Red Flags and Response Systems for the Oversight and Monitoring of Psychotropic Medications: Profiles of Wyoming and Maryland

*Psychotropic Medication Use Among Children in Foster Care: Technical Assistance Webinar Series*

Thursday, October 16, 2014
1:00 – 2:30 p.m. ET

For teleconference only, dial 415-655-0001; Passcode: 295147826
**Questions?**

*Ask a Question Online:* Click the **Q&A** icon located in the hidden toolbar at the top of your screen.
Agenda

• Introduction

• Reducing Childhood Use of Psychotropic Medications: The Wyoming Experience
  ▶ Dr. James Bush, State Medicaid Medical Officer for Wyoming Office of Health Care Financing

• Q&A

• Maryland Antipsychotic Pre-Authorization Program: Implementation, Lessons Learned, and Next Steps
  ▶ Dr. Susan dosReis, Associate Professor in the Department of Pharmaceutical Health Services Research at the University of Maryland School of Pharmacy
  ▶ Dr. Gloria Reeves, Associate Professor in the Division of Child and Adolescent Psychiatry at the University of Maryland School of Medicine

• Q&A
What Are Red Flags?

Red flags are markers used within child welfare, Medicaid, mental health, and managed care plans to identify cases in which available data suggest medication use may not be appropriate.

Laurel K. Leslie, MD et al. *Multi-State Study on Psychotropic Medication Oversight in Foster Care*, Tufts Clinical and Translational Science Institute (September 2010)
Why Are Red Flags Important?

- Safety
- Prompt case reviews
- Lab work
- Prior authorization process
- Quality assurance
- Outlier identification

Laurel K. Leslie, MD et al. *Multi-State Study on Psychotropic Medication Oversight in Foster Care*, Tufts Clinical and Translational Science Institute (September 2010)
Too Many, Too Much, Too Young

- **Too Many:** Children taking three or more medications at a time; prescription of two or more medications in the same class; prescribing multiple medications before testing the effectiveness of a single medication.

- **Too Much:** Prescription in dosages that exceed recommendations.

- **Too Young:** Young children may be especially vulnerable to adverse effects that result from using psychotropic medications.

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ACF
Administration for Children and Families

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Administration on Children, Youth and Families

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2. Issuance Date: 04-11-2012
3. Originating Office: Children’s Bureau
4. Key Words: Oversight of Psychotropic Medication for Children in Foster Care, Title IV-B Health Care Oversight & Coordination Plan

INFORMATION MEMORANDUM

To: State, Tribal and Territorial Agencies Administering or Supervising the Administration of Titles IV-B and IV-E of the Social Security Act, Indian Tribes and Indian Tribal Organizations

Subject: Promoting the Safe, Appropriate, and Effective Use of Psychotropic Medication for Children in Foster Care

Purpose: To serve as a resource to State and Tribal title IV-B agencies as they comply with requirements to develop protocols for the appropriate use and monitoring of psychotropic medications in the title IV-B plan. This Information Memorandum (IM) defines the issues surrounding psychotropic medication use by children in foster care, highlights available resources for States to consider when developing their Annual Progress and Services Report (APSR), and encourages increasing access to clinically appropriate screening, assessment, and evidence-based interventions for foster children with mental health and trauma-related needs.

Legal and Related References: Section 422(b)(15) of the Social Security Act (the Act)
Red Flags Vary by State

- Age
- Polypharmacy
- Absence of a DSM-IV diagnosis in the child’s medical record
- Prescribed dose exceeds recommendations
- Medications used for target symptoms are causing severe side effects
Reducing Childhood Psychotropics: The Wyoming Experience

James F. Bush MD, FACP
Wyoming Medicaid Medical Director
The Problem

- Wyoming had more children enter foster care and mental health systems at higher costs than ever before from 2008 to 2010
  - A 54% increase in Psychiatric Residential Treatment Facility (PRTF) bed days
- Difficulty arranging for evaluations of children with trained professionals prior to their foster care placement
- Six child/adolescent psychiatrists serving the entire state
  - Care often provided by primary care physicians
- Wyoming children in foster care and in residential placements were on more drugs, at higher doses, at younger ages
  - Physicians advisory group expressed concerns
Baseline Needs in Wyoming

- 101 primary care physicians responded to a statewide survey:
  - 62% felt they could not meet the mental health needs of their pediatric patients
  - 69% felt they could not consult with a mental health specialist in a reasonable length of time
  - 66% felt their patients got good mental health less than half the time
  - 78% felt less than half the time they could accurately diagnose behavioral health problems
The Plan

- To provide timely and appropriate screenings, psychiatric evaluations, diagnoses, and treatment recommendations for all children entering the juvenile justice system prior to review by the multidisciplinary team.

- To provide mandatory reviews of those children who have been prescribed doses of psychotropic medications beyond the standards set up by the Office of Pharmacy Services Pharmacy and Therapeutics Committee.

- To provide elective consultation and collaboration for primary care providers providing services to Medicaid eligible children through the Provider Assistance Line (PAL) contract.
Second Opinions (Red Flags)

May be mandated if a patient is:

• **Too young**
  - Children 5 or under receiving an antipsychotic or ADHD medication
  - Absence of DSM-IV diagnosis in claims history
  - The prescribed psychotropic medication is not consistent with appropriate care

• **Has too high of a dose**
  - >150% FDA Max

• **Has more than one prescription in a therapeutic class**
  - Five or more psychotropic medications prescribed concomitantly after 60 days
  - Two or more concomitant antipsychotic or ADHD meds after 60 days
Mandatory Second Opinion Process

- Pharmacy Benefits Manager pulls report on all psychotropic medications prescribed to children quarterly and sends to pharmacy technician.
- Pharmacy technician quickly identifies all those who exceed the “too young” and “too much” parameters.
- Pharmacy technician reviews those who exceed “too many” to rule out tapering doses and medication changes – 60 days is allowed for tapering medications.
- Cases that are identified as too young, too much and/or too many are referred to Seattle Children's Hospital.
- Pharmacy technician pulls Continuity of Care Document for a monthly review to ensure recommendations by Seattle Children’s Hospital are followed.
Consultation Results: 2011-2013

- 631 unique consults from January 2011 to March 2013
  - 277 elective consult calls to PAL
  - 125 mandatory second opinions
  - 229 Multi Disciplinary Team (MDT) consults
Second Opinion Results: 2011-2013

- 60% >150% of maximum FDA dosing
- 37% age 5 or younger
- 3% polypharmacy
- 48% psychiatrists
- 40% primary care physicians
- 6% psychiatric nurse practitioners
- 6% other specialists
## Patient Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Elective Telephone Consultations</th>
<th>Foster Care/MDT Televideo Consultations</th>
<th>Mandatory Medication Review Consultations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of consults</td>
<td>277</td>
<td>229</td>
<td>125</td>
</tr>
<tr>
<td>Patient age, years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-5</td>
<td>15%</td>
<td>&lt;1%</td>
<td>37%</td>
</tr>
<tr>
<td>6-12</td>
<td>50%</td>
<td>27%</td>
<td>23%</td>
</tr>
<tr>
<td>13-18</td>
<td>30%</td>
<td>72%</td>
<td>34%</td>
</tr>
<tr>
<td>&gt;18</td>
<td>5%</td>
<td>&lt;1%</td>
<td>6%</td>
</tr>
<tr>
<td>Patient sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>male</td>
<td>64%</td>
<td>62%</td>
<td>66%</td>
</tr>
<tr>
<td>female</td>
<td>36%</td>
<td>38%</td>
<td>34%</td>
</tr>
<tr>
<td>On psychotropic medications</td>
<td>63%</td>
<td>65%</td>
<td>100%</td>
</tr>
<tr>
<td>CGAS score mean</td>
<td>47</td>
<td>43</td>
<td>n/a</td>
</tr>
<tr>
<td>History of foster home placement</td>
<td>9%</td>
<td>42%</td>
<td>n/a</td>
</tr>
<tr>
<td>History of psychiatrist or psychiatric NP/PA</td>
<td>18%</td>
<td>42%</td>
<td>54%</td>
</tr>
</tbody>
</table>
What Is PAL?

- Primary care support program
- Toll free call to academic center-affiliated child psychiatrists:
  - Rapid response, often a direct connection
  - Business hour availability
  - Call about any child patient
  - Ongoing case collaboration
  - High grade of curbside consults
    - Consistent, evidence-based advice
    - Care guidelines are expert reviewed
What Does PAL Provide?

- Written feedback within 24 hours of a program contact
  - Unheard of in usual care system
- If questions remain after discussing a Medicaid client, a rapid “full” patient consult appointment is offered
  - Telemedicine then utilized
- Web page with resources
  - [www.wyomingpal.org](http://www.wyomingpal.org)
Who Uses PAL?

- 77% are primary care providers
- 7.5% are psychiatrists
- 7.5% are psychiatric nurse practitioners
- 4% are mental health therapists
- 4% administration
PAL Outcomes

- 277 consultations
- Children’s Global Assessment score 47 (mean)
- 59% Medicaid clients
- 170 recommendations on medication regimen
  - 27% to start medications
  - 16% to stop a medication
  - 84% non-medication intervention
MDT Evaluations

- Every county has an identified site where MDT evaluations can be performed
  - Services can also be developed with local child/adolescent psychiatrists if available
- Every child – prior to their MDT hearing – will have an evaluation performed by a child/adolescent psychiatrist
- A written evaluation and recommendation will be available by the time of the hearing
- Department of Family Services will request evaluations
  - Routine (2 weeks)
  - Urgent (72 hours)
- Technical support is provided by the University of Washington and Telehealth Consortium
MDT Evaluations

- **Age Range:**
  - 72% age 13-18
  - 27% age 6-12

- **Placement Type:**
  - 31% living at home
  - 21% crisis center
  - 18% foster home
  - 17% juvenile justice
  - 6.5% Residential Treatment Center
  - 6.5% Psychiatric Residential Treatment Facility
MDT Diagnoses

- Three average diagnoses per review
  - 52% disruptive disorder
  - 44% depression
  - 39% attention deficit hyperactivity disorder
  - 36% post traumatic stress disorder
  - 28% anxiety

- On average, there are three recommendations per consult
## Medicaid Psychiatric Medication Utilizers ≤ 21 Years of Age

<table>
<thead>
<tr>
<th>Date Range*</th>
<th>All Medicaid Psychotropic Utilizers</th>
<th>Utilizers ≤ 5 years of age</th>
<th>Utilizers with dose ≥150% of FDA max</th>
<th>Utilizers with ≥ 5 concurrent medications</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total number of clients</td>
<td>Percent of all Medicaid Eligibles</td>
<td>Number of clients (% of Total)</td>
<td>P-value**</td>
</tr>
<tr>
<td>SFY 2010</td>
<td>5450</td>
<td>9.14%</td>
<td>218 (4.0%)</td>
<td>--</td>
</tr>
<tr>
<td>SFY 2011</td>
<td>5616</td>
<td>9.12%</td>
<td>228 (4.06%)</td>
<td>0.98</td>
</tr>
<tr>
<td>SFY 2012</td>
<td>5617</td>
<td>9.15%</td>
<td>172 (3.06%)</td>
<td>0.0015</td>
</tr>
<tr>
<td>SFY 2013</td>
<td>5533</td>
<td>9.09%</td>
<td>126 (2.28%)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>
All Medicaid Psychiatric Medication Users ≤21 Years of Age

- ≤5 Years of Age
- >150% FDA Max Dose
- ≥5 medications concurrently

- Data from 7/1/09 to 6/30/10
- Data from 7/1/10 to 6/30/11
- Data from 7/1/11 to 6/30/12
- Data from 7/1/12 to 6/30/13
Return on Investment

- Total cost savings of $29,547 per child over 6 months
- 87 children yielded a total savings of $2,570,589
- After counting costs of program a 1.8% return on investment was achieved, not including pharmaceutical costs
Lessons Learned

- In complex situations, do not be afraid to try several approaches at once
- Identify as many barriers to improved care as possible
- Make sure to check back on cases to ensure compliance
- Educate everyone repeatedly – expect resistance at first
- Be patient
Questions

For more information:

Dr. James Bush  
Medical Director  
Wyoming Medicaid  
james.bush@wyo.gov
Questions?

**Ask a Question Online**: Click the Q&A icon located in the hidden toolbar at the top of your screen.
Maryland Antipsychotic Pre-Authorization Program: Implementation, Lessons Learned, and Next Steps

Susan dosReis, PhD
University of Maryland School of Pharmacy

Gloria Reeves, MD
University of Maryland School of Medicine
Objectives

• Describe the development of the clinical review ‘red flags’ for the Maryland Medicaid Peer Review Program

• Discuss academic projects developed to study the consumer perspective on treatment decision making and also the impact of pre-authorization on prescribing to youth in child welfare
# Pediatric Approved Antipsychotics

<table>
<thead>
<tr>
<th>Condition</th>
<th>Risperdal (risperidone)</th>
<th>Abilify (aripiprazole)</th>
<th>Risperdal (risperidone)</th>
<th>Abilify (aripiprazole)</th>
<th>Zyprexa (olanzapine)</th>
<th>Seroquel (quetiapine)</th>
<th>Invega* (paliperidone)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Irritability due to autism</td>
<td>5-17</td>
<td>6-17</td>
<td>13-17</td>
<td>13-17</td>
<td>13-17</td>
<td>13-17</td>
<td>12-17</td>
</tr>
<tr>
<td>Schizophrenia</td>
<td>13-17</td>
<td>13-17</td>
<td>13-17</td>
<td>13-17</td>
<td>13-17</td>
<td>13-17</td>
<td>12-17</td>
</tr>
<tr>
<td>Bipolar I</td>
<td>10-17</td>
<td>10-17</td>
<td>10-17</td>
<td>10-17</td>
<td>13-17</td>
<td>10-17</td>
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</tbody>
</table>

*Newest antipsychotic medication approved for pediatric treatment. Less data in youth available.
Major Concerns

“Is treatment safe?”
• Medication side effects, e.g., new onset diabetes
• Sparse safety data on treatment of youth <5 years old
• Use of medications that have no pediatric approved indications
• Side effect monitoring rates are low

“Is treatment appropriate?”
• Sharp increases in antipsychotic prescribing to youth
• “Off-label” treatment of behavioral problems (e.g., aggression)
• Disparities between Medicaid and private insured youth
Goals of the Antipsychotic Pre-Authorization Program

- Improve **safe and appropriate** prescribing
- Provide **oversight/monitoring** of antipsychotic treatment among Medicaid-insured youth
- Provide **education/outreach** to providers on pediatric antipsychotic treatment
Process for Review

**PRESCRIBER**
- Submits authorization request by phone or fax form
- Referrals processed M–F, 8:00 AM – 6:00 PM

**PHARMACIST REVIEWER**
- Reviews request per protocol criteria
- Approves or refers for consultation to address red flagged concerns

**CHILD PSYCHIATRIST REVIEWER**
- Contacts the prescriber or designee by phone to discuss concerns
- Re-consideration by Medicaid child psychiatrist also available

Authorizations are provided up to 6 months and provider must submit renewal paperwork when re-authorization is due

[https://mmcp.dhmh.maryland.gov/pap/SitePages/Peer%20Review%20Program.aspx](https://mmcp.dhmh.maryland.gov/pap/SitePages/Peer%20Review%20Program.aspx)
## Review Criteria

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Red Flag Triggers</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Indication</td>
<td>- Primary diagnosis of ADHD or Adjustment Disorder</td>
<td>AACAP practice guidelines, FDA approved indication</td>
</tr>
<tr>
<td></td>
<td>- Sole target symptom of sleep or anxiety</td>
<td></td>
</tr>
<tr>
<td>Medication Regimen</td>
<td>- High starting dose</td>
<td>AACAP practice guidelines, FDA guidelines, package insert</td>
</tr>
<tr>
<td></td>
<td>- Polypharmacy (&gt;4 meds)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Antipsychotic polypharmacy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Lapse in adherence</td>
<td></td>
</tr>
<tr>
<td>Side effect/Lab data</td>
<td>- Missing labs</td>
<td>APA/ADA guidelines, AACAP guidelines, AAP guidelines</td>
</tr>
<tr>
<td></td>
<td>- Abnormal labs</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Obesity</td>
<td></td>
</tr>
<tr>
<td>Psychosocial Treatment (Therapy)</td>
<td>- No therapy referrals or services</td>
<td>AACAP guidelines</td>
</tr>
</tbody>
</table>

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Peer Consultation

- Collaborative, problem solving review
- Avoid abrupt discontinuation of medication
- Provide resource and treatment information
- Outright denials are rare (<1%)
LESSONS LEARNED
Ongoing Stakeholder Engagement is Important

- Professional Societies
- Leadership from clinical programs
- Medicaid
- BHA
- Psychiatry
- Pharmacy
- Pediatrics
- MD Coalition of Families for Children’s Mental Health
- Providers
- Families
- Child Serving Agencies
- Health Experts
Common Prescribing Issues Discussed

• Lapses in medication adherence
• High dose co-prescribed ADHD medications
• Youth receiving medication only treatment for behavioral problems
• Request for an antipsychotic medication that does not have any pediatric FDA approved indications yet
Inter-Professional Review Team

**Psychiatry Trained Pharmacists**
Raymond Love, PharmD, BCPP, FASHP
Heidi Wehring, PharmD, BCPP
Ilene Verovsky, PharmD
Honesty Peltier, PharmD
Mark Ellow, PharmD, BCPP
Afua Addo-Abedi, PharmD, BCPS
Olufunke Sokan, PharmD
Sheryl Thedford, PharmD, PhD, BCPS
Cherry Bernardo, PharmD
Mary Ellen Shoemaker, PharmD

**Child Psychiatrists**
Gloria Reeves, MD
Kiran Iqbal, MD
Sean Pustilnik, MD
David Pruitt, MD
Mark Riddle (JHU), MD
Sean Pustilnik, MD
Nana Okuzawa, MD
Loriann Tran, MD

**Medicaid Child Psychiatrist**
Lisa Burgess, MD

**Acknowledgments:** Joshua Sharfstein, Laura Herrera, Al Zachik, Gayle Jordan-Randolph, Mary Mussman, Athos Alexandrou, Dixit Shah
Safety Monitoring Challenges

• Difficulty with blood draws – needle phobia
• Coordination of care – collaboration between specialist and primary care providers
• Obesity/weight gain – often does not plateau
• Akathisia/involuntary movements – can present similar to agitation
Academic Research to Address Prescribing to Youth in Foster Care and Consumer Perspective
Outcomes Assessment: Prescribing to Youth in Foster Care

Principal Investigator: Susan dosReis

• Psychotropic utilization
  – By therapeutic class and year
  – Age-stratified according to implementation of the pre-authorization program
Psychotropic Use by Therapeutic Class and Year: Children <5 Years Old

*Red arrows reflect the date when the pre-authorization program was implemented for the age group specified above the arrow.*
Psychotropic Use by Therapeutic Class and Year: Children 5-9 Years Old

*Red arrows reflect the date when the pre-authorization program was implemented for the age group specified above the arrow.*
Psychotropic Use by Therapeutic Class and Year: Children 10-14 Years Old

*Red arrows reflect the date when the pre-authorization program was implemented for the age group specified above the arrow.*
Opportunity to Address Family Centered Needs
The Family VOICE Study

- **Value of Information, Community Support, and Experience**
- Patient-Centered Outcomes Research Institute (PCORI) funded Request for Applications (RFA) “Improving Healthcare Systems”
- University of Maryland, School of Medicine (Principal Investigator - Gloria Reeves)
- Parents of Medicaid insured youth <13 years old approved for antipsychotic treatment
- Randomized trial: Family Navigation (FN) vs. usual care
- **Outcomes**: Parent empowerment/support, psychosocial service utilization/medication dosing, child functioning
Prioritizing Outcomes, Needs, Expectations and Recovery (PIONEER) Study

• Working with caregivers of children at highest risk of receiving antipsychotic treatment
  – Intellectual disability and a mental health diagnosis

• Giving these caregivers a voice that will help others make informed decisions about care for their child

• This will hopefully lead to better shared-decision making about the need to include antipsychotic medication as part of the child’s treatment regimen

• PCORI-funded contract to develop methods for patient-centered outcomes research (Principal Investigator – Susan dosReis)
  – Partners include family leadership organizations, the state Behavioral Health Administration and Developmental Disabilities Administration
Questions

For more information:

Susan dosReis
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Gloria Reeves
University of Maryland School of Medicine
greeves@psych.umaryland.edu
Questions?

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Webinar Takeaways

- Examples of red flags and response systems
- Program design
- Data collection/monitoring strategies
- Evaluation
- Lessons learned
Thank you for participating in today’s webinar!

Please complete the brief evaluation when you exit the webinar.