



Mindful
Continuing Education

Best Practice Guidelines for Prescribing Antipsychotic Medications to Youth



Executive Summary

Introduction

The safe and effective use of antipsychotic medications for children and adolescents [hereafter youth] in the United States is a critical issue in mental and substance use treatment. Antipsychotic medication use is substantially higher for youth in the United States when compared to rates of use among youth in most other developed countries. In response to the emergence of safety concerns in pediatric antipsychotic medication use, Federal, State, and public-sector agencies invested in a breadth of systems-level strategies to monitor antipsychotic medication use and support best practice prescribing. For example, by 2014, 31 State Medicaid programs employed an administrative tool, referred to as prior authorization, to require prescribing clinicians to receive approval before dispensing antipsychotic medications for all or a subset of youth. In recent years, a growing evidence base arose in both the peer-reviewed and grey literature documenting the effectiveness of prior authorization and other systems-level strategies.

As limited resources exist synthesizing the state of the evidence on systems-level strategies to promote antipsychotic best practice prescribing, the Substance Abuse and Mental Health Services Administration (SAMHSA) partnered with national experts to develop this guidance summarizing the available evidence and principles to support promising practice. This document is developed based on the information gathered through a series of data collection and consensus-building activities, specifically (1) steering committee meetings, (2) key informant interviews, (3) a systematic evidence review, (4) an environmental scan, (5) an analytic study, and (6) an expert convening.

The goal of this guidance document is to provide a centralized resource that articulates the scope of available systems-level strategies and the available evidence and corresponding recommendations for design and implementation of each strategy. Identified strategies reviewed in this guidance include (1) prior authorizations or mandatory peer reviews, (2) drug utilization reviews, (3) elective psychiatric consultations, (4) shared decision-making tools, (5) quality improvement and learning collaboratives, (6) trauma-informed and evidence-based systems of care, (7) public reporting and quality indicators, (8) intensive care coordination, and (9) multi-modal initiatives. This guidance intends to inform public and private sector decision-makers, prescribing clinicians, service providers, commercial insurers, and youth and their families.

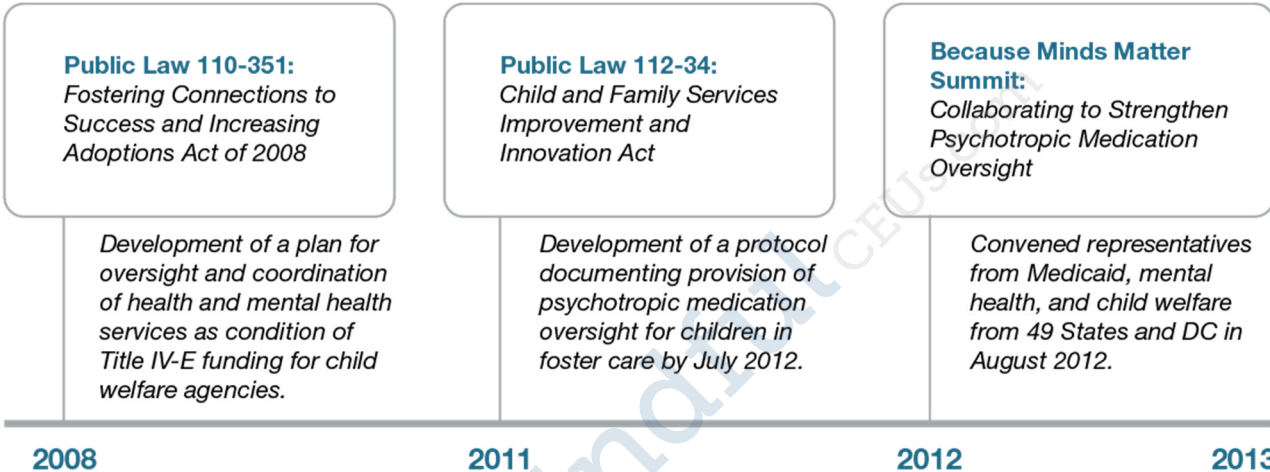
Background

At the turn of the 21st century, the rate of antipsychotic medication prescribing increased nationally. Second-generation antipsychotics (SGAs) hold U.S. Food and Drug Administration (FDA)-approved indications for schizophrenia, bipolar disorder type 1, irritability associated with autistic disorder, and Tourette's disorder among specific pediatric age groups. As rates of prescribing of SGAs increased, new evidence emerged suggesting safety and quality concerns in pediatric antipsychotic prescribing, including growing evidence of potential SGA-associated cardiometabolic side effects, limited discussions with families regarding risks and benefits of antipsychotic medications, and disproportionate prescribing patterns in specific vulnerable pediatric populations and geographic locations.

In response, Federal efforts were initially most pronounced in responding to concerns around the elevated rates of antipsychotic prescribing and associated safety concerns for youth in foster care. Figure 1 provides a description of the timeline for initial activities targeted to this vulnerable sub-population. Likely

influenced by these early efforts, a rapid expansion of strategies to monitor antipsychotic medications and to promote best practice prescribing for youth occurred for children in foster care and subsequently all Medicaid-insured children nationally. By 2013, 45 States employed a strategy to monitor psychotropic medication use (including antipsychotic medications) for children in foster care and 31 States endorsed Medicaid prior authorization programs for pediatric antipsychotic medication use as of 2014. This period of extensive growth and innovation occurred with limited evidence about the impact of these systems-level strategies on safe and quality antipsychotic prescribing, associated clinical outcomes, and potential unintended consequences.

Figure 1. Key Federal Legislative and Programmatic Responses to Psychotropic Medication Concerns for Children in Foster Care



Methodology

A multipronged approach was utilized in order to develop a conceptual framework to guide the development and implementation of effective strategies and programs. The components of the multipronged approach are listed and briefly discussed below:

Environmental Scan

- Consulted a Steering Committee—including youth and family advocates, researchers, prescribing clinicians, child and adolescent psychiatric consultants, and State and Federal partners—to set parameters, provide ongoing consultation, and review report.
- Interviewed eight key informants to provide multisectoral and interdisciplinary insights and information.
- Conducted Internet search, with key search terms, and reviewed relevant websites.
- Reviewed statewide oversight and monitoring protocols.
- Reviewed documentation of State and commercial insurer practices.

Evidence Review

- Developed and implemented protocol in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISM-A), identifying 839 peer-reviewed articles.
- Identified and summarized key components of 19 articles published from 1990 to 2018.

Analytic Study

- Conducted analyses of commercial and public insurance data on antipsychotic medication utilization among youth (1-17 years of age), examining sociodemographic and other characteristics of the patients and service use characteristics of youth prescribed antipsychotic medications.
- Conducted additional analyses of metabolic monitoring rates for youth prescribed antipsychotic medications.

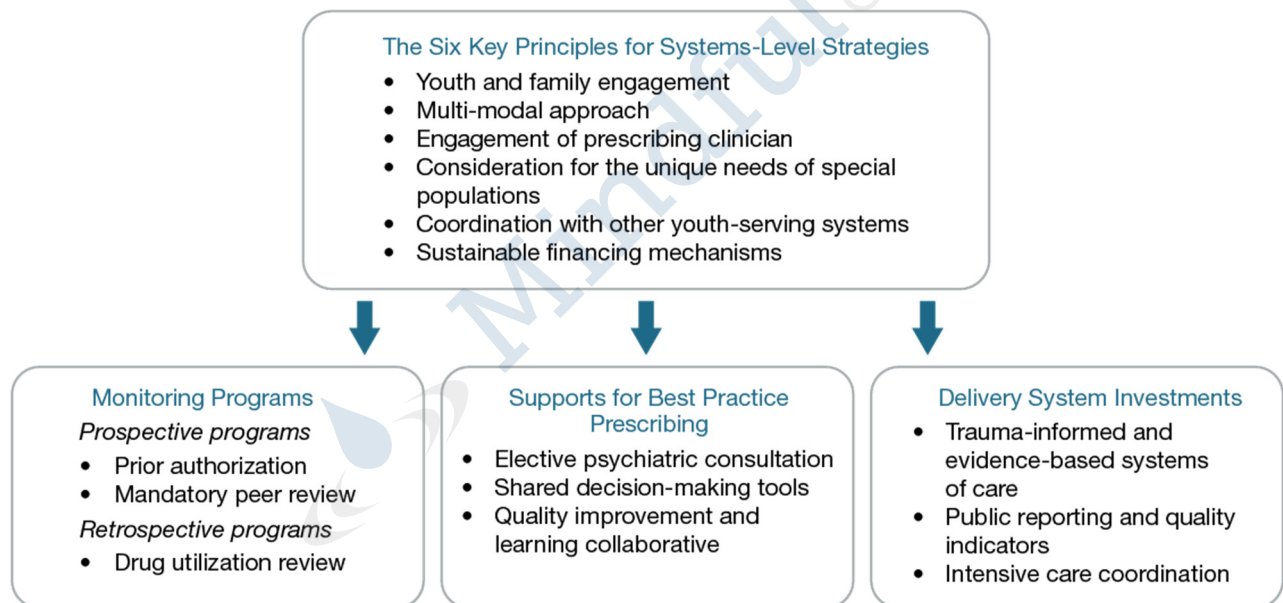
Expert Convening

- Convened a group of 40 diverse stakeholders to leverage relevant expertise in synthesizing materials and identifying the six key principles presented in the findings highlighted below.

Highlights of Guidance

The synthesis of the multipronged approach resulted in the development of a framework. Figure 2 describes the key principles, overarching types, and specific systems-level strategies to promote antipsychotic best practice prescribing.

Figure 2. Strategies to Promote Antipsychotic Medication Oversight and Best Practice Prescribing for Youth: A Framework



The following table lists the nine identified strategies and the respective findings from the evidence review and the promising practices, identified by the stakeholder-convening, for each of the strategies.

Systems-Level Strategy	Evidence Review Key Findings	Key Promising Practices
1. Prior Authorization (PA) and Mandatory Peer Review	<ul style="list-style-type: none"> • Six of seven programs led to a significant reduction in pediatric antipsychotic medication use in all targeted age groups. • One study showed significantly reduced likelihood of prescribing antipsychotic medications by child and adolescent psychiatrists but not by other types of physicians. • Three of four programs demonstrated a significant increase in antipsychotic medications prescribed for youth who fell within an age range that did not require a prior authorization. (spillover effect) 	<ul style="list-style-type: none"> • Incorporate opportunities for peer review and telephone consultation into the PA process. • Develop relationships with the office staff of the prescribing clinician when serving as a consultant. • Exercise caution when using “hard stops” at the pharmacy. • Acquire input from relevant stakeholders, including families and youth, prescribing clinicians, pharmacists, and local delivery system needs at every stage of PA program development, implementation, and evaluation.
2. Drug Utilization Reviews (DUR)	<ul style="list-style-type: none"> • A DUR program in Texas demonstrated a decrease in antipsychotic prescribing over time. • A second DUR program showed no significant changes in prescribing patterns after 2 years. 	<ul style="list-style-type: none"> • Place emphasis on supporting the prescribing clinicians, youth, and families with consensus-driven or evidence-based practice recommendations. • Employ strategies that provide opportunities for clinician education and feedback.
3. Elective Psychiatric Consultations	<ul style="list-style-type: none"> • Implementation of an elective psychiatric consultation program resulted in a 42 percent decrease in psychotropic medication use among very young Medicaid-insured children (<5 years) and 52 percent decrease in the number of children taking very high doses of psychotropic medications. 	<ul style="list-style-type: none"> • Provide phone or Web-based consultations in real time to encourage meaningful engagement and enhance shared decision-making. • Ensure consultants are trained to provide consistent messaging and understand delivery system context.

Systems-Level Strategy	Evidence Review Key Findings	Key Promising Practices
4. Shared Decision-Making Tools for Youth and Families	<ul style="list-style-type: none"> No studies were identified that specifically examined the effectiveness of a population-level implementation of shared decision-making tools to support antipsychotic treatment decisions among youth and caregivers. 	<ul style="list-style-type: none"> Provide youth and family with information on risks and benefits associated with antipsychotic medication treatment and plan for early identification of potential side effects. Target initiatives to engage special populations who are historically not adequately engaged, including use of youth and family peer support. Enhance dissemination and uptake of decision aids by leveraging technology and social media.
5. Quality Improvement (QI) and Learning Collaboratives	<ul style="list-style-type: none"> All five evaluated programs achieved significant short-term effect of at least one primary outcome (i.e., new antipsychotic initiation, antipsychotic co-pharmacy, psychotropic medication polypharmacy). Two of the five studies demonstrated significant improvement in cardio-metabolic monitoring. 	<ul style="list-style-type: none"> Incorporate stakeholder engagement at initiation of QI collaborative. Ensure multi-modal and customized QI approaches in order to address the multiple and unique challenges/needs of targeted delivery systems. Build QI initiatives into infrastructure of respective institution to mitigate sustainability uncertainties (i.e., grant funding).
6. Trauma-Informed and Evidence-Based System of Care	<ul style="list-style-type: none"> No studies were identified that examined how investments in a trauma-informed system of care and trauma-specific interventions affected antipsychotic medication treatment and evidence-based practices. 	<ul style="list-style-type: none"> Present non-pharmacological alternatives to the youth, caregiver, and/or family and decrease barriers to these services. Consider reexamining the potentially low reimbursement rates provided for psychosocial services.

Systems-Level Strategy	Evidence Review Key Findings	Key Promising Practices
7. Public Reporting and Quality Indicators	<ul style="list-style-type: none"> No studies were identified that specifically examined public reporting of antipsychotic treatment in youth. Studies that review public reporting in other contexts suggest delivery systems may improve health care quality when performance data are made public though unintended consequences may emerge. 	<p>Leverage the ability for common metrics and public reporting to be established as part of routine program review and reporting.</p>
8. Intensive Care Coordination (includes “wraparound” services)	<ul style="list-style-type: none"> One intensive care coordination program demonstrated significant decrease in concomitant antipsychotic use and statistically significant improvements in monitoring for cardio-metabolic side effects. A second intensive care coordination program demonstrated no significant reduction of polypharmacy between intervention and control groups. 	<ul style="list-style-type: none"> Provide youth- and family-driven care coordination. Support care coordination with access to ancillary data about the patient’s prior service utilization where possible. Assess fidelity to care coordination models and provide needed support.
9. Multi-modal Initiatives	<ul style="list-style-type: none"> Florida Medicaid program’s multi-modal monitoring program resulted in reductions in both the number of patients receiving unusual antipsychotic prescriptions and the number of prescribers with unusual antipsychotic prescribing practices. Montana Medicaid program’s implementation of both a PA and DUR program reduced key indicators (antipsychotic utilization and cardio-metabolic monitoring) for children in foster care. 	<ul style="list-style-type: none"> Provide additional support to prescribing clinicians given the complexity of decision-making in antipsychotic medication treatments among youth. Ensure coordination rather than duplication of efforts across systems-level strategies. Engage various stakeholders for input into configuration of strategies.

Conclusions and Next Steps

Conclusions

This guidance highlights the extensive innovation that occurred over the past decade as an array of strategies emerged to promote best practices in antipsychotic medication prescribing for youth. Such efforts likely contributed to the stabilization reported in antipsychotic prescribing among youth in foster care and very young children in the United States since 2011. However, opportunities remain to promote antipsychotic prescribing that is consistent with and informed by the best available evidence, clinical expertise of the prescribing clinician, and the preferences of the youth and their caregiver(s).

Expert consensus strongly suggests that systems-level strategies are needed to support both the initial antipsychotic treatment decision and those decisions required after treatment is initiated. This guidance is not prescriptive in its recommendations but rather highlights the need for jurisdictions to consider the specific systems-level strategies responsive to the needs of their local delivery systems and relevant stakeholders (e.g., youth, caregivers, prescribing clinicians). Given the many youth-serving public sectors systems engaged with youth, multisectoral coordination is critical at the Federal, State, and organizational levels.

Notably, this guidance is also limited by the state of the evidence evaluating these approaches. First, the majority of outlined strategies were supported by evidence that focused only on the impact on service utilization (e.g., reduction in dispensing of antipsychotic medication) and best practice prescribing (e.g., side effect monitoring). Second, three systems-level strategies had no available studies that evaluated their potential impact on antipsychotic treatment in youth (Trauma-Informed and Evidence-Based System of Care and Public Reporting, Quality Indicators, and Shared Decision-Making Tools). Additionally, limited studies were available that focused on how a specific strategy impacted functional outcomes.

Next Steps

This guidance highlights the need for multiple strategies to be implemented in a strategic and coordinated manner across youth-serving systems. Collaboration across Federal agencies, State entities, and youth-serving delivery systems is key in facilitating implementation and widespread adoption of best practice prescribing.

Federal Level. Prior collaborations of the Centers for Medicare & Medicaid Services, the Substance Abuse and Mental Health Services Administration, and Administration for Children and Families set a strong precedence as to the importance of Federal leadership on this issue. Ongoing investments in authoring additional joint letters, facilitating public sector collaboration, and supporting evaluation and research studies within and across State systems is warranted. Ongoing work to understand the long term impact of antipsychotics, and ways to mitigate their adverse effects, is necessary; collaboration with the National Institute of Mental Health and the National Institute of Child Health and Human Development is important.

State Level. Participants in the expert convening highlighted that opportunities may exist for greater involvement and coordination among commercial insurance plans, education, and juvenile justice systems in coordinating development and implementation of these strategies.

Youth-Serving Delivery Systems. Integration of additional tools to inform processes of shared decision-making and infrastructure to support continuous quality improvement also holds promise for ensuring safe and effective antipsychotic medication treatment.

Finally, participants of the expert convening emphasized that ongoing commitment to local, multi-State, and national evaluations will be critical. The emergence of antipsychotic safety and quality metrics presents new opportunities to facilitate the use of common and evidence-based safety and quality metrics to benchmark quality over time and across delivery systems. Such efforts will require investments in building an infrastructure for evaluation within the implementing agencies, as well as support for research that examines long-term safety and efficacy of these medications and trends across jurisdictions.

Part A. Introduction

The safe and effective use of antipsychotic medications for children and adolescents [hereafter youth] in the United States is a critical issue in mental and substance use treatment. Antipsychotic medication use is substantially higher for youth in the United States than in most other developed countries.²⁻⁵ Rapid growth in antipsychotic medication treatment occurred in the United States at the turn of the 21st century.^{6,7} Limited safety and efficacy data exist for antipsychotic treatment of non FDA-approved indications.⁸⁻¹¹ Moreover, evidence of potential cardio-metabolic side effects associated with second-generation antipsychotics (SGAs) for youth has accumulated since their release.¹²

In response to these concerns, Federal and State agencies developed and implemented a number of initiatives to promote systems-level strategies that incentivize the safe and effective use of antipsychotic medications among youth.¹³ Illustrative of these Federal initiatives, the Centers for Medicare & Medicaid Services (CMS), Substance Abuse and Mental Health Services Administration (SAMHSA), and Administration for Children and Families (ACF) jointly authored a letter in 2011 calling for public sector system collaboration and calling out opportunities to leverage initiatives promoted by each of the sponsoring Federal agencies.¹⁴ The U.S. Government Accountability Office (GAO) conducted multiple investigations around safe and effective antipsychotic prescribing among youth resulting in calls for additional Federal and State initiatives to address unresolved concerns. These reports provide specific recommendations for additional Federal guidance and State action to address the well-documented concerns around antipsychotic and psychotropic medication use among youth.^{15,16}

Public sector agencies subsequently invested in a breadth of strategies that sought to monitor and promote best practice prescribing of antipsychotic medications among youth. National studies document a rapid expansion in the strategies implemented to promote best practice in antipsychotic prescribing since Federal and State agencies prioritized these concerns.¹⁷⁻¹⁹ Strategies sought to monitor antipsychotic medication treatment, support youth, families, and clinicians in making treatment decisions, invest in other effective treatment modalities (e.g., psychosocial services), and implement intensive care coordination. Although little evidence was available in the initial expansion of these systems-level strategies, a substantial evidence base has emerged over the past decade.²⁰

Goals of This Guidance

This document was developed to provide guidance on systems-level strategies to promote best practice in antipsychotic medication prescribing for youth. **Of note, this guidance is not a clinical guide to antipsychotic best practice prescribing, but refers the reader to specific publicly available resources.** Rather, this guidance aims to provide youth and their families, prescribing clinicians, service providers, and public and private sector decision-makers with a centralized resource on the current evidence and promising practices for systems-level strategies that promote best practice prescribing for antipsychotic medications among youth. The guidance reflects findings from a multipronged effort, including insights provided from the ongoing consultation of a steering committee, analytic study, systematic evidence review, environmental scan, and expert convening. Appendix 1 provides additional detail on the methodology employed for the development of this report.

The synthesis of this multipronged effort resulted in the identification of an overarching framework for nine strategies promoting antipsychotic best practice prescribing, “key principles” for development and implementation of the strategies, and guidance specific to each of the nine strategies identified. The distinct strategies identified through this work aimed to promote antipsychotic best practice prescribing in

diverse ways. The diversity of strategies identified reflect the multifactorial nature of challenges to best practice prescribing of antipsychotic medication use.

The strategies emphasize different aspects of the barriers confronted by various stakeholders in attaining antipsychotic best practice prescribing for youth in the United States. For example, investments in trauma-informed and evidence-based systems of care seek to address potential shortages in treatment alternatives to antipsychotic medications.²¹ On the other hand, elective psychiatric consultation intends to address the well-documented workforce shortages in child and adolescent psychiatry.²² Furthermore, shared decision-making tools are extended to promote youth and family engagement in understanding treatment alternatives and the potential benefits and harms associated with antipsychotic medication treatment. Accordingly, **this guidance aims to support decision-makers in developing a systems-level approach to promoting antipsychotic best practice prescribing that is customized to the unique needs of their delivery systems and multiple stakeholders.**

Part B. Background

To characterize the national landscape of antipsychotic prescribing among youth in the United States, the literature documents (1) experiences of families and youth, (2) national trends in antipsychotic medication prescribing over time, (3) the safety and efficacy of antipsychotic medication treatment, and (4) national estimates around the quality of prescribing once SGA treatment is initiated. Data presented in this background integrate findings from a series of national focus groups conducted by Family-Run Executive Director Leadership Association (FREDLA),²³ an analytic study conducted for this guidance entitled Strategies for Effective Implementation of Evidence-Based Practices in Antipsychotic Prescribing for Children and Adolescents: The Analytic Study* and the peer review literature.^{1,24}

Experiences of Families and Youth

Families that participated in a series of national focus groups conducted by FREDLA reported that they are uneasy about giving antipsychotic medications to their children, especially young children.²³ Families expressed concern about the side effects, particularly weight gain, and long-term consequences of use on their children's health. They also stressed the secondary effect of stigma and bullying children may experience as a result of the side effects. Families stated the importance for availability of comprehensive information on antipsychotic medications in lay terms that families can easily understand. Families also stressed the need for prescribing clinicians to provide more information about alternatives to antipsychotic medication treatment, and additional information about the various medication treatment options, including the anticipated benefits, risks, and potential side effects. Concerns around access to accessible educational materials around antipsychotic medication and treatment alternatives have also been expressed by young adults and transition-age youth.²⁵

Trends in Antipsychotic Prescribing Among Youth

Psychotropic medication use, including antipsychotic medications, in youth rose markedly in the United States from 1990 to 2008.¹¹ However, the percentage of youth (1-17 years of age) who received

* The objectives of the analytic study was to measure antipsychotic medication use among children aged 1-17 years in 2011-2015 for both Medicaid and commercial insurance from the IBM MarketScan® Commercial Claims and Encounters (CCAЕ) database. Findings of these analyses are integrated with the peer-reviewed literature to characterize historical and present-day concerns around antipsychotic prescribing among youth.

antipsychotic medications between 2011 and 2015 declined for youth covered by Medicaid and commercial insurances, respectively; these declines were also seen among very young children (1-5 years of age) for the Medicaid and commercially insured.²⁴ Antipsychotic prescribing declined from 1.6 percent to 1.2 percent among Medicaid-insured children and from 0.5 to 0.4 percent for those children with commercial insurance. While prior studies find rates of antipsychotic prescribing were approximately twice as likely among Medicaid-insured youth as compared to commercially insured youth,²⁶ this analytic study finds Medicaid-insured youth are three times as likely to be prescribed antipsychotic medications as compared to those commercially insured.²⁴

Given elevated concern of antipsychotic medication use among young children,²⁷ stratified analyses were conducted to examine whether unique considerations were at play for the very young. These analyses found antipsychotic prescriptions for young children (1-5 years of age) occurred most frequently among males and children diagnosed with ADHD, disruptive behavior disorders, or autism and tic disorders. Reductions in antipsychotic prescribing among young children (1-5 years of age) occurred for Medicaid and commercially insured young children. Between 2011 and 2015, the percentage of children aged 1-5 years prescribed antipsychotic medications decreased from 3.5 to 2.5 and 2.0 to 1.4 for Medicaid and commercially insured young children, respectively.

The findings of this analysis are consistent with prior research, which also found elevated rates of antipsychotic medication use among youth with public insurance and living in foster care as compared to the commercially insured.^{26,2,11,27-29} For example, after controlling for diagnostic and sociodemographic factors, one study found youth in foster care were prescribed antipsychotic medications at twice the rate of other Medicaid-insured youth.³⁰ The persistence of these trends in differential use is notable in light of the extensive effort that has specifically targeted Medicaid-insured youth and those in foster care. Prior studies also suggest extensive geographic variation in rates of antipsychotic medication prescribing among youth nationally, suggesting potential over- and under-use depending on the specific jurisdiction and subpopulation.^{31,32} For example, the analytic report for this study found decreases in the proportion of antipsychotic users who were non-Hispanic Whites from 2011 to 2015 while increased rates of antipsychotic use persisted for racial and ethnic minorities, including youth who were non-Hispanic Black, Hispanic, and non-Hispanic other.²⁴

Safety and Efficacy of Antipsychotic Medication Treatment

Second-generation antipsychotic medications (SGAs) are U.S. Food and Drug Administration (FDA)-approved for schizophrenia, bipolar disorder, irritability associated with autistic disorder, and Tourette's disorder among specific age groups.³³ Two first-generation antipsychotics also received approval for limited use among youth, specifically to treat severe behavioral problems and short-term treatment of hyperactivity with excessive motor activity and accompanying conduct disorders.³⁴

Antipsychotic medications are used widely for youth without FDA-approved indications often to manage "off-label" aggressive or challenging behaviors.³⁵ Treatment may be "off-label" because of either the age of a child (e.g., 3-year-old child with severe autism) or the indication (e.g. treatment of aggression and irritability in an adolescent who is subthreshold for a diagnosis of bipolar disorder). The limited safety and efficacy data to guide "off-label" care warrants careful consideration of the risk-to-benefit ratio of antipsychotic treatment *prior to initiating medication* (e.g., Has the patient received an adequate trial of first-line, evidence-based psychosocial therapy and medication treatments before starting an antipsychotic?) and *over the course of care* (e.g., What is the plan to monitor risks and benefits of treatment and timeframe that ineffective or poorly tolerated medication will be discontinued). Practice

guidelines developed by experts are important decision-making resources when prescribing antipsychotics.^{36,37} A study of the general pediatric population found top target symptoms for antipsychotic prescribing were aggression (48 percent), irritability (19 percent), and impulsivity (11 percent), while antipsychotic prescribing for psychotic symptoms, for which evidence for pediatric patients is strongest, accounted for only 5 percent.³⁸ Available practice parameters for pediatric antipsychotic medication use emphasize that these medications are optimally provided in combination with psychosocial interventions, such as evidence-based child and parent skills training,³⁹⁻⁴² however, national estimates suggest only about one-third of youth who receive antipsychotic treatments receive psychosocial interventions as a first-line treatment.²⁶

Since their initial release, evidence of potential side effects associated with SGAs has accumulated.¹² A recent meta-analysis found youth treated with antipsychotics to hold more than a threefold increased risk for Type 2 diabetes vs. healthy controls.⁴³ Significant weight gain has been found with all studied SGAs.^{44,45} Growing evidence on risk of hyperglycemia, hyperlipidemia, insulin resistance, and other metabolic hazards has increased the urgency of calls for improved metabolic screening and management.⁴⁶ Concerns have also grown about hazards of polypharmacy and use of antipsychotics among very young children, where evidence on the safety and efficacy of both is lacking.^{35,47,48} Antipsychotic medication reviews should take into consideration the full medication regimen that the child is taking. This information is relevant to antipsychotic treatment because of (1) potential drug interactions; (2) concerns about adherence challenges (e.g., child is prescribed five medications, but claims data indicated only some of the medications are filled consistently); and (3) concerns that a medication side effect may be worsening behavior symptoms (e.g., child is given a very high dose of stimulant medication, which causes irritability and insomnia, child has behavioral disinhibition on a sedative hypnotic medication). Of note, a systematic evidence review conducted by the Agency for Healthcare Research and Quality concluded that limited safety and efficacy data exist for youth, and results of existing studies of efficacy are mixed for antipsychotic treatment of non-FDA-approved indications.⁸⁻¹¹

In addition to concerns about side effect and disproportionate prescribing to some vulnerable populations, it is also important to acknowledge that such medications have an important clinical role for specific pediatric patient populations. In the context of challenges with many individuals not having access to appropriate mental and substance use treatment, it is important to acknowledge that delayed access to antipsychotics, when clinically appropriate, could result in worsening of outcomes for some individuals, particularly those experiencing first-episode psychosis. Accordingly, members of the expert convening emphasized the goal of an antipsychotic monitoring program should not be to restrict or inhibit antipsychotic prescribing, but rather to promote safe and clinically optimal prescribing of antipsychotic medication in youth.

Quality of Prescribing Once Antipsychotic Treatment Is Initiated

Nationally, challenges persist in attaining quality indicators for antipsychotic prescribing, endorsed by the National Committee for Quality Assurance (NCQA) and the Health Employment Data Information System (HEDIS). While guidelines call for baseline and followup glucose and lipid monitoring for antipsychotic-treated youth, evidence to date is that implementation of these practice guidelines has been slow.^{26,49} From 2004 to 2006, only about one-fifth to one-third of antipsychotic-treated youth in Medicaid received both blood glucose and cholesterol testing.⁵⁰ Using the NCQA 2018 HEDIS measures of Metabolic Monitoring for Children and Adolescents on Antipsychotics, analyses suggested that statistically significant improvements occurred from 2011 to 2015, with challenges persisting in the attainment of these best practice parameters.²⁴ In 2015, only 26.1 percent and 28 percent of youth (1-17 years of age) prescribed

antipsychotic medications received metabolic monitoring among the Medicaid and commercially insured, respectively.²⁴

Practice Parameters for Antipsychotic Prescribing

Professional organizations and consensus statements endorse specific practice parameters for antipsychotic medication treatment among youth.^{36,37,51} The American Academy of Child and Adolescent Psychiatry (AACAP) endorsed practice parameters for antipsychotic medications that provide recommendations to start “low and go slow,” with routine monitoring of side effects for metabolic conditions, such as body mass index, fasting blood glucose, hemoglobin A1c [HbA1c], and fasting lipid profiles.⁴⁶ Recommendations also emphasize the limited safety and efficacy data available in prescribing two or more antipsychotic medication concomitantly and recommends avoiding such use. Other available consensus statements also emphasize the use of psychosocial treatments as a first line of treatment, use of structured rating scales to gauge treatment response, monitoring of abnormal involuntary movements, and other clinical parameters.^{37,52} The American Academy of Pediatrics published guidance on treatment for specific antipsychotic medications (e.g., risperidone).⁵³ Additionally, the Canadian Institute for Health Research developed guidelines entitled Monitoring Effectiveness and Safety of Antipsychotics in Children (CAMESA), which provides parameters for prescribing and monitoring the use of antipsychotics.⁵⁴

Table 1: Available Practice Parameters for Antipsychotic Medication Treatment Among Youth

American Academy of Child and Adolescent Psychiatry practice parameters for the use of atypical antipsychotic medications in children and adolescents. ³⁷
Canadian Alliance for Monitoring Effectiveness and Safety of Antipsychotics in Children Guidelines. ⁵¹
Treatment of Maladaptive Aggression in Youth (T-MAY). ³⁶
Treatment recommendations for the use of antipsychotics for aggressive youth (TRAAY). Part II. ⁵⁴

Part C. A Framework for Strategies to Promote Best Practice Prescribing

Federal efforts promoting safe and effective antipsychotic use focused heavily on youth in foster care initially with gradual expansion to other Medicaid-insured youth. Specifically, the Fostering Connections to Success and Increasing Adoptions Act of 2008 and the Child and Family Services Improvement and Innovation Act of 2011 initially responded to the increased rates of psychotropic medication use among youth in foster care by mandating that Title IV-E funded State child welfare agencies submit protocols for the oversight of mental health services among youth in foster care. Several reports, including those released by the GAO in 2011 and 2014, drew additional attention to use of psychotropic medications among Medicaid-insured youth and those in foster care specifically, with the first published report entitled Foster Care: HHS Guidance Could Help States Improve Oversight of Psychotropic Prescriptions.^{15,16} Subsequently, CMS has highlighted how several State Medicaid programs have promoted antipsychotic oversight.^{55,56}

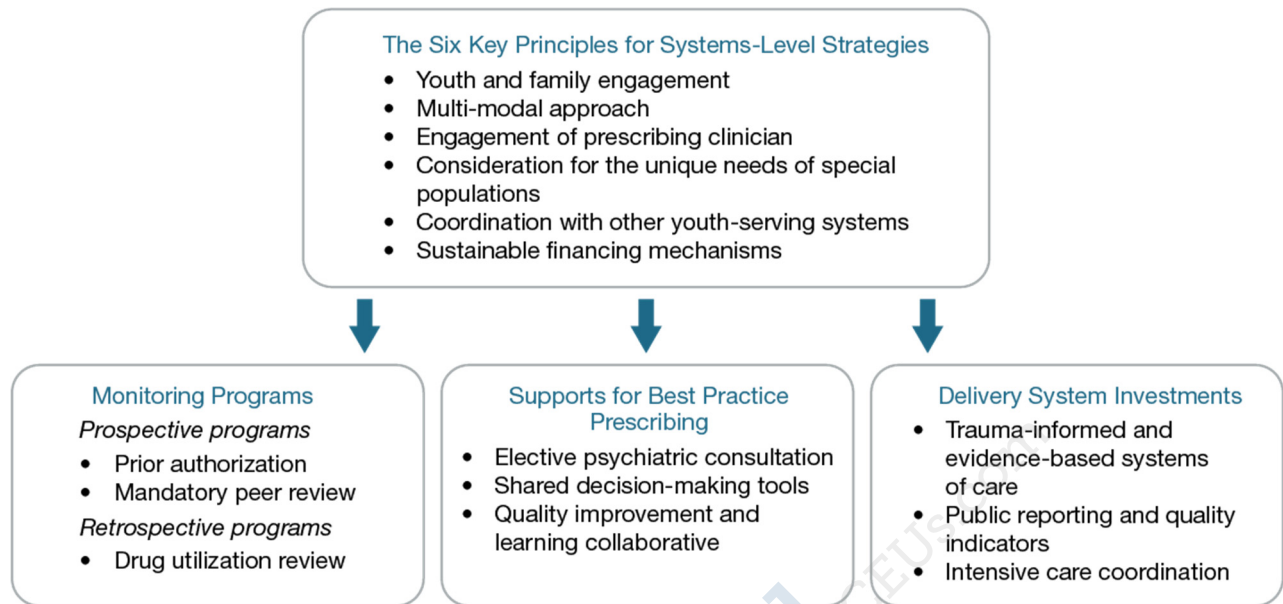
Likely reflective of these efforts, an extensive growth in State-level monitoring strategies is well-documented in the peer-reviewed literature.^{17-19,57} Before 2005, few jurisdictions had initiated strategies to promote best practice prescribing of antipsychotic medications. However, these initiatives proliferated in the late 2000s as States responded to growing concerns and Federal initiatives, with 2005-2012

representing the peak period of implementation.^{17-19,57} By 2015, 31 States provided a prior authorization for antipsychotic medications prescribed to Medicaid-insured youth.¹⁷ Of the 50 States, 45 and DC had employed at least one strategy to provide psychotropic medication oversight for youth in foster care by 2013, with over one-half of the strategies implemented between 2011 and 2013.¹⁹ This extensive innovation occurred with limited evidence available on the effectiveness of these psychotropic medication oversight programs on the targeted outcomes. Moreover, little was known about potential unintended consequences including spillover effects to other populations not targeted by the oversight strategies, substitution effects (e.g., compensatory prescribing), and adverse events (e.g., psychiatric emergency room utilization).

Multiple strategies to promote best practice in antipsychotic treatment are documented in the literature. Participants of the expert convening noted that investments in strategies are most effectively multi-modal, such that investments in monitoring programs are strategically coupled with supports for best practice prescribing and/or delivery system investments. Figure 2 provides a description of the three overarching categories of strategies identified by the expert convening participants and literature review, specifically including monitoring programs, supports for best practice prescribing, and delivery system investments. Appendix 2 provides an in-depth operational definition and illustrative example for each of the nine strategies within these overarching categories.

There are several overarching key principles and strategy-specific overviews for development and implementation of effective programs. The overall key principles include (1) use of multiple coordinated and synergistic strategies (i.e., “multi-modal approaches”), (2) youth and family engagement, (3) engagement of prescribing clinician, (4) consideration for the unique needs of special populations, (5) coordination with other youth-serving systems, and (6) sustainable financing mechanisms. Figure 2 provides an organizing framework for implementing the identified strategies. Each of the strategy-specific overviews provides guidance based upon a synthesis of the evidence review, environmental scan, and expert convening. The following strategies and an in-depth overview of each are presented in the next section: (1) prior authorization or mandatory peer review, (2) drug utilization review, (3) elective psychiatric consultation, (4) shared decision-making tools, (5) quality improvement and learning collaborative, (6) trauma-informed and evidence-based system of care, (7) public reporting and quality indicators, (8) intensive care coordination, and (9) multi-modal initiatives.

Figure 2. Strategies to Promote Antipsychotic Medication Oversight and Best Practice Prescribing for Youth: A Framework



Part D. Key Principles for Strategies to Promote Best Practice Prescribing

The expert convening participants identified six overarching principles for strategies to promote best practice in antipsychotic prescribing for youth:

Engage Youth and Families in Direct Care, Organizational Improvement, and Policy Reform

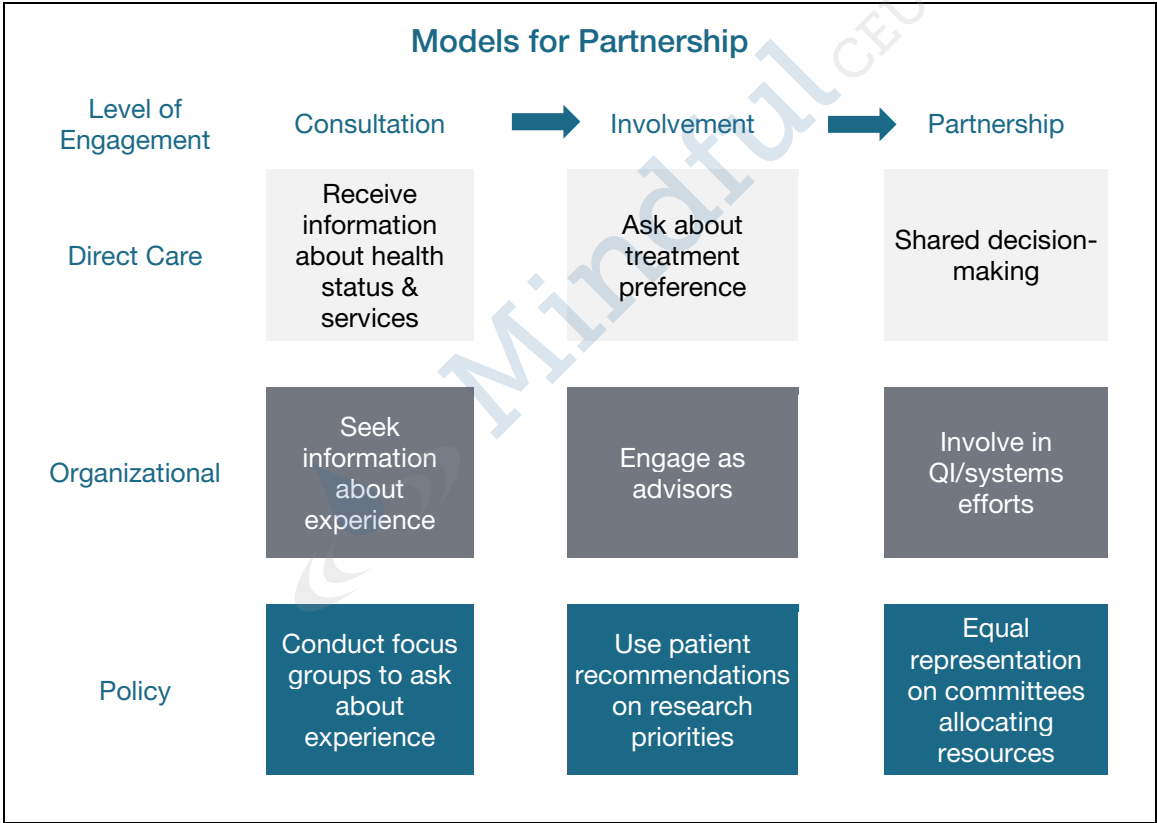
As described in Figure 3, strategies for evidence-based antipsychotic prescribing should engage youth and families at all levels of care. Youth and family partnership should be considered a cornerstone in ensuring strategies are responsive to the unique challenges that may exist within a particular youth-serving delivery system.

During the expert convening, youth, family leaders and caregivers continue to express the fact that multiple barriers exist to ensuring a process of shared decision-making in antipsychotic medication treatment among youth. Focus groups conducted with caregivers and families, led by the Family-Run Executive Director Leadership Association (FREDLA), emphasized the importance of a “team approach” and the many opportunities to attain the goal of partnership in direct care.²³ Opportunities for greater partnership in direct care existed by providing prescribing clinicians more than “10-15 minutes” to talk to the family. Additional time would facilitate opportunities for more information to be provided on potential side effects at the time of treatment decisions. Moreover, pharmacists could be additionally trained and supported to assist families in understanding this information when medications are dispensed. Families also suggested the need for redress to (1) regional shortages in child and adolescent psychiatrists, (2) insurance coverage gaps in mental health benefits, and (3) lack of evidence-based and parent- and youth-targeted information on antipsychotic prescribing for youth. These findings are consistent with other

studies that also emphasize challenges for caregivers and youth in receiving coordinated care, as well as access to psychosocial treatments and child and adolescent psychiatrists. Partnerships with youth and caregivers at both the organizational and policy levels are central to identifying and addressing concerns such as those raised in the report provided by FREDLA. Notably, engagement of youth and caregivers is critical to identifying local needs and priorities ensuring responsiveness to the diverse constituencies and contexts nationally.

Representation of youth and families ideally parallels the sociodemographic and clinical diversity of the communities served with particular efforts made to engage those youth who are historically underrepresented, including youth who are racial/ethnic or sexual and gender identity minorities, non-native English speakers, in out-of-home placements, as well as youth with intellectual and developmental disabilities (such as autism spectrum disorder). As further described in Strategy 4, opportunities for shared-making during direct care may also be supported by peer support from individuals with shared experiences or from similar backgrounds whether cultural, linguistic, or geographic.

Figure 3. Model for Youth and Caregiver Partnership, adapted by Youth MOVE National from Carman et al.¹



Invest in a Multi-Modal Approach

Participants in the expert convening emphasized that long-term change in evidence-based antipsychotic prescribing will require implementation of more than any one strategy to address the multiple challenges to safe and effective prescribing. Prescribing decisions are not solely reflective of the knowledge that prescribing clinicians have but are fundamentally multifactorial, reflecting a number of other considerations. Other considerations identified by the committee included access to non-pharmacological

trauma-informed and evidence-based interventions, workforce shortages in mental and substance use services, and pressures for antipsychotic medication treatment potentially exerted from school settings, out-of-home placements, and caregivers.

Accordingly, participants of the expert convening emphasized the importance of multi-modal initiatives that support prescribing clinicians in making evidence-based treatment decisions. This guidance reflects this recommendation by providing summary sheets on each of the multiple strategies available, the evidence supporting the respective strategy, and highlighting promising practices. As noted on the summary sheet dedicated to multi-modal strategies (Strategy 9), multi-modal strategies can be centralized to a single location of accountability (e.g., Medicaid managed care organization) or decentralized across youth-serving public sector systems. Regardless of the approach taken, particular attention should be given to ensuring the approach is supportive of both youth and their families as well as prescribing clinicians who are already operating in an overstressed and underresourced mental and substance use care delivery system.

Engage Prescribing Clinicians

Determinants of antipsychotic prescribing are multi-factorial and not exclusively reflective of provider knowledge of evidence-based practice. Strategies to encourage the use of evidence-based antipsychotic prescribing should *support* prescribing clinicians in making evidence-based decisions in light of the many factors that may be impeding their ability to do so. Promising practices outlined in the strategy-specific summaries emphasize this recommendation, including (1) collaborative peer review processes for consultation and monitoring, (2) making the consultation useful to the prescribing clinician by pursuing the opportunity for education, and (3) minimizing the “hassle” factors that may contribute to denying youth antipsychotic medications when needed. The expert convening participants also emphasized the value of providing Continuing Medical Education credits to clinicians in providing training on evidence-based antipsychotic treatment where possible.

Consider the Unique Needs of Special Populations

The needs of special populations require careful consideration at every stage of development, implementation, and evaluation of strategies for evidence-based antipsychotic prescribing. Steering Committee members pointed out the unique factors that contribute to concerns around safe and effective use of antipsychotic medications among racial and ethnic minority groups. Notably, the analytic report for this study found that increased rates of antipsychotic use persisted for racial and ethnic minorities, including youth who were non-Hispanic Black, Hispanic, and non-Hispanic other, from 2011 to 2015. Given this evidence of increased rates of antipsychotic use among many of these populations and historical and contemporary inequities in quality mental and substance use treatment, the unique context and histories of these communities require consideration. To address the unique challenges confronting these communities, attention should be provided to innovative approaches that respond to the unique needs and preferences of these communities as well as provide redress to the obstacles that youth and families from these communities face in receiving safe and effective antipsychotic medication (e.g., investments in culturally and linguistically appropriate treatment alternatives).

Youth with child welfare involvement and who are in foster care are a second population for whom particular consideration should be given to their unique needs. Having experienced maltreatment (whether abuse and/or neglect), these youth frequently have complex histories of trauma and treatment decisions need to be responsive to these experiences accordingly. In addition to disproportionate exposure to trauma, additional challenges exist for this subpopulation, including higher likelihood of

medical neglect prior to child welfare involvement, limited medical health histories (even when previously engaged in services), and multiple transitions possible once placed in care. Additionally, the State serves as “in loco parentis” or “in place of the parent” for these youth requiring additional assurances of “safe and effective” use of antipsychotic medications.

Capitalize on Opportunities to Coordinate with Other Youth-Serving Systems at All Levels of Governance

Youth with mental health conditions interface not only with the mental health entities within a given jurisdiction but also with other public sector systems as well, including early intervention, child welfare, juvenile justice, and public insurance systems (i.e., Medicaid). School systems also are an important location for developmental and mental health services.

The Joint Letter from the Administration for Children and Families, Centers for Medicare & Medicaid Services, and Substance Abuse and Mental Health Services Administration sent to Directors of State Medicaid, mental health, and child welfare agencies provided a strong framework for opportunities to coordinate public sector agencies.¹⁴ Moreover, the Federal government subsequently sponsored the *Because Minds Matter* summit, a national convening of two representatives from State Medicaid, mental health, and child welfare agencies. Given evidence of extensive innovation in public sector innovation following the *Because Minds Matter* summit, participants in this guidance’s expert convening advised that comparable efforts to facilitate multisectoral collaborations be pursued in the future. Notably, participants thought Federal agencies were uniquely and powerfully situated to further support ongoing multisectoral collaborations.

The importance of coordination across youth-serving settings at the State and county levels is an imperative given transitions that frequently occur between these public sector systems for youth, especially as they “age out” specific delivery systems. These transitions are opportunities for both treatment lapses and mismanagement, especially when resources to facilitate coordination are not deployed. For children in out-of-home placements (such as foster care), medical histories can be incomplete, so coordination, compliant with patient privacy protections, between public sector systems (e.g., schools, mental health entities, Medicaid agencies, health care systems) are of particular importance. Notably, coordination efforts across these agencies should also be youth and family centered, ensuring access to necessary medical information.

Invest in Sustainable Financing Mechanisms

Consideration should be given to how financing can be generated to facilitate longer term investments in a collaborative process with youth, families, prescribing clinicians, and other youth-serving systems. Incremental roll-out of the nine strategies outlined below, consistent with quality improvement initiatives, may be one way to gauge operational costs and potential savings and make an argument for scale-up; data on return on investment may be especially useful in ensuring sustainability, especially as cost-saving may be seen across multiple youth-serving sectors. When grant or contract funding is available, investment should be prioritized in building an infrastructure to support the sustainability of strategies and generate more sustainable approaches. Given the imperative for sustainable financing mechanisms, each of the nine strategies reviewed in the following section provides considerations for sustainable financing.

Part E. Strategies to Promote Antipsychotic Medication Oversight and Best Practice Prescribing

In this section, we provide a summary for each of the nine strategies identified that integrates the various sources of information contributing to this guidance. Each summary sheet provides the following information:

- **A Description of the Strategy.** Defines the respective strategy, extent of variation in approach, and prevalence of implementation nationally (where available).
- **Evidence of Effectiveness.** Summarizes findings from the evidence review conducted for this guidance.
- **Case Study.** Highlights a specific example with additional resources provided for further information, drawing upon the environmental scan.
- **Promising Practices.** Describes suggestions for best practice provided by participants in the expert convening and peer-review literature.
- **Financing and Sustainability.** Provides consideration for the financing and sustainability of the respective strategies.

Strategy 1: Prior Authorization and Mandatory Peer Review

Description

Prior authorization (PA) is an administrative tool used by a health plan or prescription benefits management company that requires, under the terms of the pharmacy benefits plan, the prescribing clinician to receive approval prior to the medication (e.g., antipsychotic medication) being dispensed.⁵⁸

PA programs vary in five key attributes. First, PA programs range in the age-restricted criteria applied, varying from applying only to very young children to all youth younger than 18 years.⁵⁹ Second, PA programs vary in whether they incorporate mandatory peer review into the authorization process or rely on an administrative review alone. Clinicians incorporated into a peer review process vary in their clinical training (e.g., child and adolescent psychiatrists, nurse practitioners, pharmacists, registered nurses). Third, PA programs range in the specific criteria used to trigger a review. For example, Washington State restricts access to specific types of antipsychotic medications at different age criteria (Olanzapine <3 years of age; Risperidone <3 years of age, and other atypical antipsychotic medications <5 years of age.)¹⁷ Fourth, PA programs vary in whether they provide review only at initiation of antipsychotic medication use or provide periodic reviews. For example, in the Maryland Peer Review Program, providers are required to submit updated information during periodic reviews. Administrators of the Maryland program suggest benefits of periodic reviews include opportunities to (1) monitor dose and side effects over the course of treatment; (2) support new providers during health care transitions (e.g., from specialist care to a primary care provider); and (3) inform treatment decisions when risk-to-benefit ratio changes significantly over time (e.g., patient develops pre-diabetes). Finally, PA programs vary in whether the initial antipsychotic prescription will be authorized prior to review. PA programs may not provide a “hard stop” at the time of dispensing but rather provide a specific window within which authorization must be granted after dispensing (e.g., 60 days). If access to medications are delayed during the authorization period, there is a risk of potential psychiatry decompensation or additional safety concerns (e.g., aggression). However, if the medication is dispensed without secondary peer review, there is potential for negative consequences from high start doses (e.g., child has a dystonic reaction or marked sedation) or undetected drug

interaction concerns. Programs may seek to balance these concerns by either allowing provision of an “emergency” short-term supply or specifying conditions in which the patient can fill the initial prescription (e.g., with dose restrictions). As of 2015, 31 States had implemented a PA program for Medicaid-insured youth.¹⁷

Case Study. Washington State’s Psychiatric Access Line and Mandatory Peer Review⁶⁰

Through a collaboration of Washington State Medicaid, University of Washington faculty, and Seattle Children’s Hospital, Washington State established the Partnership Access Line (or “PAL”), an elective consultation service seeking to improve access to child and adolescent psychiatric expertise for primary care settings. Although not the specific goal of the consultative line, the PAL frequently provides consultation on antipsychotic treatment within primary care settings. Subsequent to PAL implementation, PAL’s consultative team began providing mandatory medication second opinion reviews of antipsychotic prescriptions that fall outside State-set prescribing guidelines. This State approach leverages the use of peer review as part of a mandatory review process prior to dispensing of antipsychotic medications. In Washington, there was also a push to recommend psychosocial services, so the program added a social worker who helps providers identify local resources for these services. After implementation, the monthly prevalence of antipsychotic medication fell by a mean of .022 per thousand per month and subsequently by .065 following the initiation of age/dose triggered mandatory reviews ($p < .001$), and then fell another .022 after initiation of two or more concurrent antipsychotic medication reviews ($p = .001$). Moreover, high-dose antipsychotic use fell 57.8 percent in children 6 to 12 years old and fell by 52.1 percent in teenagers.

Evidence Available

Of the seven PA programs that evaluated the significance of implementation on antipsychotic medication dispensing, six PA programs yielded a significant reduction in antipsychotic medication use among all age groups targeted by the respective PA programs.⁶⁰⁻⁶² One evaluated PA program had a significant effect for young children (<6 years of age) and no discernible effect for older youth targeted in an expansion of the PA program (7 <13 years of age).⁶³

Limited evidence existed as to whether the reduction in antipsychotic medication treatment for the targeted age cohort (e.g., young children) holds a “spillover effect,” reducing antipsychotic prescribing among a non-targeted cohort (e.g., youth). Of the four programs for which a spillover effect was evaluated, three programs showed that youth who were not in the age range for which a prior authorization was required actually had a significant *increase* in prevalence of antipsychotic medication prescribed after PA implementation. In contrast, one program decreased antipsychotic prescribing in all age groups, although the prior authorization was only triggered in the youngest group.⁶¹ Of the two studies investigating potential increased prescribing in other classes of medication when antipsychotics are restricted, one study found little evidence of any substitution effects and another found all other psychotropic medications significantly decreased after initiation of the PA for antipsychotic medications among young children (<5 years old).⁶⁴

One study sought primarily to examine how PA influenced prescribing behaviors of clinicians rather than overall reductions in use.⁶⁵ This study found that PA significantly reduced the likelihood of prescribing by

child and adolescent psychiatrists but not other prescribing clinicians (e.g., pediatricians, general psychiatrists, neurologists).

Promising Practices

Based on a presentation and comments provided by participants in the expert convening, the following practices were suggested regarding prior authorizations:

- **Incorporate a routinely provided peer review process and telephone consultation into the PA process.** Expert convening participants emphasized the importance of a clinically structured review that provides opportunities for training and presents value to the prescribing clinician. Additionally, the written rationale often does not provide enough information alone, so phone consultations assist in collecting additional information and providing feedback.
- **Develop relationships with the office staff of the prescribing clinician when serving as a consultant.** Creating relationships and educating the office staff can help to increase the response rate to mandatory prospective reviews. Office staff tend to have a good response rate and low turnover, which makes them good designees for general inquiries.
- **Exercise caution when using “hard stops” at the pharmacy.** On the one hand, safety concerns can arise when medication is dispensed prior to review, such as with high start doses or drug interactions. On the other hand, some providers, youth, caregivers, and families also expressed concern when the “hard stop” resulted in inability to obtain medication when needed. Clinicians expressed particular challenges when the “hard stop” required extensive documentation. Some cases are crisis situations, so consideration should be given to opportunities for providing an authorization window. Some jurisdictions allow for an “emergency,” short-term supply while the review is pending. Other States, such as Washington, hold a 60-day authorization window while the review is pending.
- **Acquire input from relevant stakeholders, including families and youth, prescribing clinicians, pharmacists, and local delivery system needs at every stage of PA program development, implementation, and evaluation.** Concerns were expressed by multiple stakeholder groups about barriers to necessary care that may be introduced by PA programs. Such unintended consequences are possible given the relatively undifferentiated approach of PA programs, especially without an authorization window (as recommended above). Active involvement of relevant stakeholders and consideration of the potential for additional “burdens” that may be placed upon prescribing clinicians, youth, and families are important elements of PA program development and evaluation.

Financing and Sustainability

Prior authorization programs for antipsychotic medication prescribing among adults have generated immediate cost savings to Medicaid.⁵⁸ Notably, little evidence exists to inform overall return on investment for PA programs for antipsychotic use among youth; such studies would estimate implementation costs for conducting a mandatory peer review or PA program and then consider both the intended cost savings (i.e., antipsychotic dispensing) and evaluate potential unintended cost savings (e.g., substitution effects, spillover effects, other service utilization).

Strategy 2: Drug Utilization Reviews

Description

Drug utilization reviews (DURs) are an authorized, structured, and ongoing review of prescribing, dispensing, or use of medication. Although definitions vary, DUR in this guidance refers to retrospective reviews, initiated after dispensing of the antipsychotic medication. Drug utilization reviews involve a review of medications prescribed against predetermined criteria (frequently referred to as “red flag criteria”) that result in notification of the prescribing clinician.

Drug utilization reviews vary in three fundamental ways. First, DURs vary in the notification provided to prescribing clinicians, ranging from written materials to telephone consultations and academic detailing. Second, DURs vary in the specific “red flag criteria” used. Generally, DURs employ metrics that are consistent with available practice parameters or consensus statements for antipsychotic medication treatment. Third, DURs range in the extent to which they are implemented on an ad hoc basis, or routinely conducted (e.g., every quarter, biannually, or annually).

Case Study. Texas Psychotropic Medication Utilization Parameters for Foster Children⁶⁶

In efforts to “encourage proper prescribing,” Texas Department of State Health Services released best practice guidelines for both providers and the State child welfare staff entitled *Psychotropic Medication Utilization Parameters for Foster Children*. Through a process of expert consensus, these parameters were developed by a panel of child and adolescent psychiatrists, psychologists, guideline development specialists, and other mental health experts for use specifically with youth in foster care. Through a DUR process housed within the child welfare agency, State child welfare staff would identify and then work with individual prescribing clinicians whose patients’ medication regimens fell outside the specific indicators set for safety and quality concerns. These utilization parameters are routinely updated, although at the time of this guidance they included the following criteria:

- (1) Psychotropic medication prescription exceeds usual recommended doses as specified in dosage guidelines;
- (2) Psychotropic medication use without primary indication;
- (3) Prescription of psychotropic medication without mental health diagnosis;
- (4) Combination of psychotropic medication across classes of five or more psychotropic medications prescribed concurrently;
- (5) Two or more psychotropic medications prescribed before utilizing monotherapy;
- (6) Two or more concomitant medications prescribed from within the same class for: antidepressants, antipsychotics, stimulant medications;
- (7) Three or more mood stabilizer medications concurrently;
- (8) Prescribing antidepressants and antipsychotics to children younger than 4 years old;
- (9) Psychostimulants to children younger than 3 years old; and
- (10) Cardio-metabolic side effect monitoring.

Annual trends analysis reported from 2005-2007 indicate reduction in rates of antipsychotic prescribing among youth receiving the DUR since its implementation in February 2005.

Evidence Available

Drug utilization reviews were identified in two studies and both focused specifically on Medicaid-insured children in foster care.^{66,67} Implemented in Texas, one DUR process specifically targeted a set of best practice parameters that were developed through a process of expert consensus and evidence review.⁶⁸ In the second DUR, Mississippi Care Coordination implemented a review that sought to improve the monitoring of cardio-metabolic side effects among children and youth who were prescribed antipsychotics in foster care. Annual trends analysis (FY 2002-FY 2017) of key indicators and best practice parameters implemented in Texas suggest decrease in antipsychotic prescribing over time since program implementation in February 2005.⁶⁸ The Mississippi DUR program did not demonstrate significant changes in prescribing patterns 2 years after implementation.⁶⁷

Promising Practices

Based on comments provided by participants of the expert convening and extant literature, the following practices were suggested in advancing DUR programs:

- **Place emphasis on supporting prescribing clinicians, youth, and families.** DURs should *engage* prescribing clinicians with consensus-driven or evidence-based practice recommendations. Such strategies might include the integration of educational tools including access to elective or mandatory peer consultation in reconsidering treatment decisions (see Strategy 3, Elective Psychiatric Consultation).
- **Employ strategies that provide opportunities for clinician education and feedback.** DURs or red flag criteria when distributed as a letter of notification, alone, have demonstrated a small to moderate impact in aligning practice with established safety thresholds among adults.⁶⁹ When DURs are coupled with educational materials or “performance report cards” bench-marking against peers, studies suggest a moderate to strongly significant impact of the DUR on measures of medication safety for adults.⁶⁹

Financing and Sustainability

With DUR programs in place within many insurance programs (including Medicaid), the ongoing and periodic examination of claims data is frequently embedded within program operations to investigate potential abuse, inappropriate use, or medically unnecessary care and takes corrective action as needed. While limited studies have been conducted on financing and sustainability of DURs, the intention of these programs to curb inappropriate and medically unnecessary care likely facilitates cost-effectiveness.

Strategy 3: Elective Psychiatric Consultation

Description

Elective psychiatric consultations typically facilitate access to child or adolescent psychiatrists for providers in primary care settings. These models intend to help ensure that youth receive appropriate mental and substance use treatment.⁶⁰ While motivated by the primary goal of extending child and adolescent psychiatric services to areas where mental and substance use service shortages exist and integrating care, elective psychiatric consults also support primary care providers in making antipsychotic treatment decisions.⁷⁰ These psychiatric consultations offer an avenue for prescribing clinicians to discuss treatment options with a child and adolescent psychiatrist in helping to ensure youth receive appropriate treatment. Consultations may be provided in person, over the phone, or through telepsychiatry. Nationally, elective psychiatric consultation lines are reported to exist in multiple States, including Alaska, Arkansas, Florida, Illinois, Iowa, Louisiana, Maine, Massachusetts, Minnesota, New York, Ohio, Texas, Washington, and Wyoming.⁷¹

Case Study. The Massachusetts Child Psychiatry Access Project Model (MCPAP)⁷²

In 2004, Massachusetts established a statewide system of six regional children's behavioral health consultation hubs at academic medical centers. These hubs aim to provide support to any provider within an enrolled primary care practice consultation on child psychiatry regardless of the child's insurance status. Each hub is staffed with a full-time child psychiatrist, a licensed therapist, and a care coordinator. A hotline serves as an entry point for pediatric primary care providers. The hub provides services such as immediate clinical consultation over the telephone, expedited face-to-face psychiatric consultation, care coordination for assistance with referrals to community behavioral health services, and continuing professional education. MCPAP uses an individualized, educational mentoring model with each practice that is enrolled. An initial meeting allows both parties to gain an understanding of the expectations for the project and how comfortable the practice is with mental and substance use treatment. According to administrative data from 2013, 47 percent of the telephonic consultations resulted in no medication being prescribed. These findings suggest telephonic consultations were able to promote referrals to non-pharmacological alternatives in some cases. In 2014, primary care providers reported being able to manage 67 percent of the patients that they would have referred to a child and adolescent psychiatrist prior to MCPAP enrollment.

Evidence Available

The implementation of telepsychiatry programs in Washington, Wyoming, and Massachusetts have been associated with reductions in psychotropic medication prescribing.⁷³ In Wyoming, the implementation of a psychiatry access program reduced the number of Medicaid children ≤5 years of age using psychotropic medications by 42 percent ($p < 0.001$) while the number of children using psychotropic doses greater than 150 percent of the Food and Drug Administration maximum decreased by 52 percent ($p < 0.001$).⁷⁴

Promising Practices

Based on comments provided by the participants in the expert convening and extant literature, the following practices were suggested in advancing retrospective review of antipsychotic medications with elective psychiatric consultations:

- **Provide consultations in more than just the written word.** Phone conversations can help with the communication of details between providers and allow for more directed and clear feedback on best practices.
 - **Be consistent in messaging across consultants.** While multiple clinicians may provide consultations, it is important to ensure consistency in the consultation messaging and feedback.
 - **Make the consultation useful and create a bi-directional flow.** Operating in a collaborative fashion and providing education have improved the receptivity of prescribing clinicians to the secondary review. If approached as a collaborative process, prescribing clinicians see the consultation as supportive to their work.
 - **Provide consultations in real time to facilitate meaningful engagement.** Availability of the consultation in real time generates opportunities for shared decision-making among the youth, caregivers, consultant, and prescribing clinician. This also allows for timely involvement, preventing delays in treatment when necessary.
-

Financing and Sustainability

Opportunities exist to leverage funding made available in the Centers for Medicare & Medicaid Services Billing Code, in which Federal funding can cover up to 75 percent of costs incurred by States associated with consultations provided by a skilled medical professional, such as the child and adolescent psychiatric consultant. To leverage these funds, written agreements are required between the Medicaid agency and respective practice settings. In Minnesota, both the consultant and the primary care provider are able to bill for the consultation services received. Of note, an examination of an elective psychiatric consultation line in Wyoming found a financial return on investment of 1.0 to 1.8 on mental and substance use services after implementation of the elective psychiatric telephone line.⁷²

Strategy 4: Shared Decision-Making Tools for Youth and Families

Description

Shared decision-making is the process by which the potential benefits, risks, and costs of being prescribed antipsychotic medications are discussed and considered collaboratively among providers, families, and youth. Decision aids and other shared decision-making tools prioritize transparency in the potential benefits and risks of antipsychotics. Potential outcomes of decision aids for prescribing include increased patient knowledge of available treatments, greater participation in decision-making, and improved patient health status and quality of life.⁷⁵ Multiple examples of materials to support education and decision-making in psychotropic prescribing exist, although it is not clear how much they are promoted or disseminated by States. Materials are available from the American Academy of Child and Adolescent Psychiatry,⁷⁶ National Alliance on Mental Illness,⁷⁷ Texas Department of Family and Protective Services,⁷⁸ University of South Florida,⁷⁹ and Ohio Minds Matter, a partnership with the Best Evidence Advancing Child Health in Ohio Now (BEACON) and the State of Ohio.⁸⁰

Case Study. Making Healthy Choices: A Guide and Companion Guide on Psychotropic Medications for Youth in Foster Care⁸¹⁻⁸³

In 2012, the United States Children's Bureau published a guide, entitled *Making Healthy Choices: A Guide on Psychotropic Medications for Youth in Foster Care* (available in both English and Spanish) providing information for youth in foster care related to making decisions about mental and substance use treatment, treatment options, and the use of psychotropic medications (including antipsychotic medications.) The decision provides checklists and worksheets for youth to consider the potential benefits and costs associated with antipsychotic treatment in relation to their own values and preferences. In 2015, a companion guide, *Supporting Youth in Foster Care in Making Healthy Choices*, was published that aims to help caseworkers, foster parents, and other caregivers learn about the trauma experienced by children in foster care and present treatment options, including but not limited to psychotropic medications.

Evidence Available

There is limited evidence regarding the effectiveness of decision aids for antipsychotic treatment among youth specifically.^{25,84-86} However, a growing body of evidence demonstrates the effectiveness of decision aids to facilitate shared decision-making more generally for people with mental illness.⁷⁵ Future research would be especially helpful to promote use of evidence-based tools that are responsive to the well-

documented concerns of inadequate youth and family engagement around antipsychotic medication treatment decisions.^{25,84-86}

Promising Practices

Based on comments provided by participants of the expert convening and extant literature, the following practices were suggested to advance tools to promote caregiver and youth education and shared decision-making:

- **Provide evidence-based and consensus-driven information about potential benefits and side effects of antipsychotic medications.** Youth and their caregivers need to have accurate information about potential trade-offs.
- **Pursue ancillary supports for decision aids to facilitate uptake.** Development of guides that are specific to the unique needs of youth, families, and service providers should be considered. For example, the *Making Healthy Choices Guide*, referenced above, evolved to include a companion guide for caregivers in response to the need for supporting them and other service providers in assisting youth with the treatment decisions.
- **Invest in youth and family peer support.** Opportunities also exist in engaging youth and family peer support as those with lived experience may hold a unique ability to assist in educating and advocating for youth and family engagement in treatment decisions. Family and youth organizations are in almost every State and can be a valuable partner in providing peer support. More evidence is needed to determine how and when youth and family peer support should best be utilized.
- **Leverage technology and social media to encourage use and dissemination.** Relatively untapped opportunities exist to leverage technology, including phone-based apps and social media-based campaigns, to implement and disseminate decision aids and other tools to provide education to youth and their families.
- **Target initiatives to engage special populations who are historically not adequately engaged in decisions.** Shared decision-making tools and education efforts should consider and be adapted to engage youth and their caregivers who hold unique challenges in delivery system engagement, including younger children, youth with serious mental and substance use disorders (e.g., youth with Autism Spectrum Disorders, racial/ethnic minorities, and non-English speakers).
- **Incorporate youth and family voice not only in treatment decisions but also in organizational and policy improvement efforts.** Engagement of youth and caregivers in the clinical decisions is important, but so too is engagement in organizational and delivery system decision-making; for example, Youth MOVE National is currently developing a “Change Packet” to assist health plans in better understanding the perspective and leveraging youth voice.
- **Ensure potential side effects are known and develop a plan for early identification and wellness.** Processes of shared decision-making should also include planning to address potential side effects, such as developing an approach to facilitate early identification or a wellness plan for dietary adjustments and routine exercise to mitigate legitimate concerns around weight gain.

Financing and Sustainability

Shared decision-making tools have been generated through discrete financing of a specific initiative sponsored by public (e.g., Children’s Bureau), private (e.g., health insurance systems), and professional agencies (e.g., American Academy of Child and Adolescent Psychiatry). Dissemination of these tools has chiefly occurred through Web-based resources rather than active technology-based strategies. Some promising practices do exist in generating quality improvement campaigns to facilitate targeted

integration of tools supporting shared decision-making (see Strategy 5). Opportunities exist for additional study on how to proactively embed the use of these decision aids and shared decision-making tools into delivery systems through vehicles such as phone-based apps, youth and family peer support, or case managers. An integral part of studies will be assessment of return on investment and cost-effectiveness to ensure sustainability and scale-up of evidence-based decision aids.

Strategy 5: Quality Improvement and Learning Collaboratives

Description

Quality improvement (QI) initiatives, combined with a learning collaborative, are increasingly promoted to improve attainment of evidence-based practices in various health care delivery systems.⁸⁷ Although variations exist in approach, these initiatives typically engage stakeholders in the process of designing, implementing, evaluating, and continuously modifying strategies to improve delivery systems in “cycles of change.” These strategies have been used to address delivery system challenges with multifactorial quality concerns and emphasize incremental progress. Although no national estimates of the prevalence exist, examples of these initiatives have targeted safe and effective use of antipsychotic medications within specific institutions, delivery systems, and larger jurisdictions (e.g., counties and States).⁸⁸

Case Study. Ohio Minds Matter Initiative: Quality Improvement Learning Collaborative⁸⁸

Sponsored by the Best Evidence Advancing Child Health in Ohio Now! (BEACON) and the State of Ohio, multiple stakeholders were convened to develop a Medicaid statewide QI collaborative aimed to improve antipsychotic prescribing practices for youth. The initiative employed a multi-strategy approach that incorporated:

- (1) Online resources targeted to multiple stakeholders (i.e., youth and caregivers, prescribing clinicians, and school and agencies).
- (2) Targeted Web-based training.
- (3) Data-driven feedback.
- (4) Evidence-based recommendations.

Ohio Minds Matter resulted in statistically significant improvements in three measures: antipsychotics prescribed to children younger than 6 years old, dispensing of two or more concomitant antipsychotics for at least 2 months, and concomitant prescribing of four or more psychotropic medications.

Evidence Available

The evidence review identified six studies that examined QI initiatives, with five distinct initiatives examined.^{51,52} Of the five initiatives evaluated, three focused on opportunities for improvement in monitoring for cardio-metabolic side effects^{51,52,89-94} while two of the programs focused generally on opportunities for aligning antipsychotic prescribing with best practice parameters.^{27,34} Two of the initiatives explicitly used a QI framework for ongoing engagement of practice settings^{34,51,52} while three of the QI initiatives applied an educational and training framework for clinicians, youth, caregivers, and/or youth-serving partners.^{27,29,89}

Of the five initiatives evaluated, all QI programs achieved a significant short-term effect of at least one primary outcome assessed. Two of the studies found significantly improved indicators of cardio-metabolic

monitoring^{29,51} while a third found the implementation of best practice guidelines reduced facility-level psychotropic medication costs (employed as a proxy for psychotropic medication use) while not affecting facility-level aggression incidents.²⁷ Thackeray and colleagues found a QI collaborative significantly reduced multiple outcomes (i.e., new antipsychotic initiation, antipsychotic co-pharmacy, and psychotropic medication polypharmacy) in one regional QI collaborative while significantly reducing antipsychotic co-pharmacy alone in the second regional QI collaborative (with no discernible effect on new initiation or psychotropic medication polypharmacy).⁸⁸ Ronsley and colleagues found implementation of a metabolic monitoring training program significantly improved indicators of cardio-metabolic monitoring at 3 and 6 months with nonsignificant and relatively modest improvements 12 months after implementation.⁹²

Promising Practices

Participants from the expert convening and extant literature identified the following promising practices when planning and implementing QI initiatives:^{70,72}

- **Incorporate stakeholder engagement into QI initiatives.** Stakeholder engagement at the initiation of the QI collaborative is an important part of gaining investment from multiple stakeholders during implementation of the initiative.⁸⁸
- **Customize QI approach to address specific different delivery system needs.** In large-scale implementation efforts of quality improvement and learning collaboration, efforts should be taken to ensure customization of approach to the unique challenges that may confront different delivery settings (e.g., community mental and substance use treatment, residential treatment, academic medical centers).
- **Target more than one aspect of the challenges presented to safe and effective antipsychotic prescribing.** QI initiatives optimally not only address the prescribing clinician's knowledge of best practice but also consider opportunities to address the multiple other factors influencing antipsychotic treatment decisions, such as access to treatment alternatives (e.g., psychosocial therapies) or educational materials to provide information to youth-serving partners (e.g., schools, parents, courts, among others) who might otherwise place pressure to maintain medication.
- **Develop an infrastructure for QI collaboration.** Development of infrastructure for QI collaboratives is an important pre-condition to implementation, including assurances of leadership supporting the initiative, attainment of maintenance of certification competencies, and the necessary data infrastructure to facilitate the use of data to inform modifications and the "cycle of change."

Financing and Sustainability

Concerns in sustainability of discretely funded initiatives have led to recommendations that QI initiatives be built into the infrastructure of the respective institution, delivery system, or Statewide or countywide initiative (rather than funding through discrete grants or contracts). States, such as Ohio, have sought to extend QI initiatives through incorporation of the National Committee for Quality Assurance (NCQA) antipsychotic measures into the standards for patient-centered medical homes while other States have incorporated these metrics into Medicaid managed care contracts.

Strategy 6: Trauma-Informed and Evidence-Based System of Care

Description

Concerns expressed both in the peer review literature and among the expert convening participants highlight that the reliance on antipsychotic medication treatments may, in some cases, be related to

shortages in availability of non-pharmacological alternatives such as behavioral therapies, psychological therapies, and other psychosocial services. Such shortages may have multiple causes, including inadequate reimbursement rates for mental health and workforce shortages. Investment in a system of care that finances an array of services and supports for children and youth and prioritizes both trauma-informed and evidence-based psychosocial treatments is frequently identified as an important pre-condition or adjunct to monitoring and quality improvement efforts in antipsychotic treatment among youth.⁸⁸ As conceptualized by SAMHSA, a system of care is a broad array of effective services and supports for children and adolescents with mental and substance use disorders and their families that is organized into a coordinated network, integrates care planning and management across multiple levels, is culturally and linguistically competent, and builds meaningful partnerships with families and youth at service delivery, management, and policy levels.⁹⁵ Trauma-informed systems may exist in a program, organization or system that:

- “Realizes the widespread impact of trauma and understands potential paths for recovery;
- Recognizes the signs and symptoms of trauma in clients, families, staff, and others involved with the system;
- Responds by fully integrating knowledge about trauma into policies, procedures, and practices;
- Seeks to actively resist *re-traumatization*.”⁹⁶

Best practice in antipsychotic medication treatment aligns strongly with the priorities of a system of care.³⁶ The goal of the use of antipsychotic medication treatment for youth with complex mental and substance use treatment needs should be to provide safe, effective and evidence-based prescribing in the context of youth and family-centered and trauma-informed mental and substance use treatment. Particularly for youth with complex mental and substance use treatment needs, guidelines indicate antipsychotic medication should not be prescribed as the sole treatment modality and should be part of a broader treatment plan to include psychosocial supports and therapies.³⁶ Trauma-informed systems of care that finance evidence-based psychosocial treatments exist nationally although vary substantially in their approach and the service array routinely made available.

Case Study. The New Jersey Children’s System of Care⁹⁷

Highlighted by the expert convening participants as a promising practice, the New Jersey Children’s System of Care (CSOC) moved to a statewide implementation in 2008. The System of Care provides a service array that aims to assist youth in (1) living successfully with their families and reducing the need for out-of-home treatment, (2) successfully attending the least restrictive and most appropriate school setting close to home, and (3) participating successfully in the community and becoming independent, productive, and law-abiding citizens. In ensuring that youth receive necessary services, a contract service administrator creates pathways for youth and young adults to access the right care at the right time. The contracted services administrator authorizes services, based on the most recent clinical information that is submitted to them. Each child is evaluated by a local clinician, who must be approved by CSOC to perform the assessment (when there are no current clinical evaluations) to help determine the intensity of service necessary.

The New Jersey CSOC provides an array of community-based wraparound services and out-of-home treatment services to children and families. Community-based wraparound services may involve almost any service supporting community living for children, including 24/7 mobile response services in every county. All youth in out-of-home care receive an underlying foundation of trauma treatment, promoted further by a recent implementation of Six Core Strategies[®] to Reduce Seclusion and Restraint Use and The Nurtured Heart Approach.[®] In 2012 preceding the transition of children's services to CSOC, New Jersey was approved by the Centers for Medicare & Medicaid Services to implement a 1115 waiver, which included many components now managed by CSOC, including an Emotional Disturbance program, thereby allowing Federal participation in financing for additional services accessed through the CSOC.

Evidence Available

While an array of multi-State and State-specific evaluations of trauma-informed system-of-care innovations exist, the environmental scan and evidence review did not identify any studies that examined specifically how investments in a trauma-informed system of care and trauma-specific interventions affected antipsychotic medication treatment and evidence-based practices. This is an area warranting future study.

Promising Practices

Although the expert convening participants emphasized the availability of evidence-based psychosocial services as a first line or concomitant treatment approach with antipsychotic medication, participants also noted that these were frequently not being used as a first line treatment alternative. Suggestions included:

- **Provide access to psychosocial and other therapeutic services.** Provide youth and caregivers the opportunity to build skills through psychosocial and other therapeutic services provided to the youth, parent, and/or family as a first line or concomitant treatment option. As one convening member said, “medications don’t teach skills.”
- **Create a trauma-informed system of care.** Investments in a system of care that is infused with trauma-informed practice and provides family- and youth-centered services and strength-based, comprehensive, individualized, and community- and team-based services.
- **Engage youth and caregivers in treatment decisions related to non-pharmacological alternatives.** Informed youth and families may hold preferences in specific therapeutic strategies, such as manualized evidence-based strategies that are time delimited. Youth and family preferences should be instrumental in the process of treatment planning.
- **Consider reexamining reimbursement rates.** Low reimbursement rates for evidence-based psychosocial therapeutic services may generate disincentives in using these treatment alternatives as part of the comprehensive treatment plan for youth. Advocates and public administrators can therefore work with State Medicaid agencies to optimize reimbursement for psychosocial services.

Financing and Sustainability

Although challenges associated with financing and sustaining trauma-informed evidence-based psychosocial treatments are well-documented, multiple resources exist to inform approaches to finance and sustain these service arrays as well as to facilitate finance improvements for the workforce and provider network.⁹⁸ Notably, efforts have also emphasized the importance of building evaluation

structures that assess the return on investment and cost-effectiveness of these investments, including potential cost savings associated with reductions in antipsychotic medication treatment.⁹⁹

Strategy 7: Public Reporting and Quality Indicators

Description

Consensus-driven performance metrics for claims databases were recently developed to assess whether antipsychotic practice parameters are met among youth. Projects supported by the National Committee for Quality Assurance (NCQA), MEDNET and the Pediatric Quality Measurement Program, facilitated the development of three metrics subsequently selected into the Healthcare Effectiveness Data and Information Set (HEDIS) quality measure set, including (1) concurrent use of multiple antipsychotics, (2) use of first line psychosocial care for children on antipsychotic medications, and (3) use of metabolic screening for children who are prescribed antipsychotic medications.^{100,101} The first two of these performance metrics were incorporated into the CMS 2017 Core Set of Children’s Health Care Quality Measures.¹⁰² Incorporation of these quality metrics for antipsychotic prescribing among youth provide opportunities for public reporting (in addition to use in Drug Utilization Reviews and Quality Improvement Initiatives, as articulated in Strategies 2 and 3, respectively). While public reporting of hospital and provider performance occurs in other domains of health and mental health care (e.g., Hospital Compare),¹⁰³ limited examples of public reporting at the provider or hospital level were found in the environmental scan and evidence review conducted for this guidance.

Case Study. Government Accountability Office Report Entitled “Foster Children: HHS Guidance Could Help States Improve Oversight of Psychotropic Prescriptions”¹⁰⁴

Published by the Government Accountability (GAO) Office, one of the most visible public reporting efforts of antipsychotic medication treatment among youth was the 2008 report entitled “Foster Care: HHS Guidance Could Help States Improve Oversight of Psychotropic Prescriptions.” This report published Medicaid claims data on rates of antipsychotic prescribing in five states, as well as indicators of safety concern including antipsychotic prescribing at higher than maximum level doses based on FDA-approved labels (derived from the Texas Practice Parameters), and under the age of one years old. Findings were stratified by age cohort and presented in interactive maps to facilitate messaging. Demonstrating the report’s impact, the methodology employed has been cited by public reports issued by other states (such as Arizona) who conducted internal evaluations of their antipsychotic prescribing trends and benchmark their rates to those of the states included in the GAO report.

Evidence Available

Our evidence review did not find any evaluations of public reporting in antipsychotic medication treatment among youth. However, systematic evidence review of public reporting in other contexts suggests that health care providers engage in activities to improve quality when performance data are made public.¹⁰⁵ At the same time, studies generally find no or weak evidence that public reporting affects selection of health care providers by the patient or their caregiver.^{105,106}

Promising Practices

Suggestions for development and implementation in public reporting, which arose from the expert convening as well as the literature, include:

- **Leverage the ability for common metrics and public reporting to be established.** Opportunities exist for common metrics to be implemented as part of routine program review and reporting. For example, common metrics in antipsychotic prescribing could be established in the Child and Family Services Review (CFSR) employed by Title IV-E funded child welfare agencies. Given extensive variation in antipsychotic prescribing nationally (from 2.8 percent to 21.7 percent of Medicaid-insured children in foster care),³¹ such efforts would not only ensure performance tracking but also facilitate State comparisons for targeted efforts to address over- or under-use of antipsychotic treatments.
- **Diversify the datasets being used to assess antipsychotic treatment and practice parameters.** Expert convening participants emphasized that school and juvenile justice agencies have data that are valuable for supplementing claims measures and can be critical for identification of concerning patterns and assessment of strategies.
- **Employ administrative data with caution, noting the respective strengths and limitations.** While use of administrative datasets has increased drastically, caution must be taken to ensure the limitations and potential biases are assessed. For example, Medicaid claims analyses will be limited in identifying school-based interventions (which may include psychosocial treatments).

Financing and Sustainability

Limited information is available on the opportunities for financing and sustaining public reporting initiatives. Notably, States that currently provide public reporting at the State level typically employ the same measures for antipsychotic utilization and quality that are used in the Drug Utilization Reviews or Quality Improvement initiatives. Opportunities exist to leverage metrics already established for drug utilization reviews and thereby gain an economy of scale and additional transparency in antipsychotic prescribing and quality from these efforts.

Strategy 8: Intensive Care Coordination

Description

Intensive care coordination across service systems is frequently cited as being important for the well-being of children and youth with significant mental health and substance use conditions.¹⁰⁷ Wraparound specifically refers to an intensive family- and youth-driven care coordination process, which provides case management that is individualized and coordinated across youth-serving systems.¹⁰⁸ Profiles of State and community systems strategies to care coordination and wraparound have been well documented by the Center for Health Care Strategies, Inc.¹⁰⁹

Case Study. Commercial Health Plan's Case Management Services

Magellan Health, Inc. (Magellan) is a large commercial health plan that includes a medical plan (Magellan Healthcare) and a prescription plan (Magellan Rx Management). Currently, Magellan serves 36.1 million individuals and 1,000 employers. Their network includes approximately 80,000 providers and facilities. Magellan coordinates the medical, pharmacological, and behavioral health care of its members through an integrated medical and prescription plan.

The case management program at Magellan supports children and their families who are transitioning from higher levels of care such as residential treatment to community-based services. Magellan case managers oversee development of an aftercare plan

prior to discharge and ensure necessary connections to psychosocial treatments are in place at the time of discharge, including in-home therapy and family peer support. Magellan also offers transportation to facilitate successful linkage to these services. Through this system, Magellan coordinates the mental and substance use treatment needs of youth and families during transitions to community-based settings.

Evidence Available

While extensive study of wraparound has previously occurred,¹¹⁰ examination of the model on antipsychotic medication prescribing and quality is relatively recent. Two studies examined the impact of coordinated mental and substance use treatment management on indicators of polypharmacy and antipsychotic prescribing and quality.^{111,112} In the first study, care coordinators completed a Wraparound Practitioner Certificate program by receiving training to provide high-quality and intensive care coordination services (CCS), which included facilitating family, team, and community engagement meetings, with followup on action steps. The evaluation of this approach found the reduction in polypharmacy from 1 year before CCS enrollment to 1 year after discharge was 28 percent for the CCS group and 29 percent for the non-CCS group, resulting in a nonsignificant difference.¹¹¹ The second study involved a care management entity (CME) model that was a health intervention designed to support coordinated care through team-based, child-centered, and family focused services based on principles of the wraparound model. Enrollment in the CME for Medicaid-insured children was associated with a significant decrease in concomitant antipsychotic use and statistically significant improvements in monitoring for cardio-metabolic side effects.¹¹²

Promising Practices

Suggestions for care coordination arising from the expert convening as well as extant literature include:

- **Provide youth- and family-driven care coordination services.** Service coordination efforts should be driven by the informed decisions of youth and caregivers.
- **Support care coordination with access to ancillary data about the patient's prior service utilization where possible.** States, such as Texas, provide access for within network providers to a virtual interface of the administrative claims dataset; this allows prescribing clinicians to gather longitudinal information about prior service utilization of the youth.
- **Assess fidelity to care coordination models and provide needed support.** Care coordination models require periodic assessment of fidelity to key program ingredients and supports to be put in place for identified challenges.¹⁰⁸

Financing and Sustainability

While high-quality wraparound includes four phases (engagement, plan development, plan implementation, and transition) and adheres to specific steps, broad variation exists in how these programs operate structurally and financially. As many wraparound programs initially start up through grant-funding, resources are available for considering ways to ensure more sustainable financing mechanisms.¹¹³ State profiles also document variation in State billing structures and rates for wraparound.¹¹⁴

Strategy 9: Multi-Modal Initiatives

Description

Expert convening participants emphasized that attaining evidence-based antipsychotic prescribing required employing multiple strategies within the same system. Prescribing decisions are not solely

reflective of the knowledge that prescribing clinicians have and may reflect a number of other considerations, such as access to non-pharmacological interventions, workforce shortages in mental and substance use treatment services, pressures exerted from family and school settings, among others. Accordingly, suggestions from participants of the expert convening emphasized the importance of multi-modal initiatives that support prescribing clinicians in making evidence-based treatment decisions.

Case Study. A Commercial Health Plan's Multi-Modal Approach⁸²

As described in Strategy 8, Magellan Health, Inc. (Magellan) is a large commercial health plan that includes a medical plan (Magellan Healthcare) and a prescription plan (Magellan Rx Management). In addition to the case management services that facilitate access to psychosocial treatments (described in Strategy 8, Care Coordination), Magellan also conducts drug utilization reviews with targeted educational intervention, population-level monitoring of performance metrics, and general physician education outreach on appropriate use of psychotropic medications, including antipsychotic treatment. The multi-modal approach taken by Magellan is reflective of guidance provided by the American Academy of Child and Adolescent Psychiatry's Guide for Community Child Serving Agencies on Psychotropic Medication for Children and Adolescents.

Drug utilization Reviews – Pharmacy Benefit Manager. Magellan monitors the use of antipsychotics in children through Magellan Rx's pharmacy benefit manager (PBM). The PBM contains medical and pharmacy claims data for children enrolled in Magellan Healthcare. The PBM creates reports of all members' medication utilization which are reviewed by Magellan's onsite pharmacist. They also use several "red flag" indicators that include the following:

- Children currently on three or more psychotropic medications
- Children currently on two or more stimulants
- Children currently on two or more antipsychotics
- Children currently on an opioid
- Children currently on two or more benzodiazepines

When a child is flagged, a Magellan psychiatrist will discuss the child's treatment plan with the prescriber, notify the Magellan case manager if the child is in case management or, if not previously enrolled, enroll the child in Magellan's case management, and convene a conference that includes all involved Magellan staff, providers, the family, and youth. If clinical rationale cannot be clearly communicated or understood, the provider is referred to Magellan's internal quality control staff and an additional assessment of the provider is conducted.

Population-level monitoring. Magellan monitors antipsychotic utilization through the Healthcare Effectiveness Data and Information Set (HEDIS) measures. They monitor each of the antipsychotic-related measures and report them to the States where they provide services.

Provider education. Magellan also actively promotes best practice prescribing with their prescribers through the dissemination of educational materials and communication during case management. In April 2017, Magellan released *Appropriate Use of*

Psychotropic Drugs in Children and Adolescents: A Clinical Monograph. It is intended to provide information and to assist practitioners with decisions regarding care.

Magellan reports that since the implementation of its case management program, there has been a 66 percent reduction in the number of children prescribed five or more psychotropic medications and a 60 percent decrease in the number of inpatient stays. They have also seen an increased adherence to psychosocial treatments and medical appointments.

Evidence Available

Two studies of multi-modal strategies employed a combination of prospective and retrospective monitoring mechanisms.^{115,116} The first study, conducted by Lee and colleagues, examined a broad set of monitoring strategies that were subsequently enhanced with targeted efforts for prescribing clinicians with unusual antipsychotic prescribing. Following implementation of the multi-modal approach employed by the Florida Medicaid program, Lee and colleagues found that among the prescribing clinicians with unusual antipsychotic polypharmacy prescribing, substantial declines occurred in their numbers of patients with unusual antipsychotic prescribing scripts, numbers of unusual antipsychotic prescribing scripts, and number of unusual scripts per prescriber ranging from -22.4 percent to -100 percent for each of the three measures.¹¹⁵ The second evaluation conducted by the Montana Medicaid program examined the impact of a multi-modal approach that relied on prior authorization for all Medicaid-insured children and an enhanced drug utilization review for children and adolescents in foster care. The Montana Medicaid program's implementation of prior authorization and drug utilization review, specifically targeted for children in foster care, reports a reduction in key indicators of AP utilization and cardio-metabolic monitoring.

Promising Practices

The importance of multi-modal intervention was emphasized by the expert convening participants, with the following suggestions made:

- **Provide additional support to prescribing clinicians given the complexity of decision-making in antipsychotic medication treatments among youth.** Treatment decisions are multifactorial with incredible complexity especially for underserved communities. Prescribing clinicians are optimally supported to assist in making the best treatment decisions given the many complexities of treatment decisions. See Strategies 3-5 for illustrative examples.
 - **Ensure coordination rather than duplication of efforts to provide oversight of antipsychotic prescribing.** Multiple youth-serving systems may interface with the same child. Efforts to provide oversight of antipsychotic medications should recognize this circumstance and leverage the respective resources and contacts that are available in each youth-serving system (e.g., mental health entities, educational sector, juvenile justice, child welfare).
 - **Engage stakeholders in identification of where mental and substance use treatment delivery challenges and antipsychotic medication treatment concerns exist to ensure responsiveness to the specific delivery system needs.** The specific barriers and facilitators to best practice prescribing are context-specific. Engagement of the various stakeholders is critical to ensuring a configuration of strategies that are responsive to the multiple stakeholders involved in antipsychotic treatment decisions.
 - **Cautiously employ strategies that unilaterally restrict access to antipsychotics, given strategies unilaterally restricting access may prevent clinically appropriate access.** Before implementing a
-

“hard stop” or other approaches that may restrict access to antipsychotic treatment when needed, employ other strategies to ensure alternative treatment options are available (e.g., psychosocial care, care coordination) and complement elective and mandatory peer review whenever possible.

Financing and Sustainability

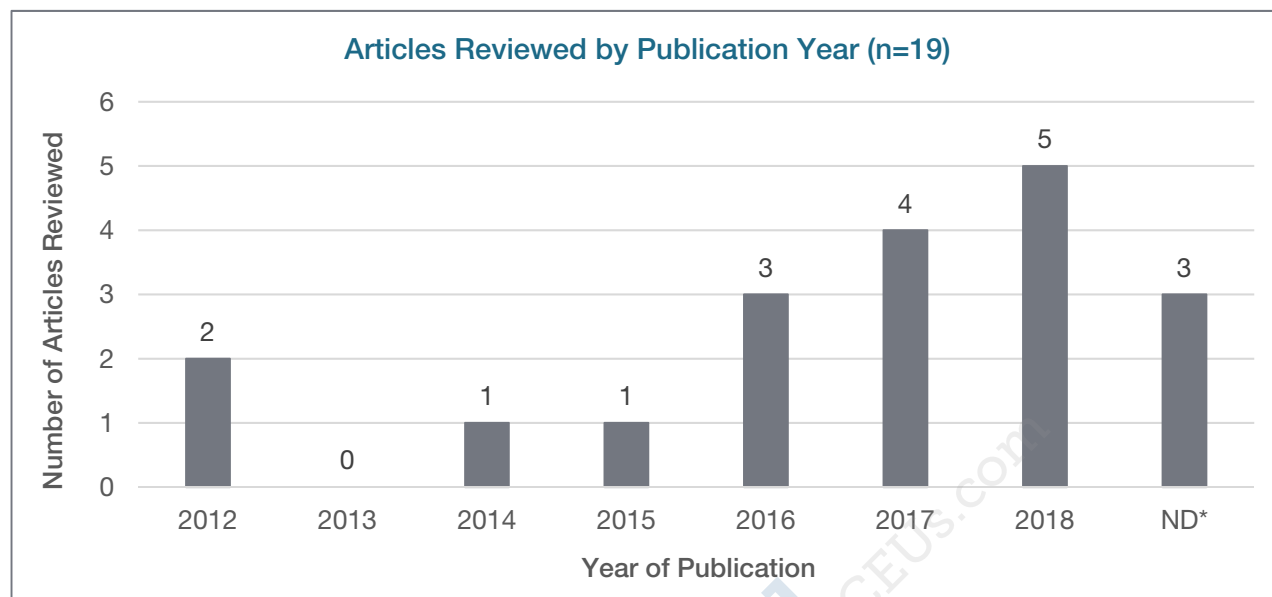
State Medicaid agencies are increasingly moving to managed care, with mental and substance use service integration, frequently referred to as “behavioral health carve-ins.”¹¹⁷ This shift provides new opportunities for managed care plans to be singularly accountable and ensure coordination of various initiatives to encourage best practice antipsychotic medication prescribing in both mental and substance use treatment settings and general pediatric settings. Incorporation of multi-modal innovations to incentivize and support evidence-based antipsychotic prescribing among providers within the network holds considerable promise. Moreover, opportunities to leverage available quality measures through HEDIS facilitate opportunities for evaluation and comparative performance assessments. Additionally, opportunities exist for multiple public sector agencies to coordinate around various aspects of a holistic approach to evidence-based antipsychotic prescribing; many of the resources and recommendations for joint-agency collaboration around antipsychotic recommendations (published in 2011) remain relevant today.¹¹⁸

Part F. Implications for Research

Research on strategies for antipsychotic prescribing is emerging. As illustrated in Figure 4, 17 of the 19 studies examining the strategies of antipsychotic prescribing were published within 5 years of this report’s publication. Ensuring youth receive evidence-based strategies to promote safe and effective use of antipsychotic medications requires multiple efforts in (1) understanding the multifactorial nature of antipsychotic prescribing and effectiveness, (2) extending the breadth and rigor of studies examining these strategies as “natural experiments,” and (3) building additional infrastructure and public-academic partnerships to conduct and learn from local evaluation efforts.

1. **Research is needed on the long-term safety and efficacy of antipsychotic prescribing in “real-world settings.”** Additional information is needed about the efficacy and safety of these medications when prescribed to children and youth. Particular concerns exist around extrapolation of studies conducted from adult models to children and adolescents who are in stages of development uniquely different from those of adults. Such studies will require considerable financial investment to facilitate the use of multiple datasets increasingly available (e.g., electronic health records, Medicaid claims datasets, data from school settings and other youth-serving systems) to conduct prospective longitudinal assessment of antipsychotic medication efficacy and safety, including impact on functional outcomes. Additional investment is necessary to facilitate the rigorous and high-quality research necessary to make these scientific discoveries.

Figure 4. Publication of Effectiveness Studies of Strategies (by year)



- Rigorous research is also needed to investigate effectiveness of strategies to promote antipsychotic best practice prescribing.** The emergence of national administrative datasets (such as the Medicaid Analytic eXtracts) provides opportunities to evaluate the systems-level strategies to promote best practice antipsychotic prescribing as “natural experiments.” Additional rigorous longitudinal analysis, with suitable comparison groups, is needed to evaluate virtually every strategy reviewed. Our evidence review found no studies in the peer review literature evaluating effectiveness of shared decision-making or trauma-informed and evidence-based non-pharmacological alternatives, such as psychosocial therapies, on antipsychotic best practice prescribing. Moreover, little examination has been given to the potential unintended consequences of these monitoring strategies. Given concerns expressed by the advisory committee about potential adverse outcomes in prior authorization programs (such as limiting access to needed antipsychotic treatments and potential substitution effects), this is an especially important line of research, where concerns for unintended consequences are greatest.
- Investment in opportunities to build the infrastructure of public sector systems in evaluating the impact of strategies is warranted.** Given the multifactorial nature of antipsychotic prescribing decisions and the many contextual factors that could be influential (e.g., accessibility of non-pharmacological alternatives), it is critical to build the infrastructure of public sector systems in using their own data to facilitate quality improvement cycles (see Summary Sheet 5). To do this, additional investments in public-academic partnerships would be warranted, including active collaboration to conduct research and to train researchers in relevant areas (e.g., administrative claims data, time series analyses, etc.).

Part G. Conclusions

This guidance highlights the achievements made in recent years in implementing an array of strategies to promote best practices in antipsychotic medication prescribing for youth. Such efforts likely contributed to the stabilization reported in antipsychotic prescribing among youth in the United States since 2011.²⁷ However, opportunities remain to promote antipsychotic prescribing that is consistent with and informed by the best available evidence, clinical expertise of the prescribing clinician, and the preferences of the youth and their caregiver(s).

Expert consensus strongly suggests that systems-level strategies are needed to support both the initial antipsychotic treatment decision and those decisions required after treatment is initiated (e.g., monitoring of side effects, access to complementary psychosocial treatments). However, this guidance on strategies to promote antipsychotic best practice prescribing is limited by the state of the evidence evaluating these approaches. Although both public reporting and investments in alternatives to antipsychotic treatment (e.g., an evidence-based system of care) were identified as strategies for antipsychotic best practice prescribing, our evidence review and environmental scan did not identify studies of effectiveness on antipsychotic use or best practice prescribing for either strategy. The majority of the strategies outlined in this guidance held emerging evidence of the impact on service utilization (e.g., reduction in antipsychotic medication dispensing) and best practice prescribing (e.g., side effect monitoring). Notably, limited evidence is available, whether antipsychotic monitoring strategies impact the functional outcomes that were emphasized as important to participants from multiple stakeholder groups during the expert convening. Additionally, limited evidence exists on the potential for unintended consequences; this topic is an area of particular importance for those strategies that may limit access to needed services (e.g., prior authorization programs). Despite limitations in available evidence, participants in the expert convening emphasized the importance of ongoing investment in these strategies and their evaluation.

This guidance also highlights the need for multiple strategies to be implemented in a strategic and coordinated manner across youth-serving systems. Collaboration across Federal agencies, State entities, and youth-serving delivery systems is key in facilitating implementation and widespread adoption of best practice prescribing.

- **Federal level.** Prior collaborations of the Centers for Medicare & Medicaid Services, Substance Abuse and Mental Health Services Administration, and Administration for Children and Families set a strong precedence for the importance of Federal leadership on this issue. Participants in the expert convening highlighted the value of both the joint letter on psychotropic medication oversight and the *Because Minds Matter* summit. Ongoing investments in authoring additional joint letters, facilitating public sector collaboration, and supporting evaluation and research studies within and across State systems are warranted.
- **State level.** Following on these calls for multisector collaborations, many jurisdictions developed interagency strategic planning committees that assisted in coordinating efforts across the respective youth-serving systems. Participants in the expert convening highlighted that opportunities may exist for greater involvement of commercial insurance plans, education, and juvenile justice systems in coordinating development and implementation of these strategies.
- **Youth-serving delivery systems.** As described in Strategy 8, recent innovations in intensive care coordination for mental, substance use, and medical care offer promise in promoting best practice prescribing. Greater attention to coordination across multiple youth-serving systems such as education, child welfare, juvenile justice, primary care, and mental and substance use services is

an important part of providing redress to concerns. Moreover, integration of additional tools to inform processes of shared decision-making and continuous quality improvement also holds promise for ensuring safe and effective antipsychotic medication treatment.

Finally, the expert convening participants emphasized that ongoing commitment to local, multi-State, and national evaluations will be critical. The emergence of antipsychotic safety and quality metrics presents new opportunities to facilitate the use of common and evidence-based safety and quality metrics to benchmark quality over time and across delivery systems. As described in the section on “implications for research,” such efforts will require investments in building an infrastructure for evaluation within the implementing agencies, as well as support for research that examines long-term safety and efficacy of these medications and trends across jurisdictions.

Although limitations exist in the available evidence, this guidance emphasizes the opportunity and importance for systems-level strategies to promote best practice antipsychotic prescribing for youth. This guidance perhaps most importantly recognizes the need for systems-level strategies that respond to the unique challenges confronting a particular delivery system. The nine strategies identified in this guidance are distinct policy levers that may promote antipsychotic best practice prescribing for youth in unique ways. Efforts should be taken to align the specific strategies with the needs of a particular delivery system or jurisdiction. The report also emphasizes the importance for multisectoral and stakeholder engagement in development, implementation, and evaluation of these strategies. Finally, this guidance ultimately aims to provide opportunities for stakeholders to learn from and build upon this “first generation” of strategies to monitor and promote antipsychotic prescribing so as to improve the well-being of some of our Nation’s most vulnerable youth.



MINDA

APPENDIX 1. Methodological Approach Employed for This Guidance

This guidance recommends strategies for pediatric antipsychotic prescribing based on an evidence review, environmental scan, and an expert convening. Additional details are provided on each of the contributing work products for this guidance below. To help provide direction to the overall guidance and set parameters for each product, a Steering Committee was assembled. Membership of the Steering Committee included representation from youth and family advocacy organizations, child and adolescent psychiatrists, pediatricians, health services researchers, Federal agencies, and technical assistance centers.

Evidence Review

Consistent with the methodology provided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA), an evidence review was conducted of 839 peer review articles. The search strategy of this evidence review included published studies drawing from the environmental scan of unpublished studies. A three-step search strategy was employed, including an initial limited search of MEDLINE and PsycINFO followed by analysis of the text words contained in the title and abstract, and of the index terms used to describe the article. A second search of all identified keywords and index terms was undertaken across all included databases (Ovid MEDLINE and PsycINFO). Next, the reference list of all identified reports and articles were searched for additional studies. Studies published in English were considered for inclusion in this review. Extracted articles were initially reviewed to ensure inclusion criteria were met. The resulting articles (n=34) then received full-text review from two researchers who reached consensus on inclusion of 18 of the 19 articles. Researchers reviewed the one article and agreed it fell within the scope of the criteria set for inclusion. Studies published from January 1, 1990, through May 14, 2018, were considered for inclusion in this review. The review of search terms used is available in the full report.^{119,120}

Environmental Scan

The environmental scan included guidance and input from SAMHSA and a Steering Committee comprising of experts in the field. The information summarized in the document, entitled “Strategies for Effective Implementation of Evidence-Based Practices in Antipsychotic Prescribing for Children and Adolescents: An Environmental Scan,” was developed with Steering Committee guidance and input through a series of meetings, including suggestions for selecting key informants, developing the interview protocol and identifying sources of information. The scan also drew upon resources and information provided through eight key informant interviews with researchers, insurance providers, a leading clinical expert, and a youth advocate. The scan also included engagement of the National Association of State Mental Health Directors Children’s Division. Finally, the scan included review of Internet searches with key search terms and targeted websites (e.g., Center for Health Care Strategies, Inc.; American Academy of Child and Adolescent Psychiatry; American Academy of Pediatrics; and American Medical Association. Documents were also reviewed including information specific to statewide oversight and monitoring protocols and review of State and commercial insurer practices.¹²¹

Analytic Study

The primary analysis of this study sought to analyze the sociodemographic and other characteristics of the patients (1-17 years of age) receiving antipsychotics, as well as related service use characteristics.

Secondary analyses used the NCQA 2018 HEDIS measure of metabolic monitoring for Children and Adolescents on Antipsychotics to calculate metabolic monitoring rates. Both sets of analyses were conducted using the IBM MarketScan® Medicaid and MarketScan Commercial Claims and Encounters (CCAЕ) database. This database includes deidentified, person-specific health data including information on outpatient and inpatient services, use of long-term care and other medical services, and prescription drug claims. The MarketScan Medicaid data provide a convenience sample derived from between 9 and 13 States over this study’s 5-year period with 8 States continuously collecting data for the whole period. Additional details of the approach taken and a complete reporting of findings are available in the full report.

Based on each of these documents, this report provides guidance for Federal policymakers, State leadership and mid-level managers, as well as prescribing community, youth, and families on the state of literature and promising practices in strategies to promote best practice prescribing of antipsychotic medications. The guidance reflects the contribution of 60 expert convening participants who represent youth and family advocates, researchers, prescribing clinicians, child and adolescent psychiatric consultants, and State and Federal partners.



APPENDIX 2. Operational Definition of Strategies, With Illustrative Examples

Mechanism	Operational Definition	Illustrative Citation
Monitoring Programs for Antipsychotic Oversight		
Prospective review of antipsychotic prescribing	Comparing requests for utilization of antipsychotic medications with established guidelines or criteria prior to dispensing the medication. Include informed consent protocols (especially relevant when children are in out-of-home placements) and prior authorization.	Stein BD, Leckman-Westin E, Okeke E, Scharf DM, Sorbero M, Chen Q, Wisdom JP. (2014). The effects of prior authorization policies on Medicaid-enrolled children's use of antipsychotic medications: evidence from two mid-Atlantic states. <i>Journal of Child and Adolescent Psychopharmacology</i> . 24(7),374-381.
Retrospective review of antipsychotic prescribing	Comparing requests for utilization of antipsychotic medications with established guidelines or criteria after dispensing the medication. Include database review, administrative case reviews, retrospective drug utilization reviews, audit, and feedback.	Texas Health and Human Services Commission. Safety and Appropriateness of Antipsychotic Medications for Medicaid Children Under Age 16. Report to the Texas Legislature, pages 179-180, https://hhs.texas.gov/sites/default/files//antipsychotic-medications-medicaid-1110.pdf
Supports for Best Practice Prescribing		
Elective psychiatric consultation lines	A telephone or Web-based consultation line available to provide behavioral and mental health expertise and consultation to clinicians prescribing antipsychotics.	Barclay RP, Penfold RB, Sullivan D, Boydston L, Wignall J, Hilt RJ. (2017). Decrease in statewide antipsychotic prescribing after implementation of child and adolescent psychiatry consultation services. <i>Health Services Research</i> . 52(2),561-578.
Targeted antipsychotic quality improvement initiatives	Demonstration of a systematic and formal approach to the analysis of practice performance and efforts to improve performance.	Cotes RO, Fernandes NK, McLaren JL, McHugo GJ, Bartels SJ, Brunette MF. Improving cardiometabolic monitoring of children on antipsychotics. <i>Journal of Child and Adolescent Psychopharmacology</i> . 2017;27(10):916-919.

Mechanism	Operational Definition	Illustrative Citation
Shared decision-making for pediatric antipsychotic use	Decision aids or other tools designed to facilitate shared decision making and patient participation in health care decisions related to antipsychotic use.	Thackeray J, Crane D, Fontanella C, Sorter M, Baum R, Applegate M. (2018). A Medicaid quality improvement collaborative on psychotropic medication prescribing for children. <i>Psychiatric Services</i> . appi-ps.
Delivery System Investments		
Systems-level investments in alternative treatment options such as psychosocial therapies	Investment in trauma-informed services or availability of evidence-based practice for youth.	Ramachandran S, Banahan III BF, Bentley JP, West-Strum DS, Patel AS. (2016). Factors influencing the use of second-generation antipsychotics in children with psychosis. <i>Journal of Managed Care & Specialty Pharmacy</i> . 22(8), 948-957.
Intensive care coordination	Provision of intensive care coordination services, such as high fidelity WRAP, for children with behavioral health conditions.	Tai MH, Lee B, Onukwugha E, Zito JM, Reeves GM, dosReis S. Impact of coordinated behavioral health management on quality measures of antipsychotic use. <i>Administration and Policy in Mental Health</i> . 2018;45(1):174-185.





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