A Time for Courage: Tuesday Academy

Andrea G. Barthwell, MD, FASAM

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Two Dreams Outer Banks

Two Dreams Chicago

Disclosures

- No conflict of interest with this content
- Potential perception of conflict:
  - Collaborator: Caron Foundation
  - Consultant: Alvee Laboratories, Braeburn Pharmaceuticals, Millennium Laboratories
  - Founder: The Parents Academy (supported, in part, by Caron Foundation)
  - Managing Partner: Treatment Partners LLC (Two Dreams Outer Banks)
  - Medical Director: Encounter Medical Group, P.C.
  - Partner: EMGlobal LLC

Objectives

- Discuss the ACA and current issues that will impact the addiction field
- Assess urine monitoring needs and issues with testing
- Analyze the role of the Institutes and FDA in defining outcomes for maintenance therapies

Affordable Care Act

Headline News

- Obama Care Revolutionizes Treatment!
- EHR and ICD-10 Incentivize Progress
  - 40 million Americans
    - 24 million need treatment (60%)
  - NHSDUH: 76% need, 5% don't seek, 2% don't get, 17% get but only 25-31% succeed and 50% of those return to use
- $4000 residential term, $1500 OP stay
- $120 billion per year in health care costs if not treated
- Tx: weird mix of self-help, CJS, Social Work, peer-mentor services (Rick Rawson)
  - Sick? Bad? Misunderstood? Not motivated? Too busy?

Affordable Care Act

- **Despite attempts to expand substance abuse benefits** under the Mental Health Parity and Addiction Equity Act of 2008 ("Equity Act"), the Equity Act's 2010 interim final rule ("Equity Regulations"), and the Patient Protection and Affordable Care Act ("ACA"), **patients with substance abuse disorders** ("SUDS") **are still consistently denied** adequate access to care. Both private and state insurers create barriers in efforts to reduce health care costs.

Common Limitations

- Denial of drug testing coverage based on
  - method,
  - frequency,
  - circumstances;
- Burdensome prior authorization requirements;
- Lack of coverage of residential care;
- Minimal coverage of counseling;
- Limitations on
  - dosages;
  - length of time a patient may be treated;

Common Limitations, continued

- “Fail first” or “step therapy”
- “Not medically necessary”
- All of these limitations are prohibited both in written policies and in actual practice under the Equity Regulations, and yet, insurers have not stopped imposing such limitations.

Why Ambiguity Exists

- Who has authority?
  - The Department of Labor ("DOL"),
  - The Department of Health and Human Services ("HHS"),
  - The Internal Revenue Department ("IRS")
    - Collaborative authority to promulgate regulations pertaining to the Equity Act.
  - Equity Regulations attempted to specify the kinds of limitations that are prohibited under the Equity Act, it also created new ambiguities.
  - Although the DOL has stated that it plans to promulgate a final rule to clarify some of these ambiguities, it has made no attempt to do so.

What Kind of Ambiguities

- Parity is limited to six classifications
  - inpatient, in-network;
  - inpatient, out-of-network;
  - outpatient, in-network;
  - outpatient, out-of-network;
  - emergency care; and
  - prescription drugs
  - Does not extend to any other classification
- These classifications are not defined, left up to insurers

What is the Effect?

- Insurers have excluded critical benefits such as “residential treatment” and a number of other ASAM PPC classifications

Rule Vagaries

- "Processes, strategies, and evidentiary standards used" in applying certain limitations to SUD benefits have to be "comparable to and applied no more stringently than… medical and surgical benefits."
- But, benefits for SUDs are not comparable to the benefits for medical/surgical services.
- Allow to discriminate as long as such limitations are based on "clinically appropriate standards of care."
- This term was not defined.

Plan Allowances

- Covers large employer plans that
  - voluntarily offer both mental health/substance abuse disorder and medical/surgical benefits.
- The ACA
  - requires at least minimum coverage of SUD benefits in small group plans, individual plans, Exchange plans, and Medicaid state plans.
- EXCLUDES coverage in large group plans.
- CMS ruled: self-insured managed care organizations that provide Medicaid plans and that have CMS-approved contracts do not have to follow the Equity Regulations.

Legal Morass

- Case law almost non-existent.
  - Department of Labor has enforcement authority, but has not heard any cases.
- Equity Act states which agencies have authority to issue regulations, but
  - provides no framework for enforcement
  - provides no private right of action for individuals to bring suit.
- So far, only one case has issued an opinion on the Equity Act.

Recommendations

- DOL must promulgate a final rule that clarifies the ambiguities and closes loopholes in the Equity Regulations.
- States should enact or amend current state parity laws so that they are more stringent than the Equity Act
  - Should require insurers to offer SUD benefits for all insurance plans, including large employer insurance plans.
- At the federal level, individuals should bring suits under ERISA to challenge the denial of benefits.

Recommendations, continued

- Plaintiffs can bring class actions
- At state level can bring individual actions
- If they pass summary judgment, most cases tend to settle and insurers amend their plans.
  - New Jersey courts have held that a private right of action to sue under the state parity act is preempted by ERISA because the New Jersey Mental Health Parity Act explicitly gives authority to the commissioners of health to hear violation claims and does not explicitly provide a private cause of action. Beye v. Horizon Blue Cross Blue Shield of N.J., 568 F.Supp.2d 556 (D.N.J. 2008); Devito v. Aetna, Inc., 536 F.Supp.2d 523 (D.N.J. 2008

Recommendations, continued

- Plaintiffs may also seek enforcement of the Equity Act or the ACA through a federal excise tax for failure to meet certain group health plan requirements under ERISA (42 U.S.C. § 4980D) or for non-compliance with the ACA (42 U.S.C. § 4980I).
- Insurers should amend their plans proactively to comply with the Equity Act, Equity Regulations, and the ACA.
  - Would recommend cost-cutting measures evenly and fairly to medical/surgical benefits if they choose to take such measures against mental health/SUD benefits.

Recommendations, continued

- Although self-insured managed-care organizations that provide Medicaid plans are not required to follow the Equity Regulations, CMS has said that they may do so, and therefore, they should choose to do so.

Practical and/or Necessary Responses

- Create “work around” level of care (see Shulman)
- Litigate
- Change what you offer


Urine Monitoring

How Did We Get Here?

- Pain and addiction-95% of long-acting opioids prescribed for non-cancer pain
  - Recent FDA action- black box is a start
  - Taking medications
  - Taking other's medications
  - Not taking medications
  - Taking drugs
- Poly pharmacy from polypractioners, poor reporting, drug-medicine interactions
- Payor preference

Where WERE We?

- Forensic model
  - Workplace
  - Illicit use
  - Qualitative
  - Immunoassay- concern about specific within class drug
  - Confirmatory testing- rule out false positives
  - Cut off levels- miss some

Where WERE We?

- Clinical Model
  - Clinical setting
  - Use of prescribed and non-prescribed, and non – use (r/o diversion)
  - Preliminary and Definitive
  - POC, confirmatory, timing, immediacy of result
  - Denials of payment
  - Abuses in system
  - Direct to insured payments

APS and AAPM Guidelines (2009)

- Benefits of testing do not remain static
  - Underlying condition
  - Presence of co-existing conditions
  - Changes in circumstances
  - Changes in medications
- Monitoring leads to identifications of
  - Benefits
  - Need to restructure
  - Evidence of additional services (MAT)
  - Evidence of harms > benefits

Variability

- Types of tests
- To test or not to test, that is the question
  - Trust, but verify
  - Random, deterrence
  - Management of complex problems
  - Frequency: vary by setting or phase in treatment?
    - Inpatient detox unit
    - OBOT
    - Pain clinic
  - Language evolution: dirty v. positive v. unexpected

Current Research, Clinical and Policy Needs

- Demonstrate human, clinical, and financial value of monitoring that results in improved life experiences in people on medication for chronic illness and working on recovery
- Value demonstrated in
  - Outcomes
  - Cost benefit
  - Adoption of clinical practices (note ASAM and efforts of NAATP)

Advance the Use of Laboratory Science

- Differentiate from forensic testing
  - Language audit
  - Avoid panels and other cookbook approaches
  - Use results in management and care of patients
    - And provide evidence of same

Strategy to Protect Patient Access to Therapeutic Testing

- Know, nurture, summarize, and close the gaps in the literature
  - Patient outcomes, cost savings, safer communities
- Show off results, garner attention of infuentials
- Nurture state legislation to curb harmful practices: requires testimonials
- Increase awareness of liability without verification and vigilance- pain, addiction, NAS

Strategy, continued

- Tie to consumer/patient education: counterfeit drugs, black market drugs, personalized medicine (slow metabolizers), “Lock Your Meds” to avoid swapping
- Highlight trends- new drugs, evolving trends to aid specificity of tests
- Highlight stories of patient harm: denied care, relapses due to check in the mail, false positive, false negative
- Beware schemes and scams- this is not a new revenue stream for addiction treatment providers, or is it?

Resources

- ASAM website for PPC, Policy Statements (http://www.asam.org/publications/patient-placement-criteria/ppc-2r)
- CLAAD for Citizen's Petition (http://clad.org/downloads/CLAAD-Citizen-Petition-130310.FINAL.pdf)
- Two Dreams (http://www.twodreams.com)
- Dr. AGB (https://twitter.com/dragb)
- Dr. AGB Goes to Back Rehab (http://drbarthwell.wordpress.com/)

Now presenting…Dr. Shulman!

Thank You!

Questions?