Compliance and Psychiatry

Developing a Partnership with Compliance

Very complicated subject. This presentation is just a very narrow slice.

DISCLAIMER
Compliance and Public Sector Mental Health

• Reality: psychiatrists are in very short supply, especially in the public mental health systems.
• Reality: child psychiatrists are like rare birds.
• Reality: physician extenders are also difficult to attract and productivity differences make them difficult to manage within many rate structures
• Reality: many states are still not paying for nursing or other supports for prescribers.

The Results of Inadequate Supply

• Just as the market predicts. When supply inadequate to meet demand –
  – The supply is more expensive, and/or
  – Quality may be compromised to get supply to the market place (diminished expectations)
    • Concerns with:
      – Who provides supply- credentials and expertise
      – Quality of care in low supply models
      – Length of time to access supply – initial and follow-up
      – How supply is managed – what demand should be the focus (e.g Quadrant 2 and 4?)
The Results of Inadequate Supply

• Medical directors with very limited role in developing and overseeing medical policy and prescribing practices.
• Management that is reluctant to question psychiatric prescribing practices: cocktails, off-label usage, benzos - because of fear of losing doc time
• Doc time is cobbled together with lots of very part timers
• Training, medical meetings, case presentations, peer review limited and not often effective without a strong medical director and sufficient time.
• Supports are generally low – skill workers

The Compliance Risk

Individual physicians – not an easy target
   Relationships to pharma
   Pill mills
   Phantom services

Organizations – much easier
   – Medical capacity
   – Internal controls focused on quality of care
   – Relationships to pharma
   – Etc.
Strategic Risk

- With integration, BH no longer sitting in a silo outside the medical community.
- Cost concerns in addition to quality – both co-morbid medical concerns, costs of psych meds themselves

The Risk: No Relationship

- Medical director in name only
  - Primarily a provider
  - Hands off manager
- Compliance Officer
  - Medical services compliance risk is only narrowly defined
    - Documentation and coding issues only
Rethinking the Relationship

- Medical director and compliance work together to provide a strong infrastructure for the provision, oversight of medical services.
  - Address and prioritize risk
  - Develop monitoring and auditing protocols
    - Monitoring of prescribing practices critical
    - Quadrant 2 and 4 integration issues – who is or is not connected to medical services?
  - Policy and procedures
  - Adequate staffing business models
  - On-going Training

Today

- Quality of care issues
  - Policy and implementation directly related to risk reduction – compliance, accreditation, licensing, and legal
  - Positions organization strategically for integration and new models of care
Critical Issues: Quality and Compliance Risk

- Use of evidence-based and best practices
- Management of black box warnings and prescribing
  - Elderly
  - Anti-depressants
- Management of off-label prescribing
  - Children
  - Elderly
- Management of poly-pharmacy prescribing practices
- Management of prescribing controlled substances

Evidence-Based and Best Practices

- Use of medication algorithms
  - Indications
  - Dosages
  - Side effects and mitigation
  - Labs and other testing – prior to and ongoing
  - Other monitoring
  - Education
Evidence-Based and Best Practices

- Use of medication algorithms
  - Standardizes practice without strangling individual care
  - Reduces medical risk (and malpractice)
  - Provides a structure for on-going monitoring
  - Allows for a team-based approach to the delivery of medical services
  - Quality is controlled – not to the floor but to a higher evidence-based standard.

EBP’s: Diagnosis Specific and Drug Class

- Examples:
  - Texas and other state medication algorithms
  - AACAP: white papers on practice re: specific diagnoses, classes of drugs
  - ARHQ:
    - DHHS product
    - Reports and summaries of research on various subjects.
    - See handout: summary of research on atypical antipsychotics
  - National and international psychiatric associations
Difficulties with EBPs

• Not available for all psychiatric diagnostic groups
• Most cannot address children except as off-label, often anecdotal
• Training and then adherence is difficult to maintain – both prescribers and individual’s receiving care
• Requires additional documentation in many cases to demonstrate adherence

Operational Risk

• Atypical anti-psychotics
  – Require baseline cardiac measurements
  – Baseline labs
  – Close and careful monitoring of side effects
    • Labs
    • Vital signs
    • BMI index
  – Education
  – Adequate follow-up for dosage management to reduce side effects and increase efficacy.

• Can prescriber do it all in a clinic setting?
Solutions

- Choose the EBPs you want incorporated into your practice
- Train – all prescribers, but also all ancillary medical staff AND case managers, therapists and rehab workers.
  - Make it a condition of employment
- Write policy
- Structure internal controls – measure adherence
- Incorporate feedback loops
- Mechanism for updating

Black Box Warnings

- FDA warning that medications may pose serious risk, including risk of death for some populations
  - E.g. 2005 - Black box warning against using anti-psychotics for elderly with dementia
Black Box Warnings

- Most serious warning given by FDA
- The black box warning has to accompany any labeling or product insert for prescription-only drugs that could cause serious side effects
- Problem: adherence
  - Enough education being done by prescriber?
  - High risk being accepted by individuals in treatment?

REMs

- Newer FDA strategy for drugs deemed high risk
- Risk Evaluation and Mitigation Strategy
  - Intended to combat problems with Black Box warnings passive cautions
REMs

- FDA to drug manufacturers, REMS can involve:
  - A Medication Guide,
  - Patient Package Insert,
  - Communication plan,
  - Elements to assure safe use,
  - Implementation system.

Risks

- The compliance officer and the medical director do not know which individuals are receiving medications in spite of the BBW.
- When a new BBW is released, there are no policies to address re-evaluation of use, peer review, or ability to identify individuals who meet criteria.
- Prescribers are not fully informed or educated about the BBW.
Solutions

- Policy on BBW - prescribers: including decision-making process, education and informed consent, follow-up and monitoring, reporting, and documentation with specific emphasis on risks and risk mitigation
- Policy on BBW – agency: identification and monitoring of numbers, peer review process and coaching by medical director, monitoring compliance with policy
- E-prescribing with reporting ability

Off-Label Prescribing

- Most medications approved for marketing based on favorable benefit/risk measurement based on clinical trials – usually in adults
  - Pharma cannot market its drugs for off-label use
- Off-label prescribing occurs when a medication is prescribed that was not specified for an age range or for a clinical indication
  - Lots of this goes on and is permissible and in some cases a common practice
  - May be prescribed even though there are drugs that are approved for a particular clinical indicator in the right age group
Off-Label Prescribing

• Common for:
  – Insomnia
  – Schizophrenia- spectrum disorders
  – Unipolar and bi-polar affective disorders
  – Anxiety disorders (including OCD)
  – Mental disorders that are related to general medical problems
  – Dementia
  – Personality disorders
  – Behavior management

Off-Label Prescribing

• However, off label prescribing should be based on some evidence of effectiveness

• Much of the off-label prescribing may be governed by anecdotal, case reports, or open study information until a body of knowledge is gathered over a long period of time
  • Potential for long term adverse effects not known for years in some cases.
  • Adverse effects not adequately reported or available
  • Effectiveness and satisfaction information not systematically collected or available
Off-Label Prescribing

• Anti-psychotics: children (including children in foster care), elderly (BBW), college students, servicemen and women – without a diagnosis of psychosis
  – Dementia, irritability, disruptive behaviors, inability to sleep and anxiety, etc

• Children and anti-psychotics
  – North Carolina addressed through a state-wide policy

North Carolina Policy on Kids and Anti-psychotics

• Requires baseline and on-going measurements labs

• Requires additional safety documentation if:
  – Scripts are off-label
  – Higher dosage than FDA guidelines
  – Two or more anti-psychotics at same time

• Pharmacies must require documentation before filling scripts.
**OIG Work Plan 2013**

**Patient Safety and Quality of Care Claims for and Use of Atypical Antipsychotic Drugs Prescribed to Children in Medicaid (New)**

We will determine the extent to which children ages 18 and younger had Medicaid claims for atypical antipsychotic drugs during the selected timeframe. On the basis of medical record reviews, we will also determine the extent to which the atypical antipsychotic drug claims were for off-label uses and for indications not listed in one or more of the approved drug compendia. (OEI; 07 – 12 - 00320; expected issue date: FY 2014; work in progress)

---

**OIG, Elderly and Anti-psychotics**
Polypharmacy

- Generally these are also off-label practices
- Need to define for your organization:
  - E.g. Multiple medications targeting multiple illnesses or multiple medications for the same illness.
  - Type 1: need for basic knowledge, communication, understanding of potential for adverse effects. May require policy depending on current practice.

Polypharmacy

- Type 1 continued: in psychiatry there is the potential to destabilize one psychiatric diagnosis by medicating another.
  - Peer review, reporting of adverse effects, access to drug databases (procedures to require checking), use of EBPs
Polypharmacy

• Type II: the prescribing of multiple medications for the same disorder.
  – More controversial but in some cases emerging research
  – Policy and procedure recommended for:
    • Prescribing different classes of medication for the same disorder. Examples are so-called antipsychotics and a mood stabilizer for Bipolar Disorder; or
    • Prescribing different classes of antidepressants for Major Depression; or
    • Prescribing different classes of medication for the different target symptoms of Posttraumatic Stress Disorder.

Polypharmacy

• Type II: the prescribing of multiple medications for the same disorder.

• Most controversial: prescribing of multiple medications of the same class for the same psychiatric disorder
  – Again policy and procedure needed – e.g. patient experiencing moderate side effects but not complete relief of symptoms
  – Ability to identify and Peer review
  – Risk is magnified by the cost of these medications

• Handout – more complex approach
Prescribing of Controlled Substances

• General philosophical approach:
  – Benzodiazepines
  – Stimulants: children, adults

• Identification of relevant research
  – Dosage corridors (possibly Medical Director or other peer review if outside)
  – Length of time
  – Age
  – Diagnoses
  – And especially: non-medication interventions

Prescribing of Controlled Substances

• Prescribing practices:
  – State and federal laws
  – No early fills
  – If access to pharmacy databases use to review med seeking
Role of Compliance Officer

- Assist in identification of risk
- Working with Medical Director to develop policy and internal controls
  - Integration with QI on expected outcomes, setting goals (e.g. % of children medicated)
- Monitoring of adherence to policy and procedure
- Ensuring that P&P, algorithms, new research are updated, e.g. BBWs

Other Solutions

- More tools and technical assistance, especially for part-time medical directors
- Medication management assistance: low tech and high tech; the algorithms more accessible and more rapidly modified in face of new information; substance abuse training; medical management best practices
- More money for psychiatry: cover costs of delivering services and oversight and on-going training
- Greater use of NPs with realistic rates associated with their work
- Greater role for nursing in medication education, medical follow-up
- Larger role for non-docs in psychiatry associations
Thank You!

Mary Thornton
Mary Thornton & Associates, Inc.
199 Winthrop Road, Suite 14
Brookline, MA 02445
617-730-5800
mthornton@marythornton.com