Healthcare Law: Current Litigation Challenges to Monitor

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SC Hospital Association 21st Annual CFO Forum
August 19, 2022

2022 LITIGATION AND REGULATORY UPDATES

FAST PACED OVERVIEW IN 45 MINUTES

- Transparency and the No-Surprises Act
- *Vaught* case – Criminalizing Medical Errors
- *Dobbs* – Current SC Abortion Law and Compliance Recommendations
- Workplace Safety in the Hospital
- Status of the Federal PHE
- New ACO Reach Model
- Telehealth and Telefraud
- Ruan – Physician Prescribing Discretion Upheld
- Covid-19 Fraud
- CMS Maternity Care Action Plan
- DOJ FCA Cooperation Guidance
- Recent FCA Cases
- DOJ Cyber Fraud Initiative

TRANSPARENCY AND THE NO-SURPRISES ACT

Since the No Surprises Act ("NSA") was passed in 2020 and became effective January 1, 2022, various rules have been promulgated to implement it

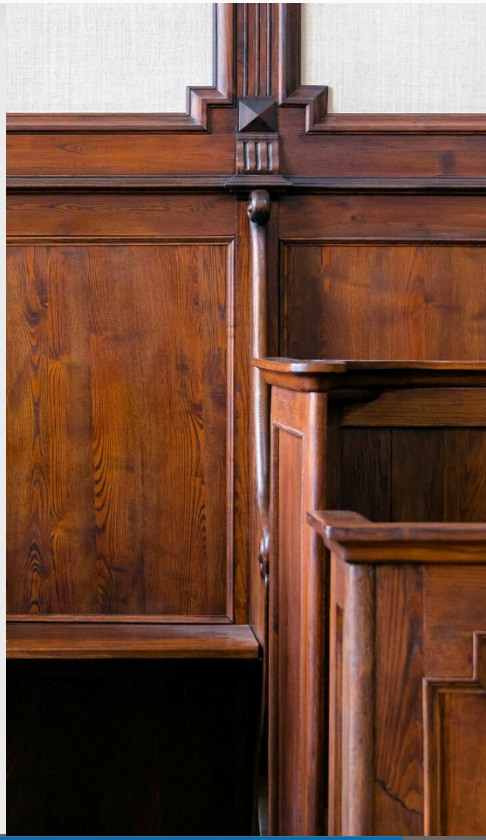
- One notable provision of the NSA provides for the establishment of reimbursement rates for insurers to pay out-of-network providers via an Independent Dispute Resolution process ("IDR")
- Departments of Health and Human Services, Labor, and Treasury charged with making rules to implement the IDR process.
  - NSA lists 5 factors that IDR entities must consider to determine the appropriate reimbursement rate.
- Departments issued a Rule in September 2021 to implement the IDR protocol
  - The rule gave near dispositive weight to one of the factors: The rate closest to the Qualifying Payment Amount ("QPA") was presumptively proper.

TRANSPARENCY AND THE NO-SURPRISES ACT: ENSUING LITIGATION

Multiple cases have challenged the Department's Rule implementing the IDR process

- In two cases, challengers have successfully argued that provisions of the Rule that established the rate closest QPA as presumptively proper for IDR purposes were invalid (*Texas Medical Association, et al. v. United States Department of Health and Human Services, et al.* & *LifeNet, Inc. v. United States Department of Health and Human Services, et al.*)
- A Final Rule implementing the IDR Process is currently pending White House OMB approval
  - It is expected these decisions will influence the forthcoming final rule
  - Whichever course the departments choose, it appears they will not be able to place a thumb on the scale in favor of any individual IDR factor to determine appropriate rates

https://www.polsinelli.com/publications/federal-court-strikes-portions-of-regulations-implementing-no-surprises-act



FEDERAL RULES REQUIRING TRANSPARENCY IN PRICING

TWO RULES WERE PROMULGATED UNDER THE TRUMP ADMINISTRATION REGARDING PRICE TRANSPARENCY: ONE FOR HOSPITALS AND ONE FOR INSURANCE COMPANIES

- The Hospital Price Transparency Rule went into effect on January 1, 2021 and it requires hospitals to release a machine-readable file of all of their negotiated rates, self-pay rates and chargemaster rates on public websites.
- Published reports indicate that less than 20 percent of all hospitals were complying with this new rule as of early 2022. PatientRightsAdvocate.org.
- CMS enhanced its ability to fine hospitals for noncompliance and began to issue warnings to hospitals.

IMPORTANCE OF COMPLIANCE: TRANSPARENCY IN COVERAGE RULE

The current enforcement climate and potentially heavy penalties tied to individual violations and affected consumers make compliance with the Hospital Pricing Rule Essential

- Although pricing agreements between healthcare providers and health plans have always been highly confidential, this is no longer the case under the rule
- **Two Georgia Hospitals (Northside Hospital Atlanta and Northside Hospital Cherokee) have already been fined nearly $1.1 million collectively for failure to comply with the rule**
  - Notably, this fine was alleged issued after the hospitals repeatedly refused to comply with the Rule after several warnings from CMS.
  - The status quo will no longer stand– it is imprudent to fail to comply based on a belief that enforcement is unlikely

https://www.nexsenpruet.com/publication-health-care-price-transparency-update-new-rules-and-recent

OTHER EFFORTS: TRANSPARENCY IN COVERAGE FINAL RULE

Enforcement of the Transparency in Coverage Final Rule began on July 1, 2022 for insurance companies

- Enforcement was initially delayed to allow covered entities to develop infrastructure necessary to comply with the Rule's disclosure requirements
- The Rule requires that health plans and health insurance issuers to publicly disclose pricing information for covered items and services in specified formats for plan or policy years beginning on or after January 1, 2022
- Most group health care plans and issuers of a group or individual health insurance must disclose pricing information through machine-readable files made available on the plan's or issuer's website. The files must be freely accessible (no requests users provide personal information or make an account)
- The files must include:
  - (1) rates for all covered items and services between the plan or issuer and in-network providers, and
  - (2) allowed amounts for, and billed charges from, make an account or provide personal information. out-of-network providers.
- CMS is empowered to enforce the Rule by requiring Remedial Actions and can issue fines of $100 per day for each violation and for each person affected by the violation

VAUGHT CASE – CRIMINALIZING MEDICAL ERRORS

RaDonda Vaught was a Nurse at Vanderbilt University Medical Center

- In 2017, she made a fatal medication error that resulted in the Death of one of her patients.
  - She was instructed to administer Versed (sedative) to a 75-year-old patient (Charlene Murphy), she instead administered Vecuronium (paralytic)
  - Vaught attempted to withdraw Versed from an automatic dispensing cabinet but was unsuccessful. **She used an override to access a larger selection of medications**
  - Patient was left braindead and died within a day.
- **Vaught's license was revoked in 2021 and she was fined $3,000**
- She was tried for gross neglect of an impaired adult, negligent homicide, and reckless homicide. Convicted on all counts except reckless homicide.
  - **Sentenced to 3 years probation, no jail time**

https://www.tennessean.com/story/news/health/2020/03/03/vanderbilt-nurse-radonda-vaught-arrested-reckless-homicide-vecuronium-error/4826562002/

VAUGHT CASE – CRIMINALIZING MEDICAL ERRORS

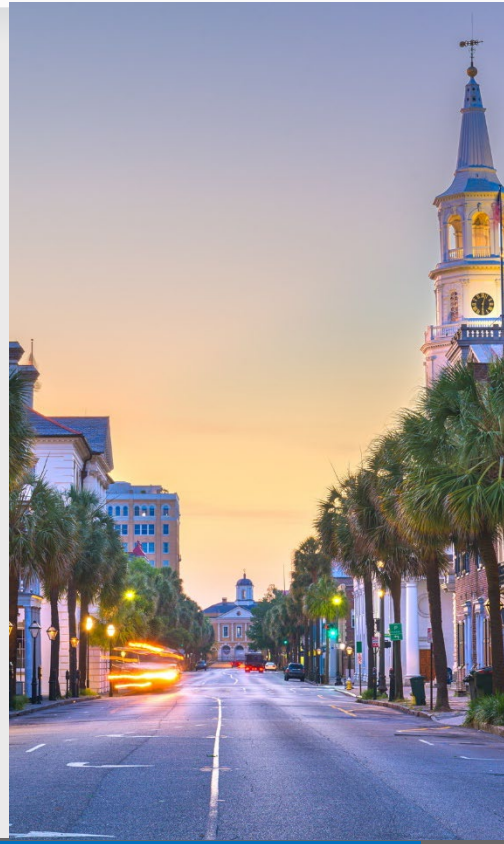
Hospital creates environment promoting non-compliance

- Vanderbilt failed to report the error to state or federal regulators and instead reported to the county medical examiner that the patient died of natural causes
  - The Hospital negotiated a settlement with the patient's family for an undisclosed amount
- Vanderbilt also allegedly instructed nurses to use their override systems every time they retrieved a medication
- Although Vanderbilt's training protocols and actions in the wake of Murphy's death have been criticized, the Hospital was not prosecuted.
- **There has been a great deal of discussion about potential follow on effects of criminalizing medical mistakes- worry about a chilling effect that will discourage honest reporting of mistakes or even discouraging individuals from entering the medical field in fear of liability**

ABORTION: THE WAKE OF DOBBS

South Carolina Law and Practical Tips for Hospitals

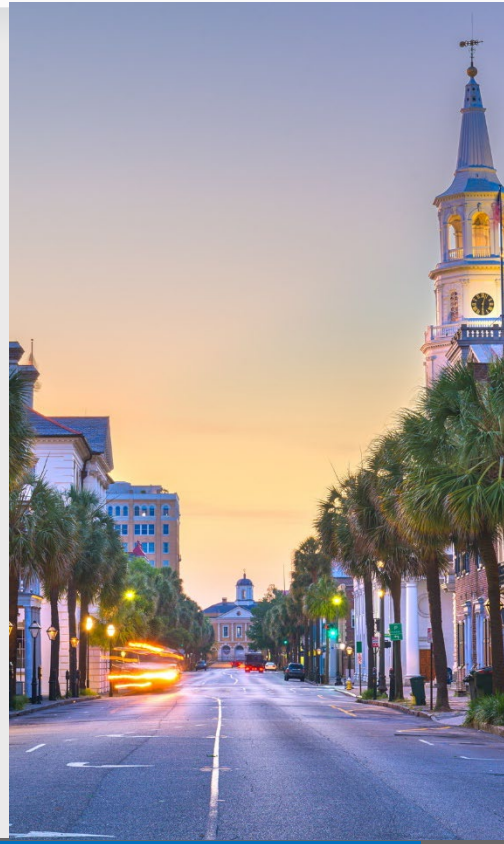
- June 24, 2022 the United States Supreme Court issues *Dobbs v. Jackson Women's Health Organization*
  - Overturns *Roe v. Wade*: The Constitution does not confer a right to abortion; the authority to regulate abortion is now an issue of State Law
- *South Carolina Heartbeat Protection From Abortion Act (signed February 18, 2021)* – became law after Dobbs on June 27, 2022



ABORTION: THE WAKE OF DOBBS

South Carolina Fetal Heartbeat Law – when Abortions are allowed

- If a fetal heartbeat is not detected
- Post-fertilization age of the fetus is fewer than 20 weeks AND the pregnancy is the result of rape or incest
  - The physician must report the rape or incest to the Sheriff and Act requires related specific medical record documentation
- Physician believes by reasonable medical judgment, the abortion is designed or intended to prevent the death of the pregnant woman or to prevent the serious risk of a substantial and irreversible impairment of a major bodily function of the pregnant woman
  - The Act requires related specific medical record documentation
- There exists a fetal anomaly (as specifically defined by statute)



ABORTION: THE WAKE OF DOBBS

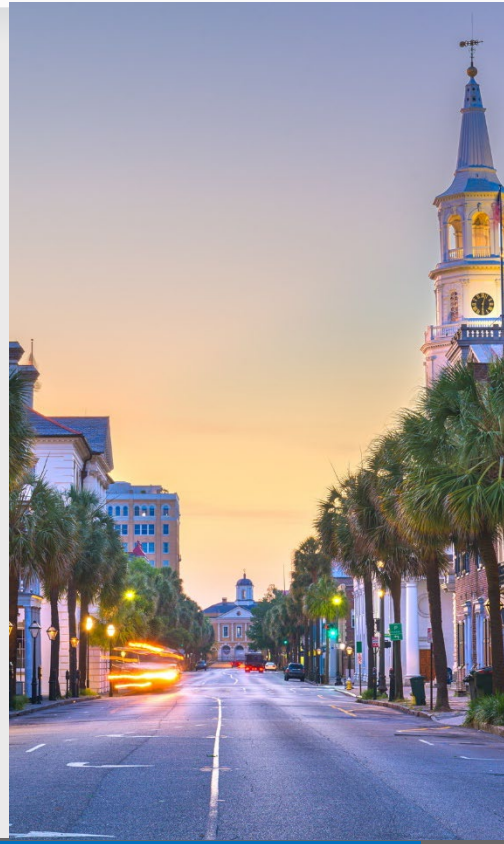
CMS Reminds Hospitals of EMTALA Obligations on July 11, 2022

- The **EMTALA statute** requires that all patients receive an appropriate medical screening examination, stabilizing treatment, and transfer, if necessary, irrespective of any state laws or mandates that apply to specific procedures. It is critical that providers know that a physician or other qualified medical personnel's professional and legal duty to provide stabilizing medical treatment to a patient who presents to the emergency department and is found to have an emergency medical condition preempts any directly conflicting state law or mandate that might otherwise prohibit such treatment.

- CMS also specifically reminded hospitals and providers that "the determination of an emergency medical condition is the responsibility of the examining physician or other qualified medical personnel." HHS Secretary Letter to Health Care Providers About Emergency Medical Care

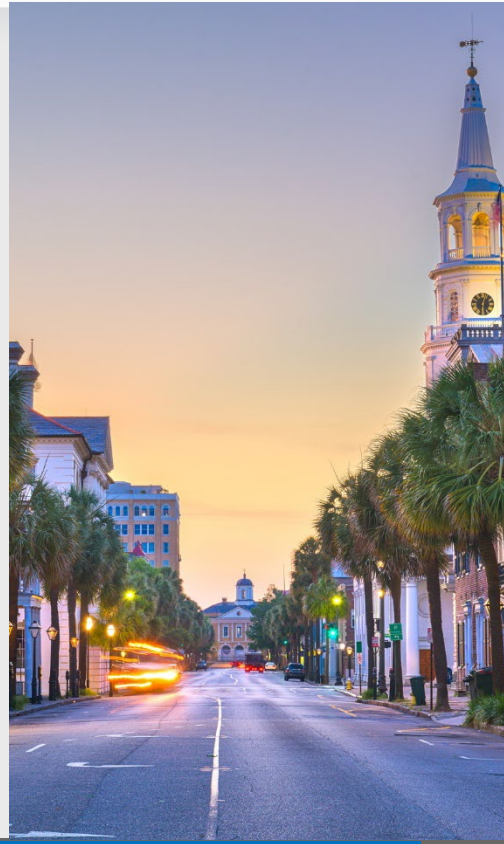
  - **Concern:** The current view is that exactly what constitutes a "life-threatening condition" under the various state laws or an "emergency medical condition" under EMTALA is unclear and complex

  - **SCMA and SCHA submit request to SC Board of Medical Examiners on July 19, 2022** for publication of some of the most common maternal medical conditions and/or circumstances that, if clearly documented in a patient's medical record, using reasonable medical judgment may warrant consideration of an abortion to preserve the life of the mother or to prevent the serious risk of a substantial and irreversible impairment of a major bodily function of the pregnant woman



ABORTION: THE WAKE OF DOBBS

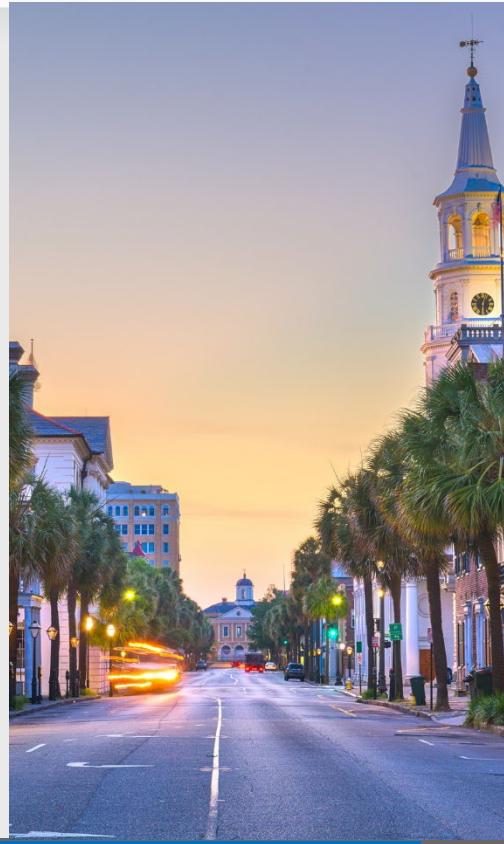
- **Compliance Actions for Hospitals and Providers to Consider**
  - **Hospitals**
    - Review Hospital EMTALA Policies, Procedures, and Processes
    - Hold Training for Emergency Room, OB-GYN, and Other Impacted Staff and Departments
    - Consider an Audit of Hospital EMTALA Compliance in All ERs
    - **Consider developing forms for providers to use to comply with Fetal Heartbeat Act's documentation requirements**
  - **Providers**
    - Pay attention to what is best for the patient
    - Clearly documenting the medical record will help provide clarity and defenses when either EMTALA or state law is enforced
    - **Know the documentation required by current SC law**



ABORTION: PRIVACY AND HIPAA MEDICAL RECORDS

Complying with HIPAA Privacy Rule Related to Disclosures of Information Related to Reproductive Health

- Office of Civil Rights Issues Guidance June 29, 2022 https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/phi-reproductive-health/index.html
- Reminded providers that covered entities (including hospitals) can only use or disclose Protected Health Information (PHI) if expressly permitted or required by law
- Law Enforcement: HIPAA permits but **does not require** disclosure of PHI for law enforcement purposes "pursuant to process and as otherwise required by law", under certain conditions
  - For example, a covered entity **may respond** to a law enforcement request made pursuant to a court order or court-ordered warrant, or a subpoena or summons
  - HIPAA **does not permit** a disclosure to law enforcement where a hospital or workforce member chooses to report an individual's abortion or other reproductive health care
  - OCR also takes the position that it is inconsistent with professional standards of ethical conduct to make a disclosure of PHI to law enforcement or others regarding an individual's interest, intent, or prior experience with reproductive health care (e.g. disclose an individual is seeking an abortion in another State).



WORKPLACE SAFETY IN THE HOSPITAL

Workplace violence in the healthcare field is up across the nation

- The American Hospital Association reports violence against hospital employees has markedly increased since the pandemic
  - "Recent studies indicate, for example, that 44% of nurses reported experiencing physical violence and 68% reported experiencing verbal abuse during the COVID-19 pandemic
  - Workplace violence has severe consequences for the entire health care system. Not only does violence cause physical and psychological injury for health care workers, workplace violence and intimidation make it more difficult for nurses, doctors and other clinical staff to provide quality patient care." https://www.aha.org/fact-sheets/2022-06-07-fact-sheet-workplace-violence-and-intimidation-and-need-federal-legislative
- **The AHA is advocating for passage of Violence for Healthcare Employees (SAVE) Act to provide protections for healthcare employees similar to airline workers**
- **Despite numerous efforts by the SCHA and other health care providers, South Carolina is unlikely to pass such protections, and is one of three states without special criminal penalties for violence towards healthcare workers**

WORKPLACE SAFETY IN THE HOSPITAL

Key to decreasing work place violence and protecting the workforce: Be intentional about developing positive relationship with local law enforcement

- Hire off-duty police officers as security officers
- Increase opportunities for local law enforcement to come on campus for security training
- Work on relationships with local solicitors to encourage them to prosecute acts of violence no matter how small

Additional Steps Hospitals can take to decrease incidences of workplace violence

- Scan for weapons at entrances to the facility
- Ensure the presence of sufficient security systems, including alarms, emergency response and available security personnel.
- Institute reporting policies and procedures
- Encourage employees to press charges against persons who assault healthcare workers, and support staff members who do

HHS RENEWS PUBLIC HEALTH EMERGENCY

- The Department of Health and Human Services renewed the state of Public Health Emergency under the Public Health Service Act on July 15th, 2022 (Now set to expire on Oct. 13, 2022)
- **HHS has repeatedly pledged to provide the public with 60 days notice before termination of the PHE – Most believe PHE will extend to end of 2022**
- August 14 was 60 days before Oct. 13
- Providers must be prepared from follow-on effects resulting from the winding down of the PHE, which will likely include:
  - Sharp decrease in number of individuals eligible for Medicaid
  - Rescission of certain telehealth waivers (though many have been extended by Congress for 151 days following lifting of the PHE)
  - FEMA public assistance has not shut down, but the agency has instituted a year end deadline to request pandemic respond funds incurred through July 1, 2022

https://www.jdsupra.com/legalnews/public-health-emergency-declaration-4220720/?origin=CEG&utm_source=CEG&utm_medium=email&utm_campaign=CustomEmailDigest&utm_term=jds-article&utm_content=article-link

BIDEN ADMINISTRATION ACO REACH MODEL

In Feb. 2022, CMS announced a redesigned Accountable Care Organization model known as REACH which will run from 2023-2026

- **This model is part of a larger effort by the administration to drive all Medicare and Medicaid beneficiaries into Accountable Care Relationships by 2030**
- Provider reimbursement is based more on patient outcomes and cost efficiency rather than volume of services provided
- Through newly offered benefits and reduced burdens, REACH also seeks to expand ACO membership and presence in underserved communities.
- **Notable requirements:**
  - Participating ACOs must develop a plan describing how they will meet the needs of people with Medicare in underserved communities
  - Each REACH ACO must have both a Medicare beneficiary and consumer advocate serving on its governing body with voting rights (may no longer be the same person)
- **Notable changes:**
  - Caps the risk score growth of each individual model participant at +/- 3 % over a two year period
  - Locks in the average risk score across the entire model

https://www.cms.gov/newsroom/press-releases/cms-redesigns-accountable-care-organization-model-provide-better-care-people-traditional-medicare

TELEHEALTH AND SUBSTANCE ABUSE DISORDER SERVICES

In June, the White House's Office of National Drug Control Policy released a report acknowledging telehealth services promoted access to care, decreased costs, and helped reduce the spread of disease

- **Individuals living with Substance Abuse Disorders were left particularly vulnerable by the onset of the pandemic**
  - Many individuals with SUD were suddenly unable to access services critical to their treatment and recovery
    - Emergency rooms, often a common first step used by patients seeking help with SUD, became less accessible
  - Health care providers and treatment centers that generally require continuity of care were "abruptly reduced or shut down" due to the pandemic and the need to physically distance
  - Similarly, group therapy became less available

- **In addition to the benefits of telehealth, the Report recognized practical barriers to access and related regulatory barrier. The Report recommended stakeholders should:**
  - Support mutual recognition and reciprocity of State practice Licenses
  - Consider making the PHE telehealth regulatory changes and waivers that loosened requirements permanent, including use of non-public-facing applications (FaceTime, Zoom, etc.)
  - Consider increasing funding for Mobile App and Assistive Telehealth Services

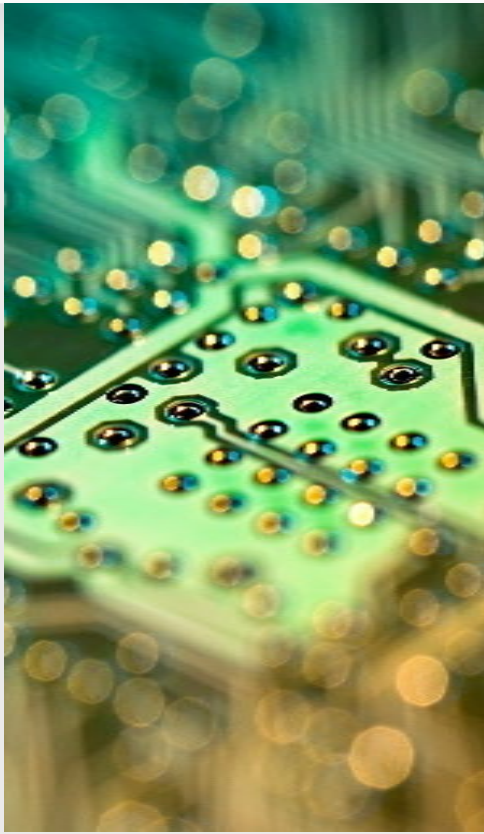
https://www.whitehouse.gov/ondcp/briefing-room/2022/06/22/ondcp-announces-report-on-improving-telehealth-services-for-substance-use-disorder/

HHS HIPAA GUIDANCE ON AUDIO-ONLY TELEHEALTH SERVICES

In June, HHS's Office of Civil Rights released guidance on the applicability of HIPAA to audio-only telehealth

- **At the beginning of the PHE, the OCR issued a notice stating it would not impose penalties for non-compliance with HIPAA for providers offering telehealth services in good faith during the PHE (the HIPAA waiver)**
  - This allowed providers to make use of applications like Apple Facetime, Zoom, and Skype for Telehealth visits
  - But in many cases, patients are unable or unwilling to use video for telehealth sessions
- **Consequently, the guidance sought to explain how providers can comply with HIPAA while providing "audio-only" telehealth. The Guidelines include:**
  - Covered entities must apply reasonable safeguards to ensure private information is not disclosed (Private setting when possible, low volume and no speakerphone when it is not practicable)
  - Providers must verify the identity of the patient, even without video
  - The Security Rule does not apply to audio-only telehealth provided using a standard telephone line but does apply to those provided over electronic communication technologies that transmit electronic PHI such as mobile technologies, internet, cellular, and Wi-Fi
    - A BAA is not required if the telecommunications provider is a mere conduit for the information transmitted but is required if the telecoms provider creates, receives, or maintains the PHI on behalf of a covered entity

https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-audio-telehealth/index.html#footnote1_yhflzt8



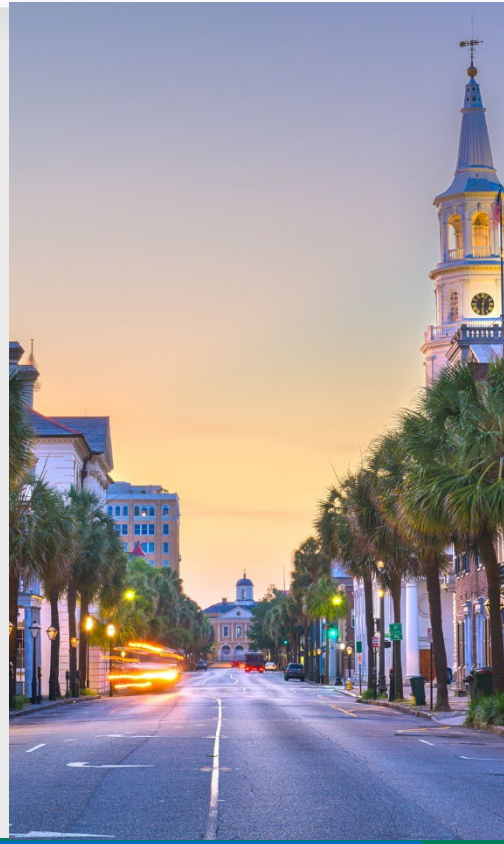
AHA URGES CONGRESS TO EXPAND ACCESS TO MENTAL HEALTH TELEHEALTH

In a letter to the Senate Finance Committee, the AHA encouraged Congress to take actions that would increase access to mental health related Telehealth

- The letter expressed support for allowing Medicare patients to receive audio-only telehealth and telehealth *without a prior in-person visit*
- AHA also noted it supported expansions of the types of providers allowed to deliver and bill for telehealth services
- Finally, the AHA urged Congress to make telehealth flexibility brought on by the pandemic permanent

- Shortly thereafter, the House passed the "Advancing Telehealth Beyond COVID-19 Act, which would extend waivers allowing Medicare reimbursement of telehealth into Dec. 2024
  - The AHA has expressed support for this legislation
  - The bill will likely be considered by the Senate when it returns from its August recess

https://www.aha.org/lettercomment/2022-07-20-letter-senate-finance-committee-discussion-draft-addressing-mental-health



OIG ISSUES TELEFRAUD ALERT

On July 20, 2022, HHS-OIG issued a special fraud alert warning practitioners to "exercise caution when entering into arrangements with purported telemedicine companies"

- The alert does not label all telehealth services as suspect and notes that in most cases "telehealth expansion is viewed positively" and has offered increased access to services and enabled better care
- However, certain telehealth companies are taking advantage of increased use and acceptance of telehealth services to engage in fraud schemes
- The OIG has recently conducted dozens of investigations into fraud in this space including schemes to pay kickbacks to physicians and other practitioners for orders or prescriptions for medically unnecessary DME, genetic testing, wound care items, and prescriptions
  - Payments are sometimes described as payment for reviewing, auditing, consulting, or assessment of medical charts
  - Providers who work with telehealth companies should review their invoices and activities for any potentially suspicious practices

https://oig.hhs.gov/documents/root/1045/sfa-telefraud.pdf

TELEFRAUD: CAUSES FOR CONCERN

The OIG Fraud Alert listed the following as suspect characteristics of arrangements between providers and telehealth companies

- The purported patients were identified or recruited by the Telemedicine Company through internet, television, or social media advertising for free or low out-of-pocket cost items or services
- The Practitioner does not have sufficient contact with or information from the purported patient to meaningfully assess the medical necessity of the items or services ordered or prescribed
- The Telemedicine Company compensates the Practitioner based on the volume of items or services ordered or prescribed
- The Telemedicine Company only furnishes items and services to Federal health care program beneficiaries
- The Telemedicine Company only furnishes one product or a single class of products (e.g., durable medical equipment, genetic testing, diabetic supplies, or various prescription creams), potentially restricting a Practitioner's treating options to a predetermined course of treatment

DOJ TELEFRAUD 2022 ENFORCEMENT

Nationwide Breadth of Schemes is Enormous

- **July 20, 2022** DOJ announced criminal charges against **36 defendants in 13 federal districts** for more than **$1.2 billion** in alleged fraudulent telemedicine, cardiovascular and cancer genetic testing, and durable medical equipment (DME) schemes
- The nationwide coordinated law enforcement action includes **criminal charges** against a telemedicine company executive, owners and executives of clinical laboratories, durable medical equipment companies, marketing organizations, and medical professionals
- The department seized over **$8 million** in cash, luxury vehicles, and other fraud proceeds.
- CMS and the Center for Program Integrity (CPI) announced today it took **administrative actions against 52 providers** involved in similar schemes
- https://www.justice.gov/opa/pr/national-health-care-fraud-enforcement-action-results-charges-involving-over-14-billion

SUPREME COURT CASE: RUAN V. UNITED STATES

2022 Supreme Court Case related to prescribing controlled substances

- Consolidated Case involving Doctors with pain management clinics across the Country - two physicians licensed to prescribe controlled substances - Each was tried for prescribing in an unauthorized manner
- A federal regulation authorizes registered doctors to dispense controlled substances but only if the prescription is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR §1306.04(a)
- At issue in physicians trials was the mens rea required to convict under §841 for distributing controlled substances not "as authorized"
- **Once a defendant meets the burden of producing evidence that his or her conduct was "authorized," the Government must prove the defendant knowingly or intentionally acted in an unauthorized manner**
  - **"Prohibited conduct (issuing invalid prescriptions) is "often difficult to distinguish" from acceptable conduct (issuing valid prescriptions)"**
  - **Requires finding that physician "subjectively believed" they were wrongly dispensing to be convicted**
  - **Standard is intended to help reduce risk of over-deterrence**

COVID-19 TASK FORCE CRACKDOWN ON PANDEMIC-RELATED FRAUD

In 2021, Attorney General Merrick Garland announced the creation of a COVID-19 Task Force targeting COVID-19 related fraud

- As of March 2022, 30 agencies has investigated COVID-19 fraud. Same month, DOJ appoints Director for COVID-19 Fraud Enforcement to lead criminal and civil enforcement efforts
- Since the start of the pandemic, the DOJ has seized over **$1.2 billion in relief funds** criminals attempted to steal, and charged over 1,000 defendants with crimes in federal districts across the country

Example prosecutions:

- Inflating payroll to receive larger loans or purchasing shell companies to apply for loans for nonexistent operations
- An individual in Texas applied for 15 PPP loans using 11 companies and uses $17 million in loans to buy homes and jewelry
- $580 million in recoveries stemming from fraudulent loan applications

- **President Biden has also signed two Bipartisan bills that extend the statute of limitations applicable to PPP or COVID-19 Economic Injury Disaster Loan Fraud to 10 years**

https://www.j

COVID-19 TASK FORCE CRACKDOWN ON PANDEMIC-RELATED FRAUD

Penalties for COVID-19 related fraud can be steep

- A South Florida lab owner was recently sentenced to nearly 7 years in prison for his role in a kickback scheme that took advantage of relaxed telehealth restrictions that allow Medicare recipients to receive care from home.
- The owner and his co-conspirators used telehealth providers to authorize thousands of medically unnecessary cancer and cardiovascular genetic testing orders.

- It is important to remain vigilant and ensure employees are complying with federal directives related to COVID-19 relief
- The Enforcement climate is ratcheting up– COVID-19 fraud will be in the DOJ crosshairs for years to come
- Telehealth appears to be an area that deserves particular scrutiny to ensure compliance with federal requirements.

CMS RELEASES MATERNITY CARE ACTION PLAN

CMS released its "Maternity Care Action Plan" on July 26, 2022

- CMS is identifying opportunities to enhance maternity care delivered to federal health plan enrollees
  - Focus is on improvements in access to and quality of care during pregnancy, childbirth, and the postpartum period
  - The effort is a central component to advancing health equity – people of color are up to five times more likely to die from pregnancy-related complications
  - The initiative will include technical assistance for states to extend postpartum coverage, policies to support a diverse provider workforce, and other equity-focused initiatives

https://www.cms.gov/files/document/cms-maternity-care-action-plan.pdf

CMS RELEASES MATERNITY CARE ACTION PLAN

CMS has identified key gaps in maternity care related to CMS programs

- **Guaranteed access to Medicaid for a year after pregnancy.** Per the American Rescue Plan Act of 2021, states (including SC) can provide continuous Medicaid and CHIP coverage for a full year after pregnancy , up from 60 days prior to the ARP
- **Protecting Patients' Access to Emergency Care.** Following the Dobbs Decision overturning Roe v. Wade, CMS issued clarifying guidance EMTALA
- **Ensuring access to the full range of contraception.** CMS is working to ensure that everyone has access to the contraceptive coverage. HHS and the Departments of Labor and Treasury, sent a letter to group health plans and health insurance issuers, reminding them of their obligations under the Affordable Care Act to provide coverage for the full range of contraceptives at no cost
- **Reducing gaps in coverage during and after pregnancy.** CMS will identify ways that policy, technology, and operations can work better together to help people understand their coverage options if they lose eligibility for Medicaid coverage
- **"Connecting Kids to Coverage" 2022 funding opportunity includes pregnant individuals as a target population.** CMS awarded $49 million to fund organizations that can connect more eligible children, parents, and pregnant individuals to health care coverage through Medicaid and CHIP
- **Protect patients from surprise medical bills.** The No Surprises Act protects most people with health coverage from a surprise medical bill when they receive emergency care, care from out-of-network providers at in-network facilities, or air ambulance services

https://www.cms.gov/files/document/cms-maternity-care-action-plan.pdf

CMS RELEASES MATERNITY CARE ACTION PLAN

- **CMS is also proposing to create a "Birthing Friendly" hospital designation.** The purpose is to create a consumer-friendly display indicating hospital commitment to improving maternal health outcomes through participation in maternity care quality activities. The designation would be displayed on a CMS website
- **CMS is collecting comments on maternity care quality improvement policies that may become new conditions of participation for hospitals**
- **Encouraging evidence-based hospital quality improvement.** In December 2021, CMS released information to the state entities responsible for overseeing hospital quality, encouraging them to consider the use of evidence-based patient safety interventions to ensure that facilities are prepared for medical, including obstetric, emergencies
- **Intensive care for people with chronic health conditions.** CMS is working to expand access to chronic disease management to help people improve their health, including before, during, and after pregnancy
- **Community-based pregnancy and childbirth care.** State Medicaid programs can cover community-based maternity services, such as those furnished by doulas and community health workers. In addition, Medicaid requires states to cover services provided through freestanding birth centers and those provided by midwives within the scope of their state licensure.

DOJ FCA COOPERATION POLICY STATEMENT

In 2019, the DOJ issued policy guidance stating it would provide credit in False Claim Act settlements to corporations for "disclosure, cooperation and remediation"

- Cooperation credit will take the form of a reduction in the damages multiplier and civil penalties.
- However, the maximum credit a defendant may earn may not exceed an amount that would result in the government receiving less than full compensation for the losses caused by the defendant's misconduct (including the government's damages, lost interest, costs of investigation, and relator share)
- An entity or individual that seeks to earn maximum credit generally should undertake a timely self-disclosure
  - The Self-Disclosure should include identifying all individuals substantially involved in or responsible for the misconduct, provide full cooperation with the government's investigation, and take remedial steps designed to prevent and detect similar wrongdoing in the future

https://www.justice.gov/jm/jm-4-4000-commercial-litigation#4-4.112

DOJ FCA COOPERATION POLICY STATEMENT

- The DOJ recognizes other avenues to obtain cooperation credit, such as meaningfully assisting the government's investigation by disclosing additional relevant documents or information, or otherwise proactively aiding the government in understanding the context or significance of the documents or information produced
- Cooperation does not include disclosure of information required by law, or responding to a subpoena, investigative demand, or other compulsory process for information
- Credit will not be given if the entity or individual conceals involvement in the misconduct by senior management or the Board, or the entity or individuals demonstrates a lack of good faith
  - Entities and individuals are entitled to assert their legal rights and, unless required by law, do not have to cooperate with a government investigation. Entities and individuals remain free to reject these options and forgo any potential credit consistent with the law.
  - Eligibility for credit for voluntary disclosure or other forms of cooperation is not predicated on waiver of the attorney-client privilege or work product protection

https://www.justice.gov/jm/jm-4-4000-commercial-litigation#4-4.112

RECENT FCA RECOVERY PER FY (HEALTHCARE INDUSTRY)

- The government recovered over $5 billion dollars in civil-fraud related actions in the health care industry in 2021
- $1.6 billion related to qui tam related recoveries. Bulk of recoveries instead related to settlements with pharmaceutical manufacturers related to the opioid crisis

https://www.natlawreview.com/article/false-claims-act-and-health-care-2021-recoveries-and-2022-outlook

WEIRTON MEDICAL CENTER FCA STARK SETTLEMENT

Weirton Medical Center is a hospital in Weirton, WV

- Agreed to pay the Government $1.5 Million to resolve claims it violated the FCA, specifically, the Stark Law
- Allegedly perpetrated a scheme resulting in "payment of compensation to referring physicians that exceeded fair market value or took into account the volume or value of the physician's referrals to the hospital."

- Notably, this case began when WMC voluntarily disclosed the prospect that it had committed Stark Law violations to the USAO for the Northern District of WV
  - WMC had a third party investigate and reported findings to the USAO that included potential violations
  - WMC did not admit any liability in the settlement agreement but this case seems to be related to another Stark / FCA settlement dealing with a different hospital but same management company
  - The extent is hard to determine, but WMC's self-reporting and cooperation likely prevented harsher penalties.
- DOJ credit for cooperation in FCA cases will likely vary on a case-by-case basis.

https://www.justice.gov/opa/pr/west-virginia-hospital-pay-15-million-settle-allegations-concerning-impermissible-financial

MEDICARE ADVANTAGE FRAUD: MSC ADVANTAGE

MSC Advantage, a Medicare Advantage plan operating out of Puerto Rico, settled allegations that it violated the federal Anti-Kickback statute and FCA on July 1, 2022 ($4.2 million)

- MSC Advantage allegedly distributed over 1,700 gift cards (typically worth $25) to administrative assistants of healthcare providers in an effort to incentivize them to refer, recommend, or arrange for the enrollment of new Medicare Beneficiaries in MCS Medicare Advantage plans.
  - The administrative staffers recommended nearly 1,650 beneficiaries into MSC Advantage plans
  - The DOJ press release stated that the settlement amount "took into consideration the company's voluntary termination of the gift card program in December 2020, disclosure of relevant facts concerning the program, and the implementation of controls and revisions to its internal policies to promote and help ensure future compliance."

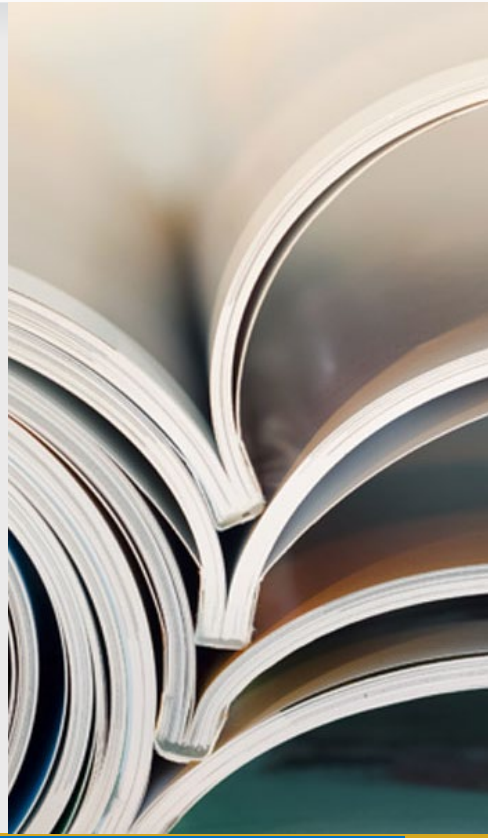
https://www.justice.gov/usao-pr/pr/mcs-advantage-agrees-pay-42-million-dollars-resolve-allegations-it-violated-false-claims

PROVIDENCE HEALTH (WASHINGTON) FCA SETTLEMENT

In April 2022, Providence Health and Services Washington of Walla Walla, Washington agreed to pay $22,690,458 to settle claims that it fraudulently billed Medicare, Medicaid, and other federal health care programs for medically unnecessary neurosurgery procedures

- Largest ever health care fraud settlement in ED of Washington
  - Allegations centered on two Neurosurgeons, one of whom was one of the most productive Neurosurgeon's in the entire Providence Health system.
  - The neurosurgeons were compensated according to a complex formula that incentivized them to perform complex surgeries as frequently as possible.
  - Despite employee complaints the surgeons were "over operating" and endangering patients, Providence allowed the surgeons to resign while on leave and did not report them to regulators.
  - Part of the settlement also required Providence to enter into a Corporate integrity agreement and conduct annual reviews of their compliance

https://www.justice.gov/usao-edwa/pr/providence-health-services-agrees-pay-227-million-resolve-liability-medically

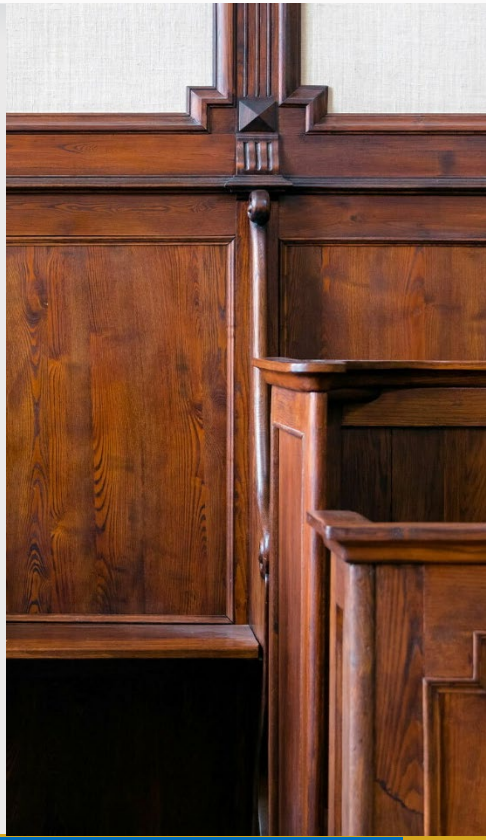


FLORIDA BAYCARE FCA SETTLEMENT: NON-BONAFIDE DONATIONS

BayCare Health System agreed to pay the $20 million to resolve claims that it violated the FCA by making donations to improperly fund the state's share of Medicaid payments to BayCare

- Under federal law, Florida's share of Medicaid payments must consist of **state or local government funds**, and not "non-bona fide donations" from private health care providers, such as hospitals
- The United States alleged that between October 2013 and September 2015, **BayCare made improper, non-bona fide cash donations to the Juvenile Welfare Board of Pinellas County (JWB)**, knowing that JWB would and then did transfer a portion of the cash donations to the State of Florida's Agency
- **The funds transferred by JWB to the state were "matched" by the federal government before being returned to the BayCare hospitals as Medicaid payments**
- This was a qui tam action– the relator received $5 million

https://www.justice.gov/opa/pr/florida-s-baycare-health-system-and-hospital-affiliates-agree-pay-20-million-settle-false



CATHOLIC MEDICAL CENTER FCA SETTLEMENT

In Feb. 2022, Catholic Medical Center of New Hampshire agreed to a $3.8 Million settlement with the government to resolve claims it violated the FCA by providing free call coverage services to a cardiologist to induce patient referrals (in violation of the Anti-kickback statute)

- CMC allegedly paid its cardiologists to cover (at no charge) for another local cardiologist's patients while she was on vacation or otherwise unavailable
- In exchange, the cardiologist allegedly referred millions of dollars in medical procedures and services to CMC over the course of a decade
- CMC submitted claims for these services to Medicare, Medicaid, and other federal health care programs—and the US therefore alleged these claims were the result of unlawful kickbacks

https://www.justice.gov/usao-nh/pr/catholic-medical-center-agrees-pay-38-million-resolve-kickback-related-false-claims-act#:~:text=Farley%20announced%20today%20that%20Catholic,of%20the%20Anti%2DKickback%20Statute.

CARE PLUS MANAGEMENT FCA SETTLEMENT

Case from Northern District of Georgia - Paul Weir and John R. Morgan, M.D. jointly created Care Plus Management and owned/operated 18 anesthesia entities

- The company and individuals agreed to pay $7.2 million to settle allegations that they agreed to kickback arrangements with referring physicians
- From 2012-2016 Care Plus purportedly induced physician owners of outpatient surgery centers to award their anesthesia centers with exclusive contracts by offering them partial ownership in the anesthesia entities.
- Under this system, Physician owners received compensation in the form of a portion of the revenue from the anesthesia services. Care Plus also allegedly subsidized the cost of drugs, supplies, and equipment in the physician's outpatient surgical centers.
- Qui tam action brought by former COO of Care Plus

https://www.justice.gov/usao-ndga/pr/paul-d-weir-john-r-morgan-md-care-plus-management-llc-and-anesthesia-entities-pay-72

HOME HEALTH COMPANY FCA SETTLEMENT

Signature HomeNow settled allegations that it improperly billed Medicare for home health services provided to Florida beneficiaries for $2.1 million in 2022

- Between 2013-2017, Signature HomeNow allegedly submitted false or fraudulent claims seeking payment from Medicare for beneficiaries who either:
  - Were not homebound
  - Did not require certain skilled care
  - Did not have a valid or appropriate plan of care in place
  - Did not have appropriate face-to-face encounters needed to be certified to receive home health services
- Complaint arose from a tip to the OIG complaint hotline and a qui tam action

https://www.justice.gov/usao-sdfl/pr/home-health-company-operating-florida-pays-21-million-resolve-false-claims-allegations#:~:text=Miami%2C%20Florida%20%E2%80%93%20SHC%20Home%20Health,to%20beneficiaries%20living%20in%20Florida.

MOLINA HEALTHCARE FCA SETTLEMENT: UNLICENSED & UNSUPERVISED STAFF

Molina Healthcare along with a former subsidiary named Pathways paid $4.625 million to resolve allegations that it violated the FCA by submitting reimbursement claims while violating several regulations related to licensure and supervision of its staff

- Molina is a managed care health services company
  - It provides health care plans to various state and federal health care programs including MassHealth, the joint federal and state Medicaid program.
  - From 2015-2018, it operated Pathways—a group of mental health centers
  - The Government alleged that Molina and Pathways illegally submitted reimbursement claims to MassHealth by:
    - Failing to properly license and supervise mental health center staff, including social workers and psychological associates
    - Failing to provide and timely document the provision of adequate clinical supervision to clinicians requiring supervision

https://www.justice.gov/usao-ma/pr/molina-healthcare-agrees-pay-over-45-million-resolve-allegations-false-claims-act#:~:text=Molina%20Healthcare%20Agrees%20to%20Pay,Department%20of%20Justice

CARDINAL HEALTH: DISCOUNTED DRUGS IN EXCHANGE FOR BUSINESS

- Cardinal Health, an Ohio-based pharmaceutical distributor, recently paid $13.125 million to resolve claims that it violated the FCA and AKS by paying "upfront discounts" to its physician practice customers

  - When physicians would purchase medications, Cardinal would apply discounts to the sales that were untethered from the size of the transaction or offer the customers rebates they customer had not earned.
  - HHS-OIG only permits these discounts to be legally offered in conjunction with large transactions and in specified circumstances.
  - Had Cardinal limited the discounts to transactions of the appropriate size, it likely would have been able to generate additional business without violating the FCA or AKS

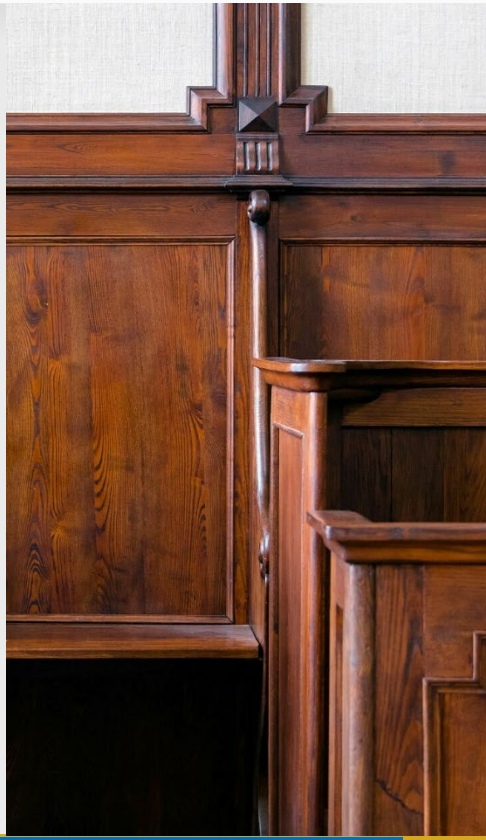
https://www.justice.gov/usao-ma/pr/cardinal-health-agrees-pay-more-13-million-resolve-allegations-it-paid-kickbacks#:~:text=BOSTON%20%E2%80%93%20Ohio%2Dbased%20pharmaceutical%20distributor,of%20the%20Anti%2DKickback%20Statute

HOSPITAL AKS CASE: CRIMINAL CHARGES

California residents Liana Karapeytan and Akop Atoyan each plead guilty to one count of conspiracy to commit healthcare fraud and one count of conspiracy to pay and receive kickbacks last year

- Through their enterprises (ANG Healthcare, Inc., Excel Home Healthcare, Inc., and Excel Hospice, Inc.) they sought Medicare reimbursement for least $2 million worth services that they provided to beneficiaries who were referred to the entities in exchange for a kickback
- Karapeytan and Atoyan's businesses submitted over 8,000 Medicare claims and received a total of $31 million--- possible the fraud was well in excess of $2 million
  - Karapeytan was sentenced to 18 months in prison
  - Atoyan has not been sentenced but faces up to 15 years in jail
  - He also must pay over $2.5 million in restitution as a condition of his guilty plea

https://www.justice.gov/usao-edca/pr/sacramento-area-home-health-care-and-hospice-agencies-owner-sentenced-18-months-prison



UNC HOSPITAL: FEDERAL FUNDING IN "IMMEDIATE JEOPARDY"

In July 2022, CMS placed UNC's hospital in Chapel Hill's Medicare and Medicaid funding in "immediate jeopardy"

- An immediate jeopardy designation represents the most serious noncompliance citation, representing "a situation in which entity noncompliance has placed the health and safety of recipients in its care at risk for serious injury, serious harm, serious impairment or death," according to CMS. The citations and result in "the most serious sanctions" for hospitals and other surveyed facilities
- **Hospital inspectors cited UNC for four violation related to "infection control, quality assessment, hospital governance, and patient rights"**
  - **UNC told the press the issues related to a patient suicide after discharge** (the patient took his own life an hour after he was discharged from the ER over the objection of his family), physical spacing of patients and visitors in the emergency department's waiting room, and failure to document vendors' COVID-19 vaccination status.
  - According to UNC, a correction plan was submitted before July 5th and was deemed acceptable.
  - UNC also stated that a follow-up inspection will be conducted in the coming weeks to ensure UNC is complying with its plan.
- Notably, CMS expected UNC to submit a remedial plan within approximately two weeks, that could place particular strain on a provider in a similar situation that lacks UNC's resources

Full Report: https://www.newsobserver.com/news/local/article263912586.html

DOJ CYBERFRAUD INITIATIVE

In October 2021, the DOJ announced a new Civil-Cyber Fraud Initiative

- The initiative is designed to combine the department's expertise in civil fraud enforcement, government procurement and cybersecurity to combat new and emerging cyber threats to the security of sensitive information and critical systems
- **The Civil Cyber-Fraud Initiative will utilize the False Claims Act to pursue cybersecurity related fraud** and is aimed at "hold[ing] accountable entities or individuals that put U.S. information or systems at risk by knowingly providing deficient cybersecurity products or services, knowingly misrepresenting their cybersecurity practices or protocols, or knowingly violating obligations to monitor and report cybersecurity incidents and breaches"
- **The DOJ negotiated the first settlement as part of this initiative in March 2022**
  - The settlement was with Comprehensive Health Services, LLC of Cape Canaveral, FL who provided medical services at Government facilities in Iraq and Afghanistan ($930,000)
  - **Comprehensive Health Services alleged falsely represented to the Government through its contracts that it was using a secure electronic medical records system to store sensitive patient records of Government officials – but actually failed to store the medical records in a secure system**
  - Comprehensive also allegedly used unapproved controlled substances at the facilities despite telling the Government it would only treat patients with FDA and EMA approved controlled substances.

https://www.justice.gov/opa/pr/medical-services-contractor-pays-930000-settle-false-claims-act-allegations-relating-medical

NEW STATE ISSUES ON THE HORIZON

- **The future of CON** will likely be decided during the 2023 Legislative Session. Will it be reformed or repealed?
- **Will DHEC be restructured and which agency will regulate hospitals or will it continue to be DHEC?** The 2023 Legislative Session will also decide this issue
- **The SC Legislature is considering even more stringent Abortion laws**
  - "South Carolina Human Life Protection Act" bill is pending in the house
  - No exceptions for rape or incest
  - Increases penalties and actions that may be maintained against practitioners who perform an abortion

NEW CMS ISSUES ON THE HORIZON

CMS issued its 2022 Strategic Framework in June - Six Key Trends:

1. MOVEMENT TO ACOs: The CMS Center for Medicare and Medicaid Innovation ("CMMI") plans to build a "health system that achieves equitable outcomes through high-quality, affordable, person centered care

- CMMI's goal is described as "launching models that increase the number of people with Medicare and Medicaid in accountable care relationships."
- In addition, CMMI aims to *increase the number of beneficiaries in ACOs, and plans to measure its progress by having* all Medicare fee-for-service beneficiaries and almost all Medicaid beneficiaries in an ACO by 2030

2. INCREASING USE OF PRE-AUTHORIZATION PROCESSES. The CMS Center for Program Integrity describes "enhancing program integrity oversight" as including "increasing the use of prior authorization

- CMS has four prior authorization initiatives currently in place: Certain Hospital Outpatient Department (OPD) Services, Repetitive, Scheduled Non-Emergent Ambulance Transport (RSNAT), Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items, and Review Choice Demonstration for Home Health Services
- CMS has not yet articulated how it will increase the use of prior authorization processes or for what services, but key concepts for providers will be how CMS can increase prior authorization while not adding to provider burden or blocking beneficiary access to services. Prior Authorization and Pre-Claim Review Initiatives | CMS

NEW CMS ISSUES ON THE HORIZON

CMS issued its 2022 Strategic Framework in June - Six Key Trends:

3. **NURSING HOME STAFFING WILL CONTINUE TO BE SCRUTINIZED**
   - CMS has added more staffing elements to the Care Compare website
   - CMS is proposing federal minimum staffing standards to be announced next year.

4. **EXPECT AVALANCHE OF NEW AND REVISED CMS REGULATIONS.** CMS' plans could be called the "great unwinding" of its waivers and flexibilities that were provided during the pandemic
   - In April, CMS announced it was phasing out certain waivers and flexibilities for nursing homes, inpatient hospices, intermediate care facilities for individuals with intellectual disabilities ("ICF/IIDs") and end-stage rental disease ("ESRD") facilities
   - The expiration of the Medicaid "continuous coverage requirement" will also expire at the end of the PHE and states will lose the increased funding they have been receiving. CMS began issuing guidance to States on reinstating eligibility requirements within 12 months after the PHE expires, but with states losing the additional federal funding, state Medicaid programs will quickly cut ineligible beneficiaries and millions could lose Medicaid coverage CMS Returning to Certain Pre-COVID-19 Policies in Long-term Care and Other Facilities | CMS

5. **CMS' EFFORTS TO ENSURE PRESCRIPTION DRUG ACCESSIBILITY WILL INCLUDE INCREASING USE OF GENERICS, BIOSIMILARS, AND INTERCHANGEABLE BIOLOGICS**

NEW CMS ISSUES ON THE HORIZON

CMS issued its 2022 Strategic Framework in June - Six Key Trends:

6. EXPECT CMS TO VASTLY IMPROVE ACCESS TO BEHAVIORAL HEALTH SERVICES

- In response to President Biden's strategy to address the national mental health crisis which includes a 2023 budget proposal that calls for mental health benefits to be covered at the same level as physical health care benefits by all health plans
- CMS plans for its Behavioral Health Strategy to cover multiple elements, "including access to prevention and treatment services for substance use disorders, mental health services, crisis intervention, and pain care."
- ***Related CMS Actions***: CMS' many plans in this area include:
  - Testing payment models that would integrate mental health and substance abuse treatment into primary care settings
  - Expanding access to mental health support in schools by increasing access to Medicaid reimbursement
  - Offering states the option to provide community-based mobile crisis intervention services
  - Providing for the continued payment of audio-only counseling and therapy services after the pandemic (where audio/video is not available).

CCI Fact Sheet Behavioral Health (cms.gov)

NEXT CHALLENGE. NEXT LEVEL.

NEXSEN | PRUET

Questions?


NEXT CHALLENGE. NEXT LEVEL.
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Thank you for your time. Enjoy the Rest of the Conference!