

Compliance Trends and Challenges for Substance Abuse and Behavioral Health

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HCCA Compliance Institute

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Agenda

- > Access to substance abuse and behavioral health services
- ➤ Legal and regulatory developments
- > Audit and enforcement trends
- Compliance challenges and best practices

Section One	Access to Services

Social and Behavioral Determinants of Health

- Providers are focused on (and structuring around) community health and integrated and wholistic care.
- Behavioral health services are essential health benefits (EHB) under the ACA
 - > All "non-grandfathered" individual and small group market health plans must offer mental health and substance abuse services.
- The healthcare industry and regulators aim to:
 - > Reduce the stigma of needing / receiving behavioral health care
 - > Increase access to behavioral health services for at-risk populations / groups
 - > Achieve earlier detection and intervention for patients in need of behavioral health services

Increased Coverage, Increased Risk

- There is significant current attention on the national "Opioid Crisis."
- There is increased legislative / regulatory and enforcement activity related to substance abuse and behavioral health services at both the federal and state levels.
- From the regulator perspective, when there are increased coverage / reimbursement / service options, "the criminals will find a way."

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Psychiatric Patient "Boarding"

- Many healthcare providers are facing challenges due to the significant volume of psychiatric patients presenting to Emergency Departments (EDs).
- Limited inpatient psychiatric unit availability and a shortage of alternative treatment options often results in extended ED stays for psychiatric patients.

"The phenomenon – often called 'psychiatric boarding' – has been reported by emergency department medical directors to occur at least weekly in 80% of hospitals and more frequently in 55% of facilities."*

- Washington State Supreme Court says "no more"*:
 - > Legal action brought on behalf of patients involuntarily held for days or even longer.
 - Washington and several other states allow 72-hour emergency holds (with appropriate authorization) while search for available psychiatric bed is performed.
 - > Court decided that "boarding" a violation of state law and potentially patients' constitutional rights.
 - State ordered to stop the practice of psychiatric boarding in 2014 and subsequently appropriated nearly \$70 million over the next several years to increase psychiatric bed capacity and access to other services.

"Source: Paul S. Appelbaum, M.D., "Boarding" Psychiatric Patients in Emergency Rooms: One Court Says "No More", Law & Psychiatry, Psychiatric Services 66:7, July 2015 (https://ps.psychiatryonline.org/doi/pdf/10.1176/appi.ps.660707)

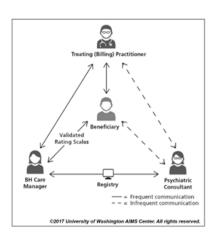
Psychiatric Patient "Boarding"

- California "Alameda Model"
 - > Alameda Health System, Oakland, CA (Scott Zeller, MD); Now more in CA
 - Regional Dedicated Psychiatric Emergency Departments (Psychiatric Emergency Services ("PES") units)
 - > Rather than holding psychiatric patients who require further evaluation in the medical ED, emergency physicians send them to a regional facility where specialized care can be provided.
 - > CA Medicaid program has "crisis stabilization" billing code for reimbursement of the regional emergency psychiatric facility.

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New Models, New Risks

- CMS "Behavioral Health Integration Services" / "Psychiatric Collaborative Care Services (CoCM)"*
 - "Integrating behavioral health care with primary care ("behavioral health integration" or "BHI") is now widely considered an effective strategy for improving outcomes for the millions of Americans with mental or behavioral health conditions."
 - "As of January 1, 2017, Medicare makes separate payments to physicians and non-physician practitioners for BHI services they furnish to beneficiaries over a calendar month service period."
 - What is CoCM? A model of behavioral health integration that enhances "usual" primary care by adding two key services: care management support for patients receiving behavioral health treatment; and regular psychiatric interspecialty consultation to the primary care team, particularly regarding patients whose conditions are not improving."



*Source: CMS MLN Fact Sheet, Behavioral Health Integration Services, January 2018 (https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/BehavioralHealthIntegration.pdf)

New Models, New Risks

- Gwinnett Medical Center (GA)
 - 5,000 square foot behavioral health unit adjacent to ED
- Parkland Center for Clinical Innovation (TX)
 - Community-based social services network for ED "frequent fliers"
- Cherokee Health Systems (TN)
 - FQHC with integrated primary care, behavioral health, and wellness programs
- N.C. Statewide Telepsychiatry Program (NC-STeP)
 - Connects 80+ sites across state to specialized psychiatry expertise
- · Advocate Health Care (IL)
 - Behavioral health hub-and-spoke system connected by telehealth technology
- · Intermountain Healthcare (UT)
 - Mental health integration clinics across system

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Section Two	Legal and Regulatory Developments

State Legislative / Regulatory Activity Involuntary Examination

Florida Mental Health Statute, § 394.463 (Involuntary examination)*

- Also referred to as "The Baker Act"
- Includes specific criteria for involuntary examination.
- > The involuntary examination period for an adult may be up to 72 hours.
- In 2017, the act was amended specify that the involuntary examination period for minors (17 or younger) must be initiated within 12 hours after the patient's arrival at the facility.

*Source: (http://www.leg.state.fl.us/Statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0300-0399/0394/Sections/0394.463.html)

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State Legislative / Regulatory Activity Involuntary Commitment

N.C. General Statutes Article 5 § 122C-201 et seq. (Involuntary commitment)

- > Establish criteria for determining when involuntary treatment is appropriate for individuals with severe mental illness who cannot seek care voluntarily
- Includes specific criteria for inpatient treatment if mentally ill, substance abuse, or dangerous to self or others
- > Also includes specific criteria for outpatient treatment:
 - > capable of surviving safely in community with available supervision;
 - > Need treatment to prevent further deterioration; and
 - > unable to make informed decision to seek/comply with treatment.
- Legislation filed in 2017 to streamline delivery of behavior health care and implement "local area crisis service plans" for managing IVC examinations and treatment

Federal Legislative Activity Opioid Crisis

- · More than two dozen bills pending in House Committees
- Two pending Senate bills, The Opioid Crisis Response Act of 2018 and CARA 2.0
- · Among the proposals:
 - Authorize FDA to require drug makers to package certain opioids in a set dose, or "blister pack"; for example, a three or seven-day supply
 - Require physicians and pharmacists to incorporate the state's Prescription Drug Monitoring Program
 - Require states to have a lock-in program that identifies at-risk Medicaid beneficiaries and assigns them to a pharmacy home program that sets reasonable limits on the number of prescribers and dispensers they may utilize, whether under a fee-for-service or managed care arrangement
 - Require states to have state-determined limitations in place for opioid refills, monitor concurrent prescribing of opioids and other drugs (such as benzodiazepines and antipsychotics)

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CMS Regulatory Activity Opioid Crisis

- On April 2, 2018, CMS finalized the 2019 Medicare Advantage and Part D Rate Announcement and Call Letter*
 - Opioid naïve patients: Implement 7 day limit for initial opioid prescriptions for the treatment of acute pain
 - High risk opioid users: Expand the Overutilization Monitoring System (OMS), which retrospectively identifies beneficiaries CMS considers at significant risk (using high levels of opioids from multiple prescribers and pharmacies)
 - Implement an opioid care coordination edit at 90 morphine milligram equivalent (MME) per day
 - Residents of a long-term care facility, in hospice care or receiving palliative or end-of-life care, or being treated for active cancer-related pain are excluded
- Through parallel rule-making, CMS proposed regulations to implement the Comprehensive Addiction and Recovery Act of 2016 (CARA) drug management program in 2019 and integrate those policies with the OMS process
 - Would permit Part D sponsors to limit at-risk beneficiaries' coverage for frequently abused drugs to certain prescribers and pharmacies ("lock-in") and apply beneficiary-specific point-of-sale (POS) claim edits

^{*}Source: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-04-02-2.html

State Legislative / Regulatory Activity

N.C. Strengthen Opioid Misuse Prevention (STOP) Act of 2017

- Effective July 1, 2017, PAs and NPs must personally consult with supervising MD on a regular schedule for extended prescribing of targeted controlled substances
- Effective Sept. 1, 2017, pharmacies required to report prescriptions to Controlled Substances Reporting System by COB on day after delivery of prescription
- Effective Jan. 1, 2018, practitioners cannot prescribe more than 5 day supply of Schedule II/III opioid or narcotic for initial consultation on treatment of acute pain
- Effective Jan. 1, 2020, practitioners must electronically prescribe for all targeted controlled substances (with certain exceptions)

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State Legislative / Regulatory Activity

Practices of Substance Abuse Service Providers Act (Florida H.B. 807)*

- "The law takes a comprehensive approach to the problem of fraudulent patient brokering and deceptive marketing practices in the business of substance use addiction services, particularly related to the economic relationship between service providers and 'recovery residences.'"
- Among other things, the bill, enacted on July 1, 2017:
 - Requires entities providing substance abuse marketing services to be licensed.
 - Strengthens substance abuse treatment provider licensure program and improves the regulation of service providers.
 - Creates new and amends existing criminal offenses (prohibited acts) related to patient brokering and marketing practices that create or increase fines and potential prison sentences.
 - Provides assistance to law enforcement and prosecutors for enforcement.

 $\textbf{`Source:} (http://www.leg.state.fl.us/Statutes/index.cfm?App_mode=Display_Statute\&Search_String=\&URL=0300-0399/0394/Sections/0394.463.html) (http://www.leg.state.fl.us/Statutes/index.cfm?App_mode=Display_Statute\&Search_String=\&URL=0300-0399/0394/Sections/0394.463.html) (http://www.leg.state.fl.us/Statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0300-0399/0394/Sections/0394.463.html) (http://www.leg.state.fl.us/Statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0300-0399/0394/Sections/0394.463.html) (http://www.leg.state.fl.us/Statutes/index.cfm?App_mode=Display_Statutes/Search_String=&URL=0300-0399/0394/Sections/0394.463.html) (http://www.leg.state.fl.us/Statutes/Search_String=&URL=0300-0399/0394/Sections/0394.463.html) (http://www.leg.state.fl.us/Search_String=&URL=0300-0399/0394/Sections/0394.463.html) (http://www.leg.state.fl.us/Search_String=&URL=0300-0399/0394/Sections/0394.463.html) (http://www.leg.state.fl.us/Search_String=&URL=0300-0399/0394/Sections/0394.463.html) (http://www.leg.state.fl.us/Search_String=&URL=0300-0399/0394/Sections/0394.463.html) (http://www.leg.state.fl.us/Search_String=Sear$

Section Three	Audit and Enforcement Trends

OIG Work Plan Reviews*

Inpatient Psychiatric Outlier Payments

- > "FY 2014 to FY 2015, claims with outlier payments increased by 28 percent, and total Medicare payments for stays that resulted in outlier payments increased from \$450.2 million to \$534.6 million (19 percent)."
- "We will determine whether Inpatient Psychiatric Facilities nationwide complied with Medicare documentation, coverage, and coding requirements for stays that resulted in outlier payments."

Opioids

- > "Data Brief" analysis of Medicare Part D prescriptions and potential high risk beneficiaries and suspect prescribers
- > Multiple new Work Plan items, including:
 - > Same Data Brief analysis for Medicaid
 - > Audit states' use of funding from SAMHSA, which could lead to more state activity
 - > Release "toolkit" on how OIG analyzed prescription data

*Source: Office of Inspector General, Work Plan, Active Work Plan Items (https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000066.asp)

Behavioral Health Fraud & Abuse Trends*

Patient Brokering

- Exchange of remuneration for delivery of a patient to a behavioral health provider
- > (e.g., per patient payment from provider to broker).

Exploitation of Insurance Benefits

Scams procure insurance policies for patients seeking help and only pay premiums for a month or so. Patients are stuck with treatment costs.

Out-of-Network Provider Exhaustion of Benefits

Providers exhaust full range of patient treatment benefits without changing the level of care or treatment plan, then discharge patient due to non-coverage.





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Behavioral Health Fraud & Abuse Trends*

Sober Homes

- "Living establishments that provide a 'bridge' from drug or alcohol treatment provider to a mainstream living arrangement."
- Little to no licensure requirements and are subject to minimal oversight.
- Vulnerable to exploitation due to kickback arrangements between the homes and treatment and lab providers. Also vulnerable to excessive, unnecessary procedures / tests.

Partial Hospitalization Programs ("PHPs")

Vulnerable to abuse by providers who inappropriately admit patients who do not qualify for placement and/or may lack capacity to participate in treatment. "As with the health care industry generally, the behavioral health care community includes both high-quality, ethical providers and some unethical providers who seek to profit by exploiting a vulnerable population."

*Source: AHLA Connections, American Health Lawyers Association, January/February 2018, Vo. 22, Issue 1

Enforcement Activities

2017 Medicare Strikeforce Takedown

> Particular focus on opioid manufacturers and distributors

Dept. of Justice Prescription Interdiction & Litigation Task Force:

- > Coordinate criminal and civil law enforcement tools "under one banner"
 - > Particular focus on opioid manufacturers and distributors
- > PIL Task Force will include senior officials from across DOJ and DEA
- > Efforts targeted towards every level of distribution system
 - > Manufacturers involved in unlawful practices and false/deceptive marketing
 - > Assist with existing state and local government lawsuits against opioid manufacturers
 - > Continued enforcement actions against pharmacies, pain management clinics, drug testing facilities, and individual physicians

Section Four	
	Compliance Challenges and Best Practices

Best Practices for Ongoing Compliance

Remember: Data will be the skeleton upon which the story is told...

- Intent is always scrutinized in hindsight by regulators

Develop and communicate the business case ... compliance is a cost center!

- When you have top-down buy-in vs. when you do not; manage up/down chain accordingly
- Know your audience; articulate risk in terms of tangible financial and business impact
- Avoid just being the doomsday voice
- Help leaders learn how to meet their goals

Build relationships with internal clients

- Getting to "Yes" in an AKS world can take time, but make the time
- Provide training inside/outside of the legal function to develop awareness
- Stay relevant and communicate interesting cases and articles → Fraud Alerts, DOJ memos, etc.

Ensure compliance programs and policies are robust before litigation ensues

- Effectively capturing, analyzing and responding to red flags can significantly mitigate risk

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Best Practices for Ongoing Compliance (cont'd.)

Harmonizing regulatory/compliance expertise with commercial expertise

- Subject matter experts and legal business partners: which model is right?
- How does Legal and Compliance work together?
- How to manage privilege properly?

Scale your compliance function according to your risk

- Hotlines: intake, triage, investigation, resolution
- Addressing internal confidentiality; is it ever ok to treat perceived "reputational" threats to senior leaders differently?
- The importance of listening during an investigation!
- Be mindful of creating self-disclosure scenarios

Proactively identify red flags to help prioritize your efforts

- Approaching potential violators with the data can be an efficient compliance tool
- Be wary of "unique patient demographics" and always confirm justifications
- Examine statistical outliers according to your own data
- Harmonize Compliance and billing functions to account for 60-Day Rule implications

Medicare Billing Requirements / Risk Areas

- Admission Order
- Psychiatric Evaluation
- Certification
- Recertification
- Treatment Plan
- Discharge Summary

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Questions?

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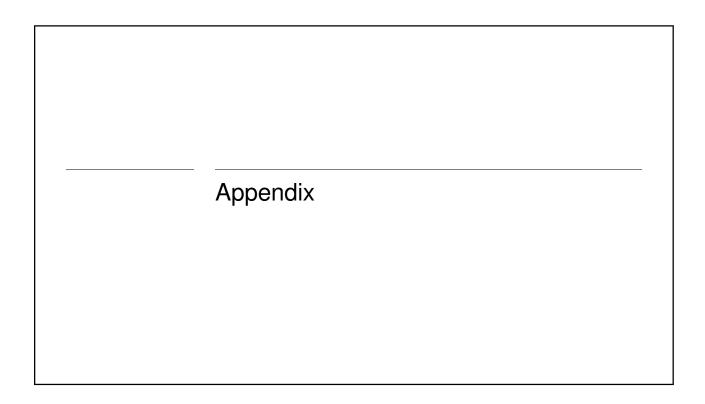
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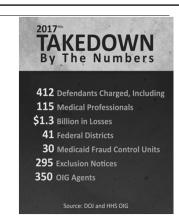
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Enforcement Activities

2017 National Health Care Fraud Takedown:

- Involved 400+ defendants in 41 federal districts for participation in schemes involving over \$1.3 billion in false billings
- "Aggressively" targeted medically unnecessary prescription drugs and compounded medications
- > Particular focus on individual medical and clinical professionals
 - > 57 doctors, 162 nurses, and 36 pharmacists excluded from participation
- Also targeted addiction treatment services, home health, mental health services, and medically unnecessary drug screenings



Enforcement Examples



Houston-area psychiatrist convicted

- > \$158 million criminal healthcare fraud scheme.
- > Psychiatrist and others submitted false and fraudulent claims for partial hospitalization program (PHP) services through Riverside General Hospital (Riverside).
- Riverside paid bribes and kickbacks to group home owners and nursing home employees; Psychiatrist admitted and readmitted patients who did not qualify for PHP services and falsified documentation.
- Psychiatrist and others (administrators, physicians) convicted and several sentenced to over 40 years in prison.
- Case was investigated by the FBI, HHS-OIG, IRS-CI, RRB-OIG and the MFCU, and was brought as part of the Medicare Fraud Strike Force.

*Source: DOJ Press Release, May 23, 2017 (https://www.justice.gov/opa/pr/houston-area-psychiatrist-convicted-health-care-fraud-role-158-million-medicare-fraud-scheme)

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Enforcement Examples



Doctors charged in sober-living home scheme:

- > Individuals charged with insurance fraud in connection with urine test billing scheme operated through sober-living homes.
- Fraudulently listed residents and non-residents of sober-living homes as employees of their four businesses and then billed for unnecessary drug testing services.
- > Accused of billing over \$1 million for drug testing to 4 insurance companies.
- > Physicians paid kickbacks for their orders.

*Source: Hanna Fry, 2 Newport doctors among six people charged in \$22-million fraud scheme tied to sober-living homes, L.A. Times, May 23, 2017 (http://www.latimes.com/socal/daily-pilot/news/tn-dpt-me-compass-rose-20170523-story.html)

Preparing a Sampling Plan

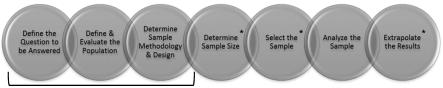
Define the following:

- Population of Interest (POI) This can help you prepare your request for data
- · Sampling Unit Population of interest is composed of all possible sampling units
- Sampling Frame Population from which the sample is drawn (explain if not equal to POI)
- · Sample Size Minimum or any other procedural requirements/thresholds
- Required Level of Precision and Confidence possibly 95% confidence $\pm 2\%$ precision
- Sample Design Simple, Stratified, Clustered, etc. Specify strata or cluster criteria
- Source of Random Numbers often RAT-STATS
- · Method of Selecting Sampling Units Ensure random numbers are applied without bias
- Procedures for Missing Data Typically failures, however spares may be appropriate
- Estimation Methodology Also referred to as extrapolation methodology

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RAT-STATS Statistical Software

- RAT-STATS is statistical software developed by the U.S. Government
 - Free software available online, along with user-guide and companion-manual
 - Key tool used by the government to help identify and quantify improper claims
- Functionally, RAT-STATS is a calculator with three main functions:
 - Calculating sample size
 - Generating random numbers to aid sample selection
 - Extrapolating (estimating) results of the sample to a broader population
- · RAT-STATS is a tool to be used in conjunction with a broader statistical strategy



Sampling Plan

* These steps involve using RAT-STATS