The Straight and Narrow Bottom Line: Law and Ethics Related to Third-Party Payment

Addiction Executives Industry Summit
Police, Treatment, and Community Collaborative
Ponte Vedra Beach, Florida
March 6, 2018

Michael C. Barnes, Esq.
@mcbtweets
Disclosure

★ DCBA Law & Policy is a Washington, D.C.-based health care law firm with a nationwide practice in the areas of substance use prevention and treatment.

★ Our clients include health care practitioners, addiction treatment programs and marketers, laboratories, and pharmaceutical developers.
Thanks to

C4 RECOVERY FOUNDATION
SPONSORS
EXHIBITORS
Preview

★ Emphasis on policy
★ Clarifications to Sunday keynote
★ AXIS themes
★ Trends
  • Aggressive legal action
  • Emphasis on medication
  • Uncertainty as to exchanges, EHBs, and parity
★ Analysis & recommendations
★ Conclusion & discussion
Emphasis on Policy

★ Practical legal landscape is largely unchanged from 2017 (AXIS, WCSAD, fall conferences)
★ Resources, recommendations, and contact information at end of presentation
★ Policy landscape is rapidly changing given activity around overdose crisis
  • Effective lobbying
    • OBOT
    • OTP
    • LA naltrexone manufacturer
  • Federal and state action
  • Emboldened insurers
Clarifications

★ Focus on issues underlying substance use, which drive demand – not on punishments

★ Principles
  • Compassion
  • Individualized health care (not medication for all, in perpetuity)
  • Sound systems
    • Health
    • Economic
    • Social
  • Ethics

★ Authorizations vs. appropriations
AXIS & PTAC Themes

- Funding is reaching communities
- New programs to screen, intervene, and treat; pre-arrest diversion
- Emboldened insurers
- Outcomes measurements and reporting
- Marketing challenges
- Consolidation and closing of programs
- Strategic planning and partnerships
  - Clinical
  - Marketing and business
AGGRESSIVE LEGAL ACTION
“We will seek to hold accountable those whose illegality has cost us billions of taxpayer dollars,” Sessions said.
<table>
<thead>
<tr>
<th>Amount</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>$2.4B</td>
<td>Collected from judgements, settlements, &amp; other impositions in federal health care proceedings</td>
</tr>
<tr>
<td>$1.6B</td>
<td>to Medicare Trust Fund</td>
</tr>
<tr>
<td>$800M</td>
<td>to U.S. Treasury &amp; individuals</td>
</tr>
<tr>
<td>463</td>
<td>Cases</td>
</tr>
<tr>
<td>888</td>
<td>Defendants</td>
</tr>
<tr>
<td>613</td>
<td>Convictions</td>
</tr>
</tbody>
</table>
Sessions announces "largest health care fraud takedown" in U.S. history

The Department of Justice, in conjunction with the Department of Health and Human Services (HHS) and other federal departments, revealed on Thursday the largest crackdown on health care fraud in U.S. history.

During a DOJ press conference, Attorney General Jeff Sessions said the Health Care Fraud Takedown, which is now operating in its eighth year, charged 412 defendants, including 56 doctors, accused of defrauding taxpayers around $1.3 billion.

"Too many trusted medical professionals like doctors, nurses, and pharmacists have chosen to violate their oaths and put greed ahead of their patients," Sessions said. "Amazingly, some have made their practices into multimillion dollar criminal enterprises. This - this litigation will be a example of doing exactly what the law asks - investigating fraud and abuses at the highest levels of the medical and pharmaceutical industries."
“Egregious fraud ring”
- Acting U.S. Attorney Benjamin Greenberg

Kickbacks and bribes to sober homes for referrals

Disguised kickbacks and bribes as “case management,” “marketing” fees

Bribes to patients to stay in treatment and submit to testing

Allowed illicit drug use

Provided controlled substances to show “relapse” on UDT

UDT not reviewed

Threats, coercion, confiscation

Prostitution

Owner sentenced to 27 years in prison

---

Owner Sentenced to More than 27 Years in Prison for Multi-Million Dollar Health Care Fraud and Money Laundering Scheme Involving Sober Homes and Alcohol and Drug Addiction Treatment Centers

Wife and Fellow Owner Sentenced to 3 Years in Prison

Two owners of sober homes and alcohol and drug addiction treatment centers were sentenced to 27 and 3 years in prison, respectively, for their participation in a multi-million dollar health care fraud and money laundering scheme that involved the filing of fraudulent insurance claim forms and defrauded health care benefit programs.

Benjamin G. Greenberg, Acting United States Attorney for the Southern District of Florida, George L. Piro, Special Agent in Charge, Federal Bureau of Investigation (FBI), Miami Field Office, Kelly R. Jackson, Special Agent in Charge, Internal Revenue Service, Criminal Investigation (IRS-CI), Dave Aronberg, State Attorney, Palm Beach County State Attorney’s Office, Jeff Atwater, Florida Chief Financial Officer, William D. Snyder, Sheriff Martin County Sheriff’s Office, George L. Dorsett, Assistant Inspector General for Investigations, Amtrak Office of Inspector General, Isabel Cohen, Regional Director, United States Department of Labor, Employee Benefits Security Administration (DOL-EBSA), and Dennis Russo, Director of Operations, National Insurance Crime Bureau (NICB), made the announcement.
Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
HEARING NOTICE

The Subcommittee on Oversight and Investigations will hold a hearing on Tuesday, December 12, 2017, at 10:15 a.m. in 2322 Rayburn House Office Building. The hearing is entitled “Examining Concerns of Patient Brokering and Addiction Treatment Fraud.” Witnesses will be announced and are by invitation only. The hearing webcast will be available at http://energycommerce.house.gov/.

Vox

The bill is being sold as CARA 2.0 — a follow-up to 2016’s Comprehensive Addiction and Recovery Act (CARA). The new bill would impose new rules to restrict access to opioid painkillers and open up access for opioid addiction treatment while adding $1 billion to facilitate those ideas.

- Create a national standard for addiction recovery housing
UnitedHealthcare accuses Dallas labs of $100 million fraud involving kickbacks for bogus drug tests

By Kevin Krause, Federal Courts Reporter

Blue Cross Says Labs Submitted $33.8M In Bogus Claims

By Rachel Graf
Sharma said he believes the raids were punishment for suing Health Net over the disputed $55 million. Health Net “engaged in a disgraceful scheme to enrich themselves by backtracking on their insurance promises to recovering addicts and the mentally ill,” Sovereign’s complaint said, adding that Health Net’s “misconduct is part of a sad pattern of prioritizing dollars over decency.”
Patients, Injured Counselor Sue Federal Agencies Over Botched, Illegal Raids At Southern California Behavioral Health Facilities

Armed agents terrified patients and illegally detained Sovereign Health personnel, including counselor who was injured. Many addiction patients left the facilities and subsequently relapsed. No charges have been filed.

Oct 2, 2017, 3:51pm EDT

RIVERSIDE, Calif., Oct. 2, 2017 /PRNewswire/ -- Several patients and employees at four Southern California behavioral health facilities filed suit today against federal law enforcement agencies for a series of botched raids in which heavily armed agents terrified patients and staff while investigating alleged insurance fraud.

Federal agencies have refused to disclose any basis for the search warrants. No one has been arrested or charged in connection with the investigation.

Further, the search warrants sought evidence of alleged violations of federal anti-kickback statute, even though Sovereign does not participate in a federal health care program covered by the statute.
UnitedHealth Group Inc
NYSE: UNH - March 6, 10:28 AM EST

226.20 ▼ 2.41 (1.05%)

Cigna Corp
NYSE: CI - March 6, 10:30 AM EST

192.53 ▲ 0.24 (0.12%)

Centene Corp
NYSE: CNC - March 6, 10:29 AM EST

101.00 ▼ 0.94 (0.92%)

Anthem Inc
NYSE: ANTM - March 6, 10:30 AM EST

231.44 ▼ 0.69 (0.30%)
Emboldened Insurers

★ Succeeding politically (federal and state)
★ Thriving financially
★ Following government’s lead in aggressive legal action
★ Refusing to pay and demanding repayment
  • Treatment programs
  • UDT labs
★ Greater resources to litigate than treatment providers
★ Paying $275 or less for $750 or more (CMS rates) in daily services
★ Out of network providers even more disfavored than previously
EMPHASIS ON MEDICATION
Medication for OUD should be successfully integrated with outpatient and residential treatment. Some patients may benefit from different levels of care during the course of their lives. These different levels include outpatient counseling, intensive outpatient treatment, inpatient treatment, or long-term therapeutic communities. Patients receiving treatment in these settings should have access to FDA-approved medications for OUD.

**Discussing medications that can treat OUD with patients who have this disorder is the clinical standard of care and should cover at least:**

- The proven effectiveness of methadone, naltrexone, and buprenorphine compared with placebo and with outpatient counseling without medication.
- Risks and benefits of pharmacotherapy with all three types of medication, treatment without medication, and no treatment.
- Safety and effectiveness of the medications when used appropriately.
- Pharmacologic properties, routes of administration, and where and how to access treatment with each medication (Exhibit 3A.1).

As is true for patients undergoing treatment for any chronic medical condition, patients with OUD should have access to medical, mental health, addiction counseling, and recovery support services that they may need to supplement treatment with medication. Medical care should include preventive...
FIVE SIGNS OF QUALITY TREATMENT

You can use these questions to help decide about the quality of a treatment provider and the types of services offered. Quality programs should offer a full range of services accepted as effective in treatment and recovery from substance use disorders and should be matched to a person’s needs.

1. Accreditation: Has the program been licensed or certified by the state? Is the program currently in good standing in the state? Are the staff qualified? Good quality programs will have a good inspection record and both the program and the staff should have received training in treatment of substance use and mental disorders and be licensed or registered in the state. Does the program conduct satisfaction surveys? Can they show you how people using their services have rated them?

2. Medication: Does the program offer FDA approved medication for recovery from alcohol and opioid use disorders? At this point in time, there are no FDA approved medications to help to prevent relapse from other problem substances.

3. Evidence-Based Practices: Does the program offer treatments that have been proven to be effective in treating substance use disorders including medication management therapies, such as motivational therapy, cognitive behavioral therapy, drug and alcohol counseling, education about the risks of drug and alcohol use, and peer support? Does the program either provide or help to obtain medical care for physical health issues?

4. Families: Does the program include family members in the treatment process? Family members have an important role in understanding the impact of addiction on families and providing support.

5. Supports: Does the program provide ongoing treatment and supports beyond just treating the substance issues? For many people addiction is a chronic condition and requires ongoing medication and supports. Quality programs provide treatment for the long term which may include ongoing counseling or recovery coaching and support, and helps in meeting other basic needs like sober housing, employment supports, and continued family involvement.
F.D.A. to Expand Medication-Assisted Therapy for Opioid Addicts

By SHEILA KAPLAN  FEB. 25, 2018

The new approach was signaled Saturday by the health and human services secretary, Alex M. Azar II, in remarks to the National Governors Association. Mr. Azar said the agency intended “to correct a misconception that patients must achieve total abstinence in order for MAT to be considered effective.”

detail to The Times, said new drugs would be eligible for approval that don’t end addiction but help with aspects of it, such as cravings, or overdoses, with the goal remaining complete abstinence.

“We will permit an endpoint that shows substantial reductions but does not require the patient to be totally clean at every visit if the measurements are fairly frequent,” a senior F.D.A. official said.
Azar’s remarks Saturday point to the challenge in obtaining this form of treatment. He said that about one-third of specialty substance abuse treatment programs offer MAT, calling failing to do so “like trying to treat an infection without antibiotics.”

“Under this administration, we want to raise that one-third number—in fact, it will be nigh impossible to turn the tide on this epidemic without doing so,” Azar says.
Legal Standard of Care

★ Determined in each legal proceeding
★ May be drawn from
  • Government-issued practice or prescribing recommendations
    • Federal
    • State
  • The medication’s FDA-approved prescribing information (label)
  • Professional associations’ practice or prescribing recommendations
  • Medical literature
  • Expert testimony
★ Facts in proceedings are drawn from medical records and witness testimony
  • May include undercover law enforcement personnel
  • May include cooperating defendants
★ Deviations from practice or prescribing recommendations must be justified by facts documented in the medical record
Medical Necessity

Cigna HealthCare Definition of Medical Necessity for other Healthcare Providers
Except where state law or regulation requires a different definition, "Medically Necessary" or "Medical Necessity" shall mean health care services that a Healthcare Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

a. in accordance with the generally accepted standards of medical practice;
b. clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury or disease; and
c. not primarily for the convenience of the patient or Healthcare Provider, a Physician or any other Healthcare Provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "generally accepted standards of medical practice" means:

- standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community,
- Physician and Healthcare Provider Specialty Society recommendations,
- the views of Physicians and Healthcare Providers practicing in relevant clinical areas and
- any other relevant factors.
State Legislation: Drug-Free Treatments

★ Indiana and Georgia bills would require coverage of non-pharmacological treatments for chronic pain, e.g., physical therapy, occupational therapy, massage, acupuncture, or chiropractic care, if deemed appropriate by the HCP.

★ In 2017, six states (CA, OR, NJ, MA, MN, and OH) passed legislation to cover acupuncture treatments for Medicaid patients.
Public Comment

- FDA is asking individuals with opioid use disorder to testify at a public meeting April 17.
- The event is part of a series of public meetings to discuss the effects of diseases on daily life, the measures of benefit that matter most to patients, and the adequacy of available treatment options.
Exchanges, EHBs, and Parity

UNCERTAINTY

DCBA | Law & Policy
Short- vs. Long-Term Health Policy

Twenty states sue the federal government, seeking an end to Obamacare

- A coalition of 20 U.S. states sued the federal government on Monday over Obamacare.
- The states claim the law is no longer constitutional after the repeal last year of its requirement that people have health insurance or pay a fine.
- The individual mandate in Obamacare was meant to ensure a viable health insurance market by forcing younger and healthier Americans to buy coverage.

Los Angeles Times

Trump administration takes new steps to loosen health insurance rules

The proposed regulations — which represent the latest in a series of administrative attacks on the Affordable Care Act since President Trump took office — could make cheaper and skimpier plans available to more Americans.

But these short-term plans — which could last up to a year under the Trump administration's proposed new rules — also threaten to further weaken insurance markets around the country and drive up costs for sicker Americans who need health plans that offer a full set of benefits, such as prescription drugs, maternity care or mental health and substance abuse services.
Avalere Health projects more than 3 million people who currently buy Obamacare in the individual and small group market are projected to turn to lassociation health plans by 2022. “Consumers are always looking for a new low-cost health insurance option, but migration of healthy people to a new product will ultimately take a toll on what is presently being sold in the market,” Dan Mendelson, president of Avalere said in a statement accompanying the research and consulting firm’s report.
Advancing Quality Health Care in the U.S.
A Roadmap for Consumer-Focused Reform
• Guarantee non-discriminatory coverage for people with pre-existing conditions;
• Maintain dependent coverage for individuals under the age of 26;
• Preserve EHBs, including coverage for prescription drugs, maternity care, and mental health and addiction treatment;
• Prohibit insurers from imposing annual and lifetime dollar limits on coverage for a person's care;
• Maintain minimum levels of coverage requirements to ensure that coverage is available if care is needed;
• Preserve annual caps on patients' out-of-pocket costs;
• Implement strong incentives for Americans to maintain health coverage;
• Reduce premiums for young people;
• Put health care providers in charge of medical decision making; and
• Empower Americans to save for health care and make informed health care decisions.
Outmaneuvering

News media, public opinion
Policy making

DCBA | Law & Policy
The Health 202: HHS chief pushes Trump opioid commission's top recommendation

Azar said he even encouraged governors who are seeking multiple changes to Medicaid to separate out their request for ducking the IMD exclusion — that way, the agency could expedite it and start expanding access to treatment sooner.

**Short-term safety through smart strategy**
- Focus on full continuum of SUD care
- Draw from CMS resources
Overview of Substance Use Disorder (SUD) Care Clinical Guidelines: A Resource for States Developing SUD Delivery System Reforms
April 2017

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>Intensive Outpatient Services</td>
<td>9 or more hours of service/week (adults); 6 or more hours /week (adolescents) to treat multi-dimensional instability</td>
<td>No</td>
<td>Yes</td>
<td>State Plan</td>
</tr>
<tr>
<td>2.5</td>
<td>Partial Hospitalization Services</td>
<td>20 or more hours of service/week for multi-dimensional instability, not requiring 24 hour care</td>
<td>Yes</td>
<td>No</td>
<td>State Plan</td>
</tr>
<tr>
<td>3.1</td>
<td>Clinically Managed Low-Intensity Residential Services</td>
<td>24 hour structure with trained personnel; at least 5 hours of clinical service/week and prepare for outpatient treatment</td>
<td>Yes (limited to subpopulations)</td>
<td>Yes (to expand to all population(s))</td>
<td>1115 demonstration</td>
</tr>
</tbody>
</table>
16 Insurance Companies Make Commitment To Address Opioid Crisis

This group includes six of the largest payers in the United States, covers over 248 million patient lives, and has provided letters of commitment and

1. Universal screening for substance use disorders across medical care settings
2. Personalized diagnosis, assessment, and treatment planning
3. Rapid access to appropriate Substance Use Disorder care
4. Engagement in continuing long-term outpatient care with monitoring and adjustments to treatment
5. Concurrent, coordinated care for physical and mental illness
6. Access to fully trained and accredited behavioral health professionals
7. Access to Food And Drug Administration (FDA)-approved medications
8. Access to non-medical recovery support services
RECOMMENDATIONS
Tactical & Practical

★ Seize opportunities
  • Interventions and warm handoffs
  • MH/SUD/criminal justice reform

★ Individualize care
  • Policies and practices to accommodate people who need medication
    • Compliance with controlled substance laws
    • Consider practitioner-administered medications to reduce post-dispensing diversion threat
  • Connect with resources, including outpatient treatment after residential

★ Program accreditation and certification
FIVE SIGNS OF QUALITY TREATMENT

You can use these questions to help decide about the quality of a treatment provider and the types of services offered. Quality programs should offer a full range of services accepted as effective in treatment and recovery from substance use disorders and should be matched to a person’s needs.

1. **Accreditation:** Has the program been licensed or certified by the state? Is the program currently in good standing in the state? Are the staff qualified? Good quality programs will have a good inspection record and both the program and the staff should have received training in treatment of substance use and mental disorders and be licensed or registered in the state. Does the program conduct satisfaction surveys? Can they show you how people using their services have rated them?

2. **Medication:** Does the program offer FDA approved medication for recovery from alcohol and opioid use disorders? At this point in time, there are no FDA approved medications to help to prevent relapse from other problem substances.

3. **Evidence-Based Practices:** Does the program offer treatments that have been proven to be effective in treating substance use disorders including medication management therapies, such as motivational therapy, cognitive behavioral therapy, drug and alcohol counseling, education about the risks of drug and alcohol use, and peer support? Does the program either provide or help to obtain medical care for physical health issues?

4. **Families:** Does the program include family members in the treatment process? Family members have an important role in understanding the impact of addiction on families and providing support.

5. **Supports:** Does the program provide ongoing treatment and supports beyond just treating the substance issues? For many people addiction is a chronic condition and requires ongoing medication and supports. Quality programs provide treatment for the long term which may include ongoing counseling or recovery coaching and support, and helps in meeting other basic needs like sober housing, employment supports, and continued family involvement.
Strategic

★ Effective lobbying and media activities
  • Exchanges, EHBs, and Parity
  • Value of psychosocial services and residential treatment
  • Coverage of non-pharmacological treatments, including residential levels of care

★ Highlight distinctions between drug dependence “care” and “treatment”: Collect and report outcomes

★ Preserve and advance residential treatment as an essential component of continuum of treatment
  • Medical-scientific literature
  • Professional society guidelines
  • Engagement with policy makers

★ Keep residential options desirable and accessible long-term
  • Affordable to working families on a self-pay basis
  • In case parity protections are weakened
  • In case government or insurer rationing exclude them
Conclusion & Discussion

★ Thanks again to C4, sponsors, and exhibitors
★ Thank you
★ Supplemental slides follow
★ Questions and feedback

Michael C. Barnes
202-644-8525
LinkedIn.com/in/MichaelCBarnes
@mcbtweets
Assignment of Benefits

★ N. Jersey Brain & Spine Ctr. v. Aetna, Inc. (3d Cir. 2015)
  • AOB at issue
    • Right to appeal to insurer on patient’s behalf
    • Assigned “all payments for medical services…”
    • Did not expressly assign right to sue for payment
  • Aetna denied or underpaid claims
  • Provider sued to obtain payment based on AOB
  • Aetna argued AOB did not confer standing
  • Held: AOB need not expressly reference right to sue for payment
Assignment of Benefits

- Peacock Med. Lab., LLC v. UnitedHealth Group, Inc. (S.D. Fl. 2015)
  - AOB assigned only the right to receive benefits
    - AOB assigned right to lab’s affiliate treatment center, not lab
  - Lab sued for more than right to payment:
    - Failure to provide criteria used to deny claims
    - Failure to provide full and fair review of denied claims
    - Failure to provide plan documents
    - Breach of fiduciary duty
  - Held: AOB insufficient
    - AOB only assigned rights to affiliate treatment center
    - AOB gave limited standing – not enough to bring other types of claims under ERISA
Anti-Assignment Clauses

- Advanced Ortho. V. BCBS of Mass (D.N.J. 2015)
  - Provider sued for unpaid benefits and other ERISA claims
  - Plan contained anti-assignment clause
  - NJ Statute: In the event a covered person assigns right to reimbursement to out-of-network provider, carrier shall remit payment directly to provider
  - Held: Provider did not have standing
    - Statute did not prohibit anti-assignment clauses
    - Statue only regulates method of payment when assignment occurs
    - Statute does not address whether such clauses are void
AOB Recommendations

★ AOB Language
  • Assign rights to all providers who may make claim
  • Assign right to pursue administrative appeals
  • Assign right to benefits and
  • Assign right to sue for all causes of action, including ERISA claims

★ Support state assignment of benefits legislation
  • Ensure such bills would override anti-assignment clauses
Co-Pay Collection: Routine Waiver

- May violate AKS
  - Forgiving financial obligations may be an inducement to purchase items or services payable by a federal health care program
- May violate state law
  - Florida State Statue 817.234: Insurance fraud to agree to waive co-pays or deductibles to obtain business or simply not bill co-pays or deductibles as part of the normal business practice
Co-Pay Collection

Insurers require proof of collection of entire co-pay before covering services

“Proportionate share analysis”
Payment in proportion to co-pays the provider collected
Cigna v. Humble Surgical Hospital

- Cigna alleged Humble waived co-pays
  - Withheld payment of claims
  - Paid proportionally to amounts Humble collected
- Cigna acted in bad faith, court found
- Cigna’s methods for processing claims were arbitrary and predetermined to deny Humble’s claims
- Court awarded Humble $13M on its counterclaims
Payment of Premiums

- AKS violation to pay premiums of federal health care program beneficiary
  - Paying value in exchange for referral of Medicare/Medicaid beneficiaries
  - HHS: exchange plans not “federal health care programs” for purpose of AKS
- May implicate state anti-kickback laws
  - Broad: Not limited to state-funded programs
  - Narrow: Limited to state-funded programs
Payment of Premiums

- HHS encourages rejection of third-party payment for exchange plans
  - Concerns
    - Skews the insurance risk pool
    - Steering Medicaid and Medicare beneficiaries into exchange plans in order to receive higher reimbursements
- Private insurers are amending plans to prohibit third-party payment