc.*

- Supreme Court of Alabama
- November 8, 2019
- Case No. 1180183



The Supreme Court found that the exclusivity provisions in Alabama Code § 25-5-52 and § 25-5-53, which protect “employers” from being held civilly liable for injuries sustained by employees while on the job, did not apply in this case. Ultratec argued that it and Ultratec HSV operated as a single employer group, but they did not assert that it provided assistance in administering Ultratec HSV’s workers’ compensation plan. Therefore, Ultratec did not qualify as an “employer” under Alabama Code § 25-5-1(4), and therefore unable to rely on the exclusivity provisions of the Worker’s Compensation Act.



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# Alabama Update 2020

## WORKERS' COMPENSATION CASES:

### 6. *Ex parte* Sea Coast Disposal, Inc.

- Alabama Court of Civil Appeals
- November 15, 2019
- Case No. 2180978



Employee sued for workers' compensation benefits for left shoulder, neck, and lower back injuries he claimed to have suffered while working as a garbage truck driver. The accident occurred on November 24, 2017, but he did not experience any neck pain until after he had shoulder surgery in January 2018. Significant lower back pain didn't manifest until November 2018. The Court of Appeals noted that a trial court has wide discretion with regard to findings about medial causation, and stated that there was sufficient evidence finding that the employee's neck injury was compensable. However, no evidence was presented that the employee's lower back injury was related to the 2017 accident, and the Court granted the employer's petition for writ of mandamus regarding the trial court's ruling regarding the back injury.

# Alabama Update 2020

## WORKERS' COMPENSATION CASES:

### 7. Colby Furniture Co., Inc. v. Overton

- Alabama Court of Civil Appeals
- December 6, 2019
- Case No. 2180532



Alabama Code § 25-5-77(a) provides that an employee who is dissatisfied with treatment provided by a physician selected by the employer may demand from the employer a panel of four physicians from which the employee may select a second authorized physician. Employer argued that after employee had selected a second physician, she had no statutory right to additional panels from which to select a new physician. The Court of Appeals rejected the employer's argument and also held that the clean hands doctrine did not bar the employee from receiving future medical benefits.



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# Alabama Update 2020

## WORKERS' COMPENSATION CASES:

### 8. *Ex parte* Burkes Mechanical, Inc.

- Supreme Court of Alabama
- December 6, 2019
- Case No. 1180402



The Supreme Court denied a writ of mandamus petition by an employer because, where the employee had asserted claims based on additional injuries he alleged arose from conduct that occurred immediately after his workplace injury, it was a fact-intensive inquiry whether or not his claims were “too tenuous to bring the later activities under the coverage” of the Act. Therefore, the employer had not demonstrated a clear legal right to have the employee’s tort claims against it dismissed.

# Alabama Update 2020

## WORKERS' COMPENSATION CASES:

### 9. *Ex parte Kohler Company, Inc.*

- Alabama Court of Civil Appeals
- January 17, 2020
- Case No. 2190081



Employer petitioned for a writ of mandamus after the trial court ordered it to refer the employee to an orthopedic specialist for a second opinion regarding her work-related left-foot injury. The Court of Appeals held that employer's failure to refer claimant to an orthopedic specialist, as the trial court had ordered, prevented the employer from arguing that the trial court's order violated the statutory maximum on panels from which claimants could select a treating physician, under Alabama Code § 25-5-77(a).



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# Alabama Update 2020

## WORKERS' COMPENSATION CASES:

### 10. *Ex parte Drury Hotels Company, LLC (Diaz v. Drury Hotels Co., LLC)*

- Alabama Court of Civil Appeals
- February 28, 2020
- Case No. 1181010



Employee worked as a housekeeper for the employer, and brought both tort and workers' compensation claims for bodily and emotional injuries arising from a sexual assault and robbery she suffered at work. The Court of Appeals rejected the employer's defense of employer immunity under the exclusive remedy provisions of Alabama Code § 25-5-1, because the proper place for the employer to discuss that sort of substantive law was in light of the trial court's denial of the Rule 12(b)(6) motion, rather than a writ of mandamus.



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# Alabama Update 2020

## WORKERS' COMPENSATION CASES:

### 11. Ex parte Wal-Mart Associates, Inc. (Martin v. Wal-Mart Associates, Inc.)

- Alabama Court of Civil Appeals
- April 24, 2020
- Case No. 2190468



Martin filed a workers' compensation claim against his employer, Wal-Mart. Wal-Mart filed a motion to transfer venue. After the trial court denied the motion to transfer, Wal-Mart filed a petition for writ of mandamus. The Court granted the writ of mandamus reasoning that Wal-mart had met its burden of proving that the transferee forum was significantly more convenient than the plaintiff's chosen forum.



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# Alabama Update 2020

## WORKERS' COMPENSATION CASES:

### 12. Nucor Steel Birmingham, Inc. v. Otwell

- Alabama Court of Civil Appeals
- May 22, 2020
- Case No. 2180542



Otwell brought a workers' compensation claim against his employer Nucor Steel, alleging that he was permanently and totally disabled as a result of on-the-job injuries resulting from cumulative trauma and deterioration of his lumbar spine. Nucor first alleged that the trial court's finding that Otwell's lumbar spine disorder was an occupational disease arising from his employment was never plead in the motions by Otwell. The Court of Appeals accepted this argument and reversed this part of the trial court finding, stating that the complaint does not state that Otwell suffered from an occupational disease, cite any statutory provisions regarding occupational diseases, or allege facts particular to the elements of an occupational disease. The Court also held that under the "last injurious exposure rule," Nucor was only responsible for providing workers' compensation benefits to Otwell if the injury he claimed was either a new injury or an aggravation of a prior injury. Without any evidence of either, they reversed and remanded the trial court's decision.



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# Alabama Update 2020

## MEDICAL MALPRACTICE CASES:

### 1. Youngblood v. Martin

- Supreme Court of Alabama
- January 10, 2020
- Case No. 1171037



Plaintiff Martin brought a wrongful death claim against treating physician Dr. Youngblood, among others. After Dr. Dennis Doblar provided expert testimony on behalf of Martin at trial, the defendant filed a JML, claiming that Dr. Doblar was not a “similarly situated health care provider” as defined in Alabama Code § 6-5-548(c). Furthermore, that section also requires that the expert witness provide testimony demonstrating that they are licensed by the appropriate regulatory board of Alabama, which Dr. Doblar did not do. The Supreme Court held that Dr. Doblar was not qualified to testify under § 6-5-548(c), and remanded the case for the trial court to enter a JML in favor of the defendant.

# Alabama Update 2020

## MEDICAL MALPRACTICE CASES:

### 2. Ex parte BBH BMC, LLC

- Supreme Court of Alabama
- January 24, 2020
- Case No. 1180961



Gaston, the widow of a deceased psychiatric voluntary outpatient brought a wrongful-action against Brookwood Baptist Medical Center after his wife Donna committed suicide by leaping from a parking deck on the premises. Brookwood maintained that Gaston's discovery requests were overly broad, and violated the confines of Alabama Code § 6-5-551 because it did not seek discovery related to the particular treatment rendered to Donna, or other policies and procedures in place to promote the safe care of Donna. The Court granted Brookwood's writ of mandamus, finding that Gaston's requested discovery should have been limited to the alleged standard of care owed to Donna, and the trial court's discovery should be vacated in accordance with § 6-5-551 and Alabama Rule of Civil Procedure 26(b)(2).

# Alabama Update 2020

## MEDICAL MALPRACTICE CASES:

### 3. Pollard v. H.C. Partnership

- Supreme Court of Alabama
- March 13, 2020
- Case No. 1180795



The estate of Ed Young, on May 7, 2017, sued Hill Crest Behavioral Health Services for the wrongful death of Ed Young on May 9, 2015, alleging that Hill Crest improperly administered antipsychotic drugs to Young. Pollard was appointed administrator of Young's estate on May 8, 2017, one day before the two-year limitations under Alabama's wrongful death act (Alabama Code § 6-5-410(d)) expired. The Supreme Court held that the relation back provision of Alabama Code § 43-2-831 did not apply here, because a wrongful-death action does not benefit the estate. Rather, Rule 17(a) of the Alabama Rules of Civil Procedure made it permissible to substitute a personal representative as the real party in interest before the limitations period expired, and to allow the substitution to relate back to the filing of the original wrongful-death complaint.

# Alabama Update 2020

## MEDICAL MALPRACTICE CASES:

### 4. Ex parte Russell

- Supreme Court of Alabama
- June 26, 2020
- Case No. 1180317, 1180318, 1180319



This is a fictitious defendant case. Personal representative of estate of deceased patient, Tameca Miles, brought a wrongful-death action against Coosa Valley Medical Center and some medical center employees, alleging that some employees had breached applicable standards of care when they allowed police to remove a patient from the emergency room before she was treated. The patient was taken to the city jail and was later brought back to Coosa Valley Medical Center, where she died a short time later. The estate later learned that four specific employees of the medical center were involved in removing Tameca from the emergency room, and amended the complaint to include those four employees as defendants. The employees moved for summary judgement, arguing that claims against them were filed outside the allowed two-year statute of limitations. The Supreme Court denied the petition of three of the four employees, and found that the plaintiff's initial fictitiously named defendants were specific enough to assert a cause of action against three of the four.

# Alabama Update 2020

## MEDICAL MALPRACTICE CASES:

### 5. Williams as next friend of Williams v. Barry

- Supreme Court of Alabama
- June 26, 2020
- Case No. 1180352



Angela Williams, mother of deceased juvenile patient Li'Jonas Earl Williams, brought action against surgeon and surgeon's practice based on wrongful death from alleged medical malpractice related to surgery to remove patient's gallbladder. The trial court granted the defendant's motion for a judgement as a matter of law, and the plaintiffs appealed. The Supreme Court determined through the conflicting testimony of expert witnesses that there was a factual dispute regarding the applicable standard of care shown by the surgeon and that the gallbladder removal surgery could have been the proximate cause of Li'Jonas' death. The case was reversed and remanded.

# Alabama Update 2020

## MEDICAL MALPRACTICE CASES:

### 6. *Ex parte* Freudenberger

- Supreme Court of Alabama
- June 30, 2020
- Case No. 1190159



The plaintiffs, Rhonda and Charlie, sued Dr. Freudenberger and Sportsmed Orthopedic claiming medical malpractice based on injuries Rhonda allegedly suffered during the course of a surgical procedure performed by Dr. Freudenberger. The defendants petitioned the Supreme Court for a writ of mandamus to direct the circuit court to vacate its protective order imposing conditions upon *ex parte* interviews defense counsel intends to conduct with physicians who treated Rhonda. The Supreme Court found that Alabama law, nor HIPPA, prohibits *ex parte* interviews with a plaintiff's treating physicians as a means of informal discovery by the defense counsel. Here, the plaintiffs failed to demonstrate the existence of any circumstances warranting limitations on *ex parte* communications with Rhonda's treating physicians; therefore, the trial courts was directed to vacate its order.

# Alabama Update 2020

## MEDICAL MALPRACTICE CASES:

### **7. Ex parte Gulf Health Hospitals, Inc., d/b/a Thomas Hospital (Faison v. Gulf Health Hospitals, 29 ALW 37-1.**

- Alabama Supreme Court
- September 4, 2020
- Case No. 1180596

This was a mandamus case involving alleged medical malpractice for additional doses of Levophed to increase blood pressure. The plaintiff amended their complaint several times, after taking several hospital employee depositions. The Hospital sought a writ of mandamus when the trial judge refused to strike the amendments to the complaint. The petition was denied. The Alabama Supreme Court seems to be saying "We are getting too many of these!"



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# Alabama Update 2020

## MEDICAL MALPRACTICE CASES:

### 8. **Spencer v. Remillard, 29 ALW 37-2.**

- Alabama Supreme Court
- September 4, 2020
- Case No. 1180650

This is a very factually complicated case involving a notification of a "High PSA" blood test, where the decedent developed prostate cancer that spread throughout his body. A family practitioner and "Certified Medical Assistant" were allowed to testify as experts about notification of results and the standard of care per Section 6-5-548, *Code of Alabama*.



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Alabama Update 2020

# **ALABAMA GOVERNOR'S COVID-19 PROCLAMATIONS 2020**



# Alabama Update 2020

## 1. APRIL 2, 2020 – FIFTH SUPPLEMENTAL COVID-19 PROCLAMATION



This was the Fifth Supplemental Executive Order issued by Governor Ivey in response to the COVID-19 pandemic. The first goal was to cut red tape for health care providers, in anticipation of a surge of COVID-19 cases in health care facilities. The order relaxed some of the state qualification requirements for health care professionals such as nurse practitioners, nurse midwives, and nurse anesthetists in order to allow certified health care professionals who had received the appropriate license from another state/territory of the United States or a province of Canada to practice in Alabama during the period of the public health emergency. Physicians practicing outside of a licensed health care facility were also granted temporary emergency approval for collaboration agreements with nurse practitioners and nurse midwives, so long as the agreements did not exceed 360 hours per week. A policy for the expedited reinstatement of medical licenses to qualified physicians who maintained good standing while they practiced in Alabama, and had no disciplinary history elsewhere, was also implemented as an emergency rule.



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# Alabama Update 2020

## 1. APRIL 2, 2020 – FIFTH SUPPLEMENTAL COVID-19 PROCLAMATION (CONTINUED)



Second, state health care departments and agencies were granted temporary relief from certain laws and rules concerning the state's healthcare infrastructure. The State Health Planning and Development Agency, the Statewide Health Coordinating Council, and the Certificate of Need Review Board were directed to promulgate emergency rules providing for temporary waivers to the Certificate of Need process. The Alabama Board of Pharmacy was directed to pass similar rules expediting temporary pharmacy permits.

# Alabama Update 2020

## 1. APRIL 2, 2020 – FIFTH SUPPLEMENTAL COVID-19 PROCLAMATION (CONTINUED)



Third, in order to reduce the necessity of in-person meetings, the order authorized notaries in Alabama to notarize signatures through videoconferencing programs, and confirm the signatures of witnesses who participated virtually through videoconferencing. All public meetings scheduled by law to take place during the pandemic were also permitted to be postponed by the chair or other person responsible for setting it. Otherwise, meetings could be conducted virtually within the requirements of the Open Meetings Act, so long as the meeting is limited to matters necessary to respond to COVID-19 and the communications equipment allows all persons participating in the meeting to hear each other at the same time. In addition, corporations were permitted to conduct shareholder meetings remotely. This practice would be permissible so long as the corporation has implemented reasonable measures to verify membership of each person participating, and the corporation has provided stockholders participating remotely a reasonable opportunity to communicate, participate, and vote on matters submitted to the stockholders over the course of the meeting.



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# Alabama Update 2020

## 2. MAY 8, 020 – EIGHTH SUPPLEMENTAL COVID-19 PROCLAMATION



The Eighth Supplemental Executive Order issued by Governor Ivey in response to COVID-19 was largely concerned with providing liability protections for businesses and health care providers. The order granted businesses and health care providers liability protection for death or injury to persons or damage to property, in any way related to COVID-19 transmission or a covered COVID-19 response activity, unless a claimant can show by clear and convincing evidence that the death/injury/damage was caused by the entity's wanton, reckless, willful, or intentional misconduct. Where liability is established, damages would be limited to actual economic compensatory damages, or in the case of wrongful death claims, only punitive damages. Notably, the order also extended these protections to COVID-19-related causes of action that had accrued prior to the issuance of the executive order. These protections could be overcome only if the claimant displays by clear and convincing evidence that the entity did not reasonably attempt to comply with the then applicable public health guidance.

# Alabama Update 2020

## 2. MAY 8, 020 – EIGHTH SUPPLEMENTAL COVID-19 PROCLAMATION (CONTINUED)



Next, the order clarifies that nothing within the executive order shall be construed to supersede any defense or right that exists under law and would be applicable here; the immunity provided by the executive order is in addition to and cumulative of other defenses and rights that exist under law. Furthermore, the liability protections afforded by the executive order do not limit nor supersede any provisions of the original March 13 executive order or other applicable State laws regarding civil actions against health care providers. For cases where the health care services provided do not result from and or not affected by the COVID-19 pandemic or the State's response to the pandemic, then previous executive orders and existing Alabama law shall still govern, as outlined under Alabama Code §§ 6-5-540 *et seq.*



# Alabama Update 2020

## 2. MAY 8, 020 – EIGHTH SUPPLEMENTAL COVID-19 PROCLAMATION (CONTINUED)



The executive order concludes with some general provisions. Included in this section are clarifications that nothing in the executive order shall be construed to affect the rights of any person to receive benefits under the Alabama Emergency Management Act (AEMA) or the Workers' Compensation Act. Nor should anything in the executive order be construed *in pari material* with the AEMA and with any subsequently enacted immunity protections. Importantly, there is also a severability provision; if any provision within the executive order is declared invalid or unconstitutional, its remaining provisions will continue in full effect. If a court holds that the standard of care (wanton, reckless, willful, or intentional misconduct) mentioned above is invalid, then the following will apply in its place: (1) failure to comply with or reasonably attempt to comply with applicable public health guidance; or (2) willful misconduct, gross negligence, or bad faith.



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# Alabama Update 2020

## 2. MAY 8, 2020 – EIGHTH SUPPLEMENTAL COVID-19 PROCLAMATION (CONTINUED)



The executive order was signed May 8, 2020 and is retroactive and effective for acts or omissions from March 13, 2020, until the COVID-19 public health emergency is terminated.

# Alabama Update 2020

## 3. MARCH 18, 2020 – FIRST SUPPLEMENTAL COVID-19 PROCLAMATION



The First Supplemental Executive Order suspended the March 31, 2020, primary runoff election until July 14, 2020, as a result of the COVID-19 health threat. It also required the closure of all K-12 public schools at the end of the day Wednesday, March 18, 2020, with reopening tentatively scheduled for Monday, April 6, 2020. Next, the order allowed members of governmental bodies to participate in meetings, establish a quorum, deliberate, and take action by virtual methods of communication within the boundaries of the Open Meetings Act (§ 36-25A-2). State agencies and local awarding authorities also received authorization to enter into contracts for goods and services without public advertisement to the extent necessary to respond to COVID-19. Lastly, State employees required to perform response services away from their home base of operations were allowed to apply for reimbursement for actual expenses incurred while performing these services.

# Alabama Update 2020

## 4. MARCH 23, 2020 – THIRD SUPPLEMENTAL COVID-19 PROCLAMATION



The Third Supplemental Executive Order postponed certain state tax obligations. The Commissioner of Revenue was delegated the authority to postpone the April 15, 2020 due date for the payment of the following state taxes until July 15, 2020 for any “person,” as that term is defined in Alabama Code § 40-1-1(8): (1) individual income tax; (2) corporate income tax; (3) financial institutions excise tax; and (4) business privilege tax.

# Alabama Update 2020

## 5. APRIL 3, 2020 – SIXTH SUPPLEMENTAL COVID-19 PROCLAMATION



The Sixth Supplemental Executive Order granted temporary relief from residential evictions and foreclosures; all state, county, and local law enforcement officers were directed to cease enforcement of any order that results in the displacement of a person from his or her place of residence. However, nothing in the order relieved any obligations of paying rent, making mortgage payments, or any other obligation that an individual may have under a rental agreement or mortgage.

# Alabama Update 2020

## 6. MAY 21, 2020 – TENTH SUPPLEMENTAL COVID-19 PROCLAMATION



The Tenth Supplemental Executive Order set a deadline for the “Protection Against Evictions” provision of the April 3 and May 8 supplemental proclamations. It stated that the State Health Officer’s current “Safer at Home” order allows citizens to return to work and therefore earn income to satisfy their rental and mortgage payment obligations. Accordingly, the protections against evictions provisions will expire at 12:00 a.m. on June 1, 2020.

# Alabama Update 2020

## **7. JUNE 30, 2020 – TWELFTH SUPPLEMENTAL COVID-19 PROCLAMATION**



The Twelfth Supplemental Executive Order extends the “Safer at Home” health order until 5:00 P.M. on July 31, 2020.

# Alabama Update 2020

## 8. JULY 2, 2020 – THIRTEENTH SUPPLEMENTAL COVID-19 PROCLAMATION



The Thirteenth Supplemental Executive Order authorizes remote meetings for nonprofit corporation if the guidelines and procedures for remote participation are approved by the corporation's trustees and directors. Members who participate remotely may be counted as present and vote if 1) the corporation has implemented measures to verify the membership of each person participating, and 2) the corporation has provided opportunities for communication, participation, and voting. Notice describing the means of remote communication must be sent to members. Next, the order extends the Public Health Emergency to September 8, 2020.



# Alabama Update 2020

## 9. JULY 15, 2020 – FOURTEENTH SUPPLEMENTAL COVID-19 PROCLAMATION



The Fourteenth Supplemental Executive Order adds a mask requirement to the current “Safer at Home” health order. The requirement makes facial coverings mandatory for individuals if they are within six feet of another person from a different household in the following places: (1) an indoor space open to the general public; (2) a vehicle operated by a transportation service; or (3) an outdoor public space where ten or more people are gathered. A number of exceptions are listed in the order, including exceptions for practical necessity, exercise, effective communication, facilitation of constitutionally protected activity, and exceptions for essential job functions.

# Alabama Update 2020

## 10. JULY 29, 2020 – FIFTEENTH SUPPLEMENTAL COVID-19 PROCLAMATION



The Fifteenth Supplemental Executive Order extends the statewide “Safer at Home” health order until August 31, 2020. This executive order also expands the statewide facial covering requirement to require all school employees and students (second grade and above) to wear a mask or other facial covering that covered their nostrils and mouths at all times when they are within six feet of a person from a different household.

# Alabama Update 2020

## 11. AUGUST 27, 2020 – SEVENTEENTH SUPPLEMENTAL COVID-19 PROCLAMATION



In effect, the Seventeenth Supplemental Executive Order extends the mask order until October 2, 2020, and the Emergency Order until November 8, 2020.

# Alabama Update 2020

## **12. SEPTEMBER 30, 2020 – AMENDMENT TO ORDER OF THE STATE HEALTH OFFICER SUSPENDING CERTAIN PUBLIC GATHERINGS DUE TO THE RISK OF INFECTION BY COVID-19**



### **Hospitals and similar institutions:**

Effective October 2, 2020, all Hospitals and Nursing Home/Long Term Care Facilities (including Assisted Living and Specialty Care Assisted Living Facilities) shall ensure that each patient or resident may be accompanied by one caregiver at a time (in the case of hospitals) or receive visits from one visitor at a time (in the case of nursing homes and long term care facilities), subject to reasonable restrictions imposed on the entrance of persons because of the COVID-19 county positivity rate, the facility's COVID-19 status, a patient's or resident's COVID-19 status, caregiver/visitor symptoms, lack of adherence to proper infection control practices, or other relevant factors related to the COVID-19 pandemic, consistent with the following guidance from the federal government:

# Alabama Update 2020

## 12. SEPTEMBER 30, 2020 – AMENDMENT TO ORDER OF THE STATE HEALTH OFFICER SUSPENDING CERTAIN PUBLIC GATHERINGS DUE TO THE RISK OF INFECTION BY COVID-19 (CONTINUED)



- For hospitals: "Hospital Visitation — Phase II Visitation for Patients who are Covid-19 Negative" issued by the Centers for Medicare and Medicaid Services (CMS) on June 26, 2020, and available at <https://www.cms.gov/files/document/covid-hospital-visitation-phase-ii-visitation-covid-negative-patients.pdf>.
- For nursing homes: "Nursing Home Visitation — COVID-19" issued by CMS on September 17, 2020, and available at <https://www.cms.gov/files/document/qso-20-39-nh.pdf>.
- For assisted living facilities and specialty care assisted living facilities: "Nursing Home Visitation — COVID-19" issued by CMS on September 17, 2020, and available at <https://www.cms.gov/files/document/qso-20-39-nh.pdf>, with the exception of the requirement that "resident and staff testing [be] conducted as required at 42 CFR 483.80(h)."



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# Alabama Update 2020

## **12. SEPTEMBER 30, 2020 – AMENDMENT TO ORDER OF THE STATE HEALTH OFFICER SUSPENDING CERTAIN PUBLIC GATHERINGS DUE TO THE RISK OF INFECTION BY COVID- 19 (CONTINUED)**



In addition, each facility subject to this paragraph shall post in a conspicuous location at each public entrance a statement substantially similar to the following statement:

By order of the Governor of Alabama and the State Health Officer, each patient or resident of this facility enjoys certain rights to have one caregiver or one visitor present at a time, subject to reasonable restrictions. If you have questions, you may ask to inspect the facility's written policies concerning visitation.

This order is in effect through 5:00 p.m., on November 8, 2020.

# Questions?

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## Annual Health Law Update For Hospitals

# Privacy / Security Update



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# Ransomware Not Letting Up.

- United Health Services – Ransomware attack weekend of September 27. Disabled computer systems, internet and phone service and data centers in hundreds of locations in CA, FL, PN and AZ. Result of phishing email. Not clear whether patient information was compromised. Ransom unknown. Response ongoing
- Blackbaud – Ransomware attack against cloud vendor occurred between February 7 – May 20 (ransomware deployed May 14). Targeted hospital, other nonprofit foundations. Approximately 6 million individuals affected. 10+ separate class actions filed in various federal district courts – so far (notification began in August).
- DCH – October 2019 ransomware attack forced DCH hospitals (3) to close to all but critical services for 10 days.
- During last 12 months, Microsoft blocked 13 *billion* malicious and suspicious emails.
- Healthcare data breaches most expensive (\$400+ per record); hardest to detect (9 months on average); and the stolen information is the most valuable (10x+ greater than SSN, etc.).
- Cyber attacks account for 60%+ of reported data breaches – up from < 10% a few years ago.
- Implicates ***patient safety*** (e.g., German patient died while being diverted)

Jessica Davis, Ransomware Spurs EHR Downtime at UHS Health System, 3 More Providers, HealthITSecurity (Sept. 29, 2020); available at <https://healthitsecurity.com/news/ransomware-spurs-ehr-downtime-at-uhs-health-system-3-more-providers>. Jessica Davis, Ransomware Reigns, as Cyberattacks Increase in Sophistication, Frequency, HealthITSecurity (Sept. 30, 2020); available at <https://healthitsecurity.com/news/ransomware-reigns-as-cyberattacks-increase-in-sophistication-frequency>. Nicole Westman, Woman dies during a ransomware attack on a German hospital, The Verge (Sept. 17, 2020), available at <https://www.theverge.com/2020/9/17/21443851/death-ransomware-attack-hospital-germany-cybersecurity>.





# Enforcement Not Letting Up

- HHS OCR entered into 3 seven-figure dollar settlements in the last 3 weeks:
  - ❖ Premiera Blue Cross - \$6.85M settlement; phishing attack; 10.4 million individuals affected; OCR cited failure(s) to conduct enterprise-wide risk analysis, implement risk management, audit controls.
  - ❖ CHSPSC - \$2.3M settlement; vendor/BAA; did not promptly respond to FBI tip; 6.1 million individuals affected; OCR cited failure(s) re: risk analysis, system activity review, incident response, access controls
  - ❖ Athens Orthopedic Clinic - \$1.5M settlement; 200,000+ individuals affected; OCR cited defects re: risk analysis / risk management, policies and procedures, training, BAAs
- Anthem Blue Cross - \$48 million settlement (total) with 42 state attorneys general (not Alabama) re: 2014 cyberattack that affected 79 million individuals (in addition to \$115 million class action settlement, \$16 million OCR settlement)
- New / pending legislation in CA (CCPA), NY and other states (and federal) – among other things, provide for statutory damages.

U.S. Department of Health & Human Services Office of Civil Rights (“OCR”), Health Insurer Pays \$6.85 Million to Settle Data Breach Affecting Over 10.4 Million People (Sept. 25, 2020), available at <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/premera/index.html>

OCR, HIPAA Business Associate Pays \$2.3 Million to Settle Breach Affecting Protected Health Information of Over 6 Million Individuals (Sept. 23, 2020), available at <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/athens-orthopedic/index.html>.

OCR, Orthopedic Clinic Pays \$1.5 Million to Settle Systemic Noncompliance with HIPAA Rules (Sept. 25, 2020), available at <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/athens-orthopedic/index.html>.





## What To Do? *Be prepared . . .*

Ten “never” events in privacy / cybersecurity – *no excuse* for not:

1. Engaging in ongoing, comprehensive, risk-based risk analysis and risk management
2. Doing all you can raise awareness
3. Implementing robust security safeguards
4. Prioritizing third-party assurance.
5. Responding timely to security incidents.
6. Regularly testing existing safeguards – and taking appropriate corrective actions.
7. Backstopping privacy and security safeguards with appropriate insurance coverage.
8. Board not being engaged, taking a leadership role on privacy and security.
9. Reaching out to valuable third-party resources, and ensuring they work together.
10. Documenting compliance.



# Legislative / Regulatory Matters

- Legislative / regulatory uncertainty – Patchwork of state laws / uncertainty at federal level.
- OCR – 2019 “Right of Access Initiative” – 8 resolution agreements in 2020 (so far): Focused on complying with HIPAA requirements to provide individuals (patients) with access to their PHI.
- CMS / ONCHIT Interoperability Rules
  - i. Telehealth - OCR will not impose HIPAA penalties in regard to the good faith provision of telehealth during the COVID-19 nationwide public health emergency.
  - ii. Community Based Testing Sites (“CBTS”) – A mobile, drive-through or walk-up site that only provides COVID-19 specimen collection or testing services to the public.
  - iii. Business Associates - OCR will not impose penalties against a business associate (or its covered entity) that uses or discloses PHI for public health or health oversight activities, even if not specifically authorized in BAA.

See, e.g., OCR Settles Five More Investigations in HIPAA Right of Access Initiative (Sept. 15, 2020), available at <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/right-of-access-initiative/index.html>.

Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency -

<https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html>.

Department of Health and Human Services, Notification Enforcement Discretion Regarding COVID-19 Community-Based Testing Sites (CBTS) During the COVID-19 Nationwide Public Health Emergency, <https://www.hhs.gov/sites/default/files/notification-enforcement-discretion-community-based-testing-sites.pdf>

Department of Health and Human Services, Notification Enforcement Discretion under HIPAA to Allow Uses and Disclosures of Protected Health Information Business Associates for Public Health and Health Oversight Activities in Response to COVID-19,

<https://www.hhs.gov/about/news/2020/04/02/ocr-announces-notification-of-enforcement-discretion.html>



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# Additional Resources

- ❖ Cybersecurity – [HHS guidance](#)
- ❖ Risk Analysis – [HHS guidance](#)
- ❖ Encryption – [HHS guidance](#)
- ❖ Breach notification – [HHS guidance](#); [OCR notification \(online\)](#)
- ❖ HIPAA Security Rule – [HHS guidance](#)
- ❖ HIPAA enforcement – [HHS / OCR resolution agreements](#)

# Questions?

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Annual Health Law Update For Hospitals

# OIG Work Plan for 2020



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# OIG/DOJ Year In Review

## OIG WORK PLAN FOR 2020



- Updated monthly now – need to check at least on a monthly basis.
- New and ongoing reviews are summarized.
- Office of Audit Services.
- Office of Evaluation and Inspections.
- Office of Investigations – Check Specific Hospital Audits (Cares Act Audits will be carried out by OIG and others).
- Office of Counsel to the Inspector General
- Executive Management.





# OIG/DOJ Year In Review



2020 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.
- Vulnerabilities related to the provider enrollment and ownership disclosure.
- Drug coverage issues.
- Outpatient Services provided to Inpatients: should be “under arrangements” and one bill.



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# OIG/DOJ Year In Review

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

- Rural Add-on Payment Methodology.
- Medicare Lab Billing – COVID-19 Add-on Testing.
- Medicare Telehealth & COVID-19.
- MAT Treatment for Opioid Use.
- Hospital Inpatient Billing.
- Nursing Home Transfers.
- Telehealth/Behavioral Health.



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# OIG/DOJ Year In Review

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

- Payments to New Hospitals.
- Inpatient-Rehab Discharges to Home Health.
- Audit of Payments for Inpatient Discharges – Diagnoses with COVID-19:
  - Audit of CARES Act Relief Funds.
  - Swing Bed Services at CAH's.
  - Expedited enrollment during COVID-19 Pandemic.
  - Hospital collection of Bad Debt.
- DME infusion drugs (compounding pharmacies).



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# OIG/DOJ Year In Review

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

- 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):



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- 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.



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# OIG/DOJ Year In Review

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

- Inpatient Claims paid as Outliers.
- IRF Claims.
- Outpatient Medical Devices.
- Rural Add-On Payment Methodology:
  - Medicare Lab Billing – COVID-19 Add-on Testing.
  - Medicare Telehealth & COVID-19.
  - MAT, Treatment for opioid use.
  - Hospital Inpatient Billing.



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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:



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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 – waived 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.



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"This is a new stress test; we just put on the news."



# 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.



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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.





# 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.





# 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.



2020 WORK PLAN



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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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"So if Mrs. Anderson does her grading at home,  
is she breaking the law?"





# 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.







# 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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"It would be quite an expensive treatment, and since you've still got 7 lives left your insurance isn't going to cover this."



# 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.



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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.



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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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"I'm just saying, with as many laws as are on the books, the chances I'd break one of them are actually pretty good."



# OIG/DOJ Year In Review

## 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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# OIG/DOJ Year In Review

## 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.)





# OIG/DOJ Year In Review

## 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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# OIG/DOJ Year In Review

## 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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# OIG/DOJ Year In Review

## 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.





# OIG/DOJ Year In Review

## 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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# OIG/DOJ Year In Review

## 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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# OIG/DOJ Year In Review



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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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# OIG/DOJ Year In Review

## Medical Equipment and Supplies:

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



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# OIG/DOJ Year In Review

## 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.





# OIG/DOJ Year In Review

## Other Steps:

- Sign up for email update at “HHSOIG.”
- See what you get.
- Baylor Scott & White – Specific Hospital: College Station. Audits of Outpatient Outlier Patients (Yearly Payments went up from \$89K to \$2.5M).
- Medicare Hospital Provider Compliance Audit: Texas Health Presbyterian Hospital in Dallas. Looked at inpatient rehabilitation, observation and others.



# Questions?

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# Health Law Update For Hospitals

Alabama Hospital Association

Presented by:

Gilpin Givhan, PC

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