



## Testimony

Before the Subcommittee on Federal Financial Management,  
Government Information, Federal Services, and  
International Security, Committee on Homeland Security  
and Governmental Affairs, U.S. Senate

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# FOSTER CHILDREN

## HHS Guidance Could Help States Improve Oversight of Psychotropic Prescriptions

Statement of Gregory D. Kutz, Director  
Forensic Audits and Investigative Service

U.S. Government Accountability Office



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Highlights of [GAO-12-270T](#), a testimony before the Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security; Committee on Homeland Security and Governmental Affairs; U.S. Senate

## Why GAO Did This Study

Foster children have often been removed from abusive or neglectful homes and tend to have more mental health conditions than other children. Treatment may include psychotropic drugs but their risks to children are not well understood. Medicaid, administered by states and overseen by the Department of Health and Human Services (HHS), provides prescription drug coverage to foster children.

This testimony examines (1) rates of psychotropic prescriptions for foster and nonfoster children in 2008 and (2) state oversight of psychotropic prescriptions for foster children through October 2011. GAO selected Florida, Maryland, Massachusetts, Michigan, Oregon, and Texas primarily based on their geographic diversity and size of the foster care population. Results cannot be generalized to other states. In addition, GAO analyzed Medicaid fee-for-service and foster care data from selected states for 2008, the most recent year of prescription data available at the start of the audit. Maryland's 2008 foster care data was unreliable. GAO also used expert child psychiatrists to provide a clinical perspective on its methodology and analysis, reviewed regulations and state policies, and interviewed federal and state officials.

## What GAO Recommends

In our draft report, GAO recommended that HHS consider endorsing guidance for states on best practices for overseeing psychotropic prescriptions for foster children. HHS agreed with our recommendation. Agency comments will be incorporated and addressed in a written report that will be issued in December 2011.

View [GAO-12-270T](#) or key components. For more information, contact Gregory D. Kutz at (202) 512-6722 or [kutzg@gao.gov](mailto:kutzg@gao.gov).

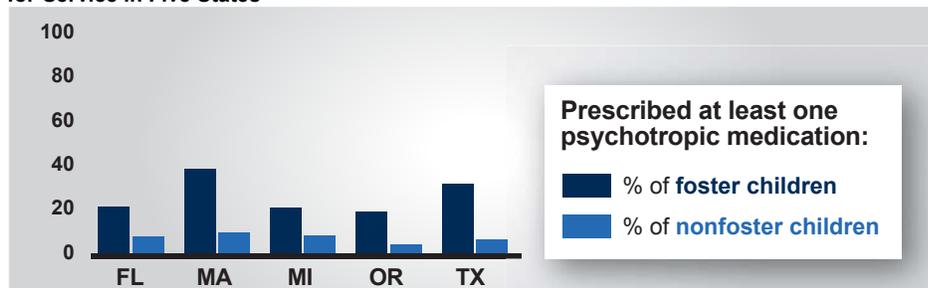
## FOSTER CHILDREN

### HHS Guidance Could Help States Improve Oversight of Psychotropic Prescriptions

#### What GAO Found

Foster children in the five states GAO analyzed were prescribed psychotropic drugs at higher rates than nonfoster children in Medicaid during 2008, which according to research, experts consulted, and certain federal and state officials, could be due in part to foster children's greater mental health needs, greater exposure to traumatic experiences and the challenges of coordinating their medical care. However, prescriptions to foster children in these states were also more likely to have indicators of potential health risks. According to GAO's experts, no evidence supports the concomitant use of five or more psychotropic drugs in adults or children, yet hundreds of both foster and nonfoster children in the five states had such a drug regimen. Similarly, thousands of foster and nonfoster children were prescribed doses higher than the maximum levels cited in guidelines developed by Texas based on FDA-approved labels, which GAO's experts said increases the risk of adverse side effects and does not typically increase the efficacy of the drugs to any significant extent. Further, foster and nonfoster children under 1 year old were prescribed psychotropic drugs, which GAO's experts said have no established use for mental health conditions in infants; providing them these drugs could result in serious adverse effects.

**Psychotropic Prescription Rates for Foster and Nonfoster Children Age 0-17 in Medicaid Fee-for-Service in Five States**



Source: GAO analysis of state Medicaid and foster care data.

Selected states' monitoring programs for psychotropic drugs provided to foster children fall short of best principle guidelines published by the American Academy of Child and Adolescent Psychiatry (AACAP). The guidelines, which states are not required to follow, cover four categories.

- **Consent:** Each state has some practices consistent with AACAP consent guidelines, such as identifying caregivers empowered to give consent.
- **Oversight:** Each state has procedures consistent with some but not all oversight guidelines, which include monitoring rates of prescriptions.
- **Consultation:** Five states have implemented some but not all guidelines, which include providing consultations by child psychiatrists by request.
- **Information:** Four states have created websites about psychotropic drugs for clinicians, foster parents, and other caregivers.

This variation is expected because states set their own guidelines. HHS has not endorsed specific measures for state oversight of psychotropic prescriptions for foster children. HHS-endorsed guidance could help close gaps in oversight of psychotropic prescriptions and increase protections for these vulnerable children.

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Chairman Carper, Ranking Member Brown, and Members of the Subcommittee:

Thank you for the opportunity to discuss psychotropic drug prescriptions provided to foster children under state care. Children placed in foster care are among our nation's most vulnerable populations. Often having been removed from abusive or neglectful homes, they tend to have more numerous and serious medical and mental health conditions than do other children.<sup>1</sup> Treatment of mental illness may include prescribing psychotropic drugs, such as antidepressants and antipsychotics. Because foster children are under state care they typically receive prescription drugs and other medical services through Medicaid, a joint federal-state program that finances health care coverage for certain low-income populations.<sup>2</sup>

This testimony discusses, for selected states, (1) rates of psychotropic drug prescriptions for foster children compared with nonfoster children covered by Medicaid in 2008, including indicators of health risks, and (2) federal and state oversight policies as of October 2011 for psychotropic drugs prescribed to foster children. We have received comments on a draft of the report this testimony is based on from the Department of Health and Human Services (HHS) and relevant state agencies. We plan to incorporate their comments into the report that we will issue in December 2011. We contracted with two child psychiatrists with clinical and research expertise in the use of psychotropic drugs in children to provide a clinical perspective on our methodology and data analysis. To compare rates of psychotropic drug prescriptions, we reviewed calendar year 2008 fee-for-service prescription claims and foster care data for

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<sup>1</sup>GAO, *Foster Care: State Practices for Assessing Health Needs, Facilitating Service Delivery, and Monitoring Children's Care*. [GAO-09-26](#), (Washington, D.C.: February 6, 2009).

<sup>2</sup>Medicaid programs vary from state to state.

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Florida, Maryland, Massachusetts, Michigan, Oregon, and Texas.<sup>3,4</sup> At the start of our audit, 2008 data were the most recent calendar year prescription claims data available from the Centers for Medicare & Medicaid Services (CMS). These states were selected primarily for geographic diversity and the size of their foster care populations. However, we then excluded Maryland from our analysis due to the unreliability of their foster care data.<sup>5</sup> To identify potential health risk indicators, we consulted with our experts, performed literature searches, and reviewed state guidelines. The final indicators of potential health risks were: concomitant prescriptions of five or more drugs, prescriptions exceeding dosage guidelines in the Psychotropic Medication Utilization Parameters for Texas Foster Children based on Food and Drug Administration (FDA) approved labels, and psychotropic prescriptions to children under 1 year old. In addition, we evaluated gaps of 7 to 29 days in prescriptions of a drug to identify nonadherence to drug regimens, which can pose significant risks to a patient.

To determine federal and state oversight policies, we interviewed officials from CMS, the Administration for Children and Families (ACF), and the six selected states' Medicaid and foster care agencies. We also reviewed policies and regulations related to the prescribing of psychotropic drugs to foster children. Based on a literature review and discussions with officials

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<sup>3</sup>Some states' prescription drugs are covered by Medicaid managed care plans in which drug payments are included in the capitated payments that plans receive from states. For this review, we selected states that cover psychotropic medications largely under fee-for-service programs so that individual drug claims could be analyzed. In Michigan, Oregon, and Texas, psychotropic medications were primarily paid on a fee-for-service basis. In Florida and Massachusetts, psychotropic prescription claims for most foster children were paid on a fee-for-service basis, with the remaining children largely covered by managed care. In these states, since we examined only fee-for-service data, we were more likely to identify psychotropic prescriptions to foster children during calendar year 2008 than to nonfoster children.

<sup>4</sup>In addition, the Medicaid prescription claims data do not include diagnosis codes, and therefore, we cannot be sure that all the drugs in our analysis were prescribed for mental health purposes.

<sup>5</sup>We performed data checks to determine the reliability of the MSIS prescription claims data provided by CMS, state Medicaid files provided by Medicaid agencies in the six selected states, databases of children in foster care provided by child welfare agencies in the six selected states, and Thomson Reuters Redbook. While a small number of Medicaid and foster care records may contain inaccurate personal data or prescription information likely resulting from data entry errors, based on our discussions with agency officials and our own testing, we concluded that the data elements in five of the six states used for this report were sufficiently reliable to address our audit objectives.

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from HHS, we selected the American Academy of Child and Adolescent Psychiatry's (AACAP) guidelines as a basis for assessing the extent to which selected states were implementing recommended practices.<sup>6</sup>

We performed this audit from February 2010 through November 2011 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives. Our full scope and detailed methodology will be provided in our report that will be issued in December 2011.

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## Background

Foster care begins when a child is removed from his or her parents or guardians and placed under the responsibility of a state child welfare agency. Removal from the home can occur because of physical abuse or neglect. It can also occur when a child's own behavior or condition is beyond the control of his or her family or poses a threat to their community. Foster care may be provided by a family member, caregivers previously unknown to the child, or a group home or institution. Ideally, foster care is an intermediate step towards a permanent family home. When reuniting the child with his or her parents or guardian is not in the child's best interest, caseworkers seek a new permanent home for the child, such as an adoptive home or guardianship. However, some children remain in foster care until they reach adulthood. As we have previously reported, children in foster care exhibit more numerous and serious medical conditions, including mental health conditions, than do other children.<sup>7</sup>

States are responsible for administering their Medicaid and foster care programs; the programs are overseen at the federal level by HHS through CMS and ACF, respectively. HHS may issue regulations, provide guidance on some issues, or simply provide informational resources for

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<sup>6</sup> AACAP guidelines are available at [http://www.aacap.org/galleries/PracticeInformation/FosterCare\\_BestPrinciples\\_FINAL.pdf](http://www.aacap.org/galleries/PracticeInformation/FosterCare_BestPrinciples_FINAL.pdf)

<sup>7</sup> GAO, *Foster Care: State Practices for Assessing Health Needs, Facilitating Service Delivery, and Monitoring Children's Care*, GAO-09-26 (Washington, D.C.: Feb 6, 2009).

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states to consider for their programs, the latter being the case for psychotropic drugs provided to children in state custody. Among these resources are best principles developed by AACAP, a nonprofit professional association. While HHS does not require states to follow these guidelines, AACAP developed them as a model to help inform state monitoring programs for youth in state custody. AACAP guidelines point out that, “as a result of several highly publicized cases of questionable inappropriate prescribing, treating youth in state custody with psychopharmacological agents has come under increasingly intense scrutiny,” leading to state implementation of consent, authorization, and monitoring procedures. More recently, Congress passed the Child and Family Services Improvement and Innovation Act in September 2011, requiring states that apply for certain federal child welfare grants to establish protocols for the appropriate use and monitoring of psychotropic drugs prescribed to foster children.<sup>8</sup>

The use of psychotropic drugs has been shown to effectively treat mental disorders, such as attention deficit hyperactivity disorder (ADHD), bipolar disorder, depression and schizophrenia. While many psychotropic drugs that have been approved by the FDA as safe and effective in adults have not been similarly approved for children of all ages, prescribing them to children is legal and common medical practice in many instances. According to the National Institute of Mental Health (NIMH), some children with severe mental health conditions would suffer serious consequences without such medication.<sup>9</sup> However, psychotropic drugs can also have serious side effects in adults, including irreversible movement disorders, seizures, and an increased risk for diabetes over the long term. Further, additional risks these drugs pose specifically to children are not well understood.<sup>10</sup>

Psychotropic drugs affect brain activity associated with mental processes and behavior. These drugs are also called “psychotherapeutic” drugs.

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<sup>8</sup>Pub. L. No. 112-34, § 101(b)(2), 125 Stat. 369.

<sup>9</sup>National Institute of Mental Health, *Treatment of Children with Mental Illness*, NIH Publication No. 09-4702, (Bethesda, MD.: Revised 2009).

<sup>10</sup>For example, see Medicaid Medical Directors Learning Network and Rutgers Center for Education and Research on Mental Health Therapeutics. *Antipsychotic Medication Use in Medicaid Children and Adolescents: Report and Resource Guide from a 16-State Study*, MMDLN/Rutgers CERTs, Publication 1 (July 2010).

While psychotropic drugs can have significant benefits for those with mental illnesses, they can also have side effects ranging from mild to serious. Table 1 highlights the psychotropic drug classes studied in this report and provides examples of drugs within those classes, as well as conditions treated and possible side effects.

**Table 1: Psychotropic Drug Classes**

| <b>Drug class</b> | <b>Examples of drugs</b>  | <b>Types of conditions treated by drug class</b>   | <b>Examples of possible adverse side effects</b>  |
|-------------------|---|--|---|
| ADHD drugs        | Atomoxetine (Strattera)<br>Lisdexamfetamine dimesylate (Vyvanse)<br>Methylphenidate (Ritalin, Concerta)<br>Amphetamine (Adderall)<br>Dextroamphetamine (Dexedrine, Dextrostat)                | Attention deficit hyperactivity disorder   | Decreased appetite<br>Tics<br>Psychosis   |
| Anti-anxiety      | Clonazepam (Klonopin)<br>Lorazepam (Ativan)<br>Alprazolam (Xanax)   | Generalized anxiety disorder<br>Post-traumatic stress disorder<br>Social phobias             | Dependence<br>Drowsiness and dizziness<br>Blurred vision<br>Nightmares  |
| Antidepressants   | Fluoxetine (Prozac)<br>Citalopram (Celexa)<br>Sertraline (Zoloft)<br>Paroxetine (Paxil)<br>Escitalopram (Lexapro)<br>Venlafaxine (Effexor)<br>Duloxetine (Cymbalta)<br>Bupropion (Wellbutrin) | Depression<br>Generalized anxiety disorder<br>Obsessive-compulsive disorder<br>Social phobia | Suicidal thoughts<br>Sleeplessness or drowsiness<br>Agitation<br>Sexual dysfunction   |
| Antipsychotics    | Chlorpromazine (Thorazine)<br>Haloperidol (Haldol)<br>Risperidone (Risperdal)<br>Olanzapine (Zyprexa)<br>Quetiapine (Seroquel)<br>Ziprasidone (Geodon)<br>Aripiprazole (Abilify)              | Bipolar disorder<br>Schizophrenia<br>Tourette's syndrome                                     | Rigidity (muscular tension)<br>Tremor<br>Tardive dyskinesia (uncontrollable movements)<br>Diabetes<br>High cholesterol<br>Weight gain<br>Neuroleptic malignant syndrome (a life-threatening, neurological disorder most often caused by an adverse reaction to antipsychotic drugs) |
| Hypnotics         | Quazepam (Doral)<br>Zolpidem (Ambien)<br>Eszopiclone (Lunesta)  | Insomnia<br>Anxiety  | Dependence<br>Sleep-walking   |

| Drug class       | Examples of drugs  | Types of conditions treated by drug class | Examples of possible adverse side effects   |
|------------------|--|---|---|
| Mood stabilizers | Lithium<br>Divalproex sodium (Depakote)<br>Carbamazepine (Tegretol)<br>Lamotrigine (Lamictal)<br>Oxcarbazepine (Trileptal) | Bipolar disorder                          | Suicidal thoughts<br>Loss of coordination<br>Hallucinations<br>Kidney, thyroid, liver and pancreas damage<br>Polycystic ovarian syndrome<br>Weight gain |

Source: NIMH, NIH, and our experts.

Note: The drug class categorizations and the corresponding examples of medications used in this analysis are intended to capture the common uses of psychotropic drugs and were reviewed by our experts. However, some of the drugs may have been developed and used for different purposes. For example, certain anti-anxiety drugs, such as benzodiazepines, may also be prescribed for insomnia. Similarly, some medications developed to treat depression, such as selective serotonin reuptake inhibitors (SSRI) and tricyclic antidepressants, may also be used to treat anxiety disorders.

## Foster Children Have Higher Rates of Psychotropic Drug Prescriptions and Indicators of Potential Health Risks

Foster children in each of the five selected states were prescribed psychotropic drugs at higher rates than were nonfoster children in Medicaid during 2008.<sup>11</sup> These states spent over \$375 million for prescriptions provided through fee-for-service programs to foster and nonfoster children.<sup>12</sup> The higher rates do not necessarily indicate inappropriate prescribing practices, as they could be due to foster children's greater exposure to traumatic experiences and the unique challenges of coordinating their medical care.<sup>13</sup> However, psychotropic

<sup>11</sup>We also examined Maryland, but found that its 2008 data on foster children were not sufficiently reliable for this study. State officials told us that Maryland's transition to a new records system in 2007 resulted in incorrect and missing data for foster children. A state audit in 2008 reported duplicate records with different identifying numbers for the same child, records showing children who had exited foster care as still enrolled in the program, and personal information for the mother recorded as that of the child. Our analysis of the data Maryland provided to us identified 8,869 children in foster care as of September 30, 2008—about 16 percent more than the 7,613 children that Maryland reported to ACF that year. However, audit reports for Maryland indicated that the state had taken some corrective actions as of March 2011.

<sup>12</sup>Based on our analysis of Medicaid fee-for-service claims data, these five states spent over \$317 million on psychotropic drugs for nonfoster children and about \$59 million on psychotropic drugs for foster children (in care 30 days or more) during 2008. This amount paid includes only claims paid for by a fee-for-service program and does not include manufacturer rebates or costs such as managed care (e.g., health maintenance organization (HMO)).

<sup>13</sup>For example, see Leslie et al, *Multi-State Study on Psychotropic Medication Oversight in Foster Care*, Tufts Clinical and Translational Science Institute (Boston, Mass.: 2010)

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drug claims for foster children were also more likely to show the indicators of potential health risks that we established with our experts. According to our experts, no evidence supports the concomitant use of five or more psychotropic drugs in adults or children, yet hundreds of both foster and nonfoster children were prescribed such a medication regimen. Similarly, thousands of foster and nonfoster children were prescribed doses exceeding maximum levels cited in guidelines based on FDA-approved drug labels, which our experts said increases the potential for adverse side effects, and does not typically increase the efficacy of the drugs to any significant extent.<sup>14</sup> Further, foster and nonfoster children under 1 year old were prescribed psychotropic drugs, which our experts said have no established use for mental health conditions in infants and could result in serious adverse effects.

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### Higher Rates of Psychotropic Drug Prescriptions among Foster Children

Foster children in Florida, Massachusetts, Michigan, Oregon, and Texas were prescribed psychotropic drugs at rates 2.7 to 4.5 times higher than were nonfoster children in Medicaid in 2008.<sup>15</sup> The rates were higher among foster children for each of the age ranges—0 to 5 years old, 6 to 12 years old, and 13 to 17 years old—that we reviewed. See figure 1 for rates by state. Although a higher proportion of foster children received psychotropic drug prescriptions compared with nonfoster children, the vast majority of children receiving psychotropic drug prescriptions in these states were nonfoster children because the population of nonfoster children is much larger. In addition, according to our experts the higher rates of psychotropic drug prescriptions among foster children do not necessarily mean that the prescriptions were inappropriate; determining so would require, at minimum, a full review of each child's medical

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<sup>14</sup> According to our experts, medications are approved based on therapeutic research and doses above the recommended level have generally not been shown to be safe or effective.

<sup>15</sup> The kinds of drugs included in prescription data reported to CMS in 2008 varied by state. Because the claims data we obtained from CMS contained fewer types of medications for Michigan and Oregon, we may understate the rates of psychotropic prescriptions for both foster and nonfoster children in those states. While rates of psychotropic prescriptions are not comparable across states, they are comparable between foster and nonfoster children within the same state. Similarly, the ratio of prescriptions to foster children to prescriptions to nonfoster children is comparable across states.

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history.<sup>16</sup> Figure 1 shows prescription rates for children in each state for various age ranges.

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<sup>16</sup>In Florida, nonfoster children were in fee-for-service Medicaid an average of 2 months less than foster children. Therefore, the number of nonfoster children with psychotropic prescriptions may be understated.

Figure 1: Psychotropic drug prescription rates for 5 selected states

Interactive Graphic



Rollover the shaded states for more information



Print-friendly version

State: \_\_\_\_\_

**\$** Medicaid amount paid for psychotropic medications prescribed to foster and nonfoster children during 2008: \_\_\_\_\_



| Percentage of children prescribed psychotropic medication age: | Foster children | Nonfoster children | Ratio of foster to nonfoster children |
|--|-----------------|--------------------|---------------------------------------|
| 0–17 years old   |                 |                    |                                       |
| 13–17 years old  |                 |                    |                                       |
| 6–12 years old   |                 |                    |                                       |
| 0–5 years old  |                 |                    |                                       |

**Note:** Rates for foster and nonfoster children are comparable within the same state and the ratio of prescriptions to foster children to prescriptions to nonfoster children is comparable across states. However, prescription rates are not comparable across states because certain states covered more psychotropic drugs than other states. In addition, we excluded children whose prescriptions were not reported to CMS because they were covered by an HMO in the two states with both fee-for-service and HMO prescription coverage. Percentages and ratios are rounded to the nearest tenth, and therefore the reported ratio may be slightly different than the ratio of the rounded percentages.

Source: GAO analysis of state Medicaid and foster care data.

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Through our interviews with state and federal officials and our experts, and our review of academic studies, we identified several factors that may contribute to these higher rates of prescribed psychotropic drug regimens. These factors included the greater exposure to trauma before entering state care, frequent changes in foster placements, and varying state oversight policies. However, our literature search identified a relatively small number of studies that have been conducted to determine to what extent each of these factors contributes to higher prescription rates, or whether additional factors are involved.

**Greater exposure to trauma.** Research and interviews with certain state officials suggest that children entering foster care have more emotional and behavioral issues than do nonfoster children. For example, an analysis of 1996 service claims in one county revealed that 57 percent of foster children were diagnosed with a mental disorder—nearly 15 times that of nonfoster children receiving Medicaid assistance. ADHD, depression, and developmental disorders were the most common diagnoses.<sup>17</sup> According to the National Survey of Child and Adolescent Well-Being (NSCAW), 46 percent of children investigated by child welfare services (CWS) primarily came to the attention of CWS from a report of neglect, while 27 percent had experienced physical abuse as the most serious form of recorded maltreatment.<sup>18</sup> According to another study based on NSCAW data, approximately half of youths aged 2 to 14 years with completed child welfare investigations had clinically significant emotional or behavioral problems.<sup>19</sup>

State officials and our contracted child psychiatrists stated that higher levels of psychotropic drug prescriptions may be appropriate to deal with

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<sup>17</sup>S. dosReis, et al., Mental health services for youths in foster care and disabled youths, *Am J Public Health*, 2001, 91(7): pp. 1094-9.

<sup>18</sup>Children in states that required CPS to initially contact the family before the study's field staff were excluded from the study. Those states are not represented. See National Survey of Child and Adolescent Well-Being (NSCAW), *No. 7: Special Health Care Needs Among Children in Child Welfare*, Office of Planning, Research and Evaluation, Administration for Children and Families. (Washington, D.C.: 2007).

<sup>19</sup>Children in states that required CPS to initially contact the family before the study's field staff were excluded from the study. Those states are not represented. See B. J. Burns, et al., *Mental health need and access to mental health services by youths involved with child welfare: A national survey*, *Journal of the American Academy of Child and Adolescent Psychiatry*, 43, (2004), pp.960-70.

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the increased prevalence and greater severity of mental health conditions among foster children. Further, Dr. Naylor noted that past trauma creates unique treatment challenges for those with multiple severe symptoms. In some cases, their symptoms do not clearly fit into existing diagnoses, which may cause them to receive multiple diagnoses that change with time, foster care placement, and medical provider. Dr. Naylor also noted that very little research has been done on the use of psychotropic drugs in foster children with severe symptoms. This limits the information available to providers on how best to treat their conditions.<sup>20</sup>

**Frequent changes in foster placements.** Foster children who change placements often do not have a consistent caretaker to plan treatment, offer consent, and provide oversight. As we have previously reported, changes in placement pose significant challenges for agencies, foster parents, and providers with regard to providing continuity of health care services and maintaining uninterrupted information on children's medical needs and courses of treatment.<sup>21</sup> Several studies of the utilization of psychotropic drugs have also noted that multiple foster care placements over short periods prevent an individual familiar with the child from coordinating and overseeing his or her long-term medical care.<sup>22</sup> Children entering foster care may lack medical care prior to entry, while children with prior medical care may have experienced disruptions in care and have missing or incomplete records. (We discuss how each of the six states oversee psychotropic drug prescriptions in the next section of this testimony that discusses federal and state oversight over psychotropic drugs prescribed to foster children.)

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<sup>20</sup>As we have previously reported, some steps have been taken to address the lack of drug research in the pediatric population. For example, as part of the Food and Drug Administration Amendments Act of 2007, Congress reauthorized two laws, the Pediatric Research Equity Act (PREA) and the Best Pharmaceuticals for Children Act (BPCA). The PREA requires that sponsors conduct pediatric studies for certain products unless the FDA grants a waiver or deferral. See GAO, *Pediatric Research: Products Studied under Two Related Laws, but Improved Tracking Needed by FDA*, [GAO-11-457](#) (Washington, D.C.: May 2011).

<sup>21</sup>GAO, *Foster Care: State Practices for Assessing Health Needs, Facilitating Service Delivery, and Monitoring Children's Care*, [GAO-09-26](#) (Washington, D.C.: Feb 6, 2009).

<sup>22</sup>For example, see Leslie et al, *Multi-State Study on Psychotropic Medication Oversight in Foster Care*, Tufts Clinical and Translational Science Institute (Boston, Mass.: 2010).

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**Varying state oversight policies.** States surveyed by the Tufts Clinical and Translational Science Institute in 2010 reported on several challenges that may affect prescribing patterns for foster children. These included a lack of collaboration among state agencies, professionals, and organizations responsible for the care of foster children; the consent process for foster children, which may require the input of multiple individuals or organizations; and the need for access to up-to-date guidelines on clinical practices regarding psychotropic prescriptions for foster children across stakeholder groups, including caregivers, child welfare agencies, schools, and prescribers. For example, the study found that 34 of 48 states had not implemented a system to identify prescriptions with dosages exceeding current maximum recommendations set by the product manufacturer, professional or federal standards, or state expert panels.<sup>23</sup>

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### Higher Rates of Potential Health Risk Indicators among Foster Children

In each of the five states analyzed, psychotropic prescription claims data for foster children showed higher rates of potential health risk indicators than those of nonfoster children in Medicaid. According to our experts, the following three prescribing practices carry increased levels of risk for children, concomitant prescriptions of five or more medications,<sup>24</sup> doses exceeding maximum levels in FDA-approved drug labels, and prescriptions for infants.<sup>25</sup> Figure 2 provides more information on these indicators by state.

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<sup>23</sup>Leslie et al, *Multi-State Study on Psychotropic Medication Oversight in Foster Care*, Tufts Clinical and Translational Science Institute (Boston, Mass.: 2010).

<sup>24</sup>According to one of our experts, this may be justified in rare cases of children with serious, complex mental health issues.

<sup>25</sup>These indicators are similar to those used by Texas to identify cases for further review, and were cited by our experts as indicators of potential health risks.

Figure 2: Psychotropic drug potential health risk indicators for 5 selected states

Interactive Graphic

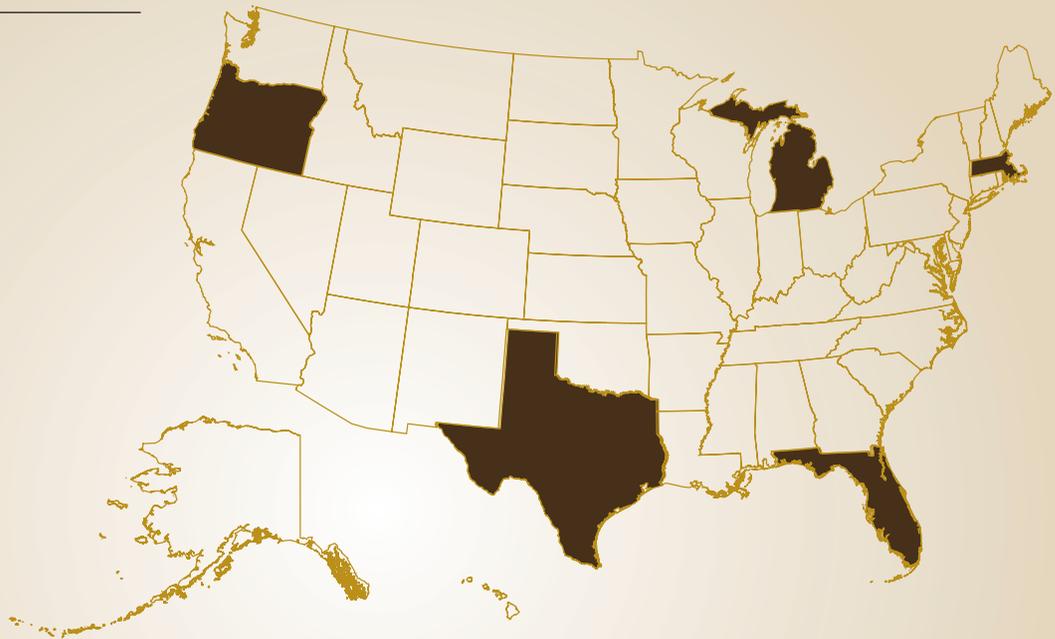


Rollover the shaded states for more information



Print-friendly version

State: \_\_\_\_\_



|   | Percentage of foster children | Percentage of nonfoster children |
|---|-------------------------------|----------------------------------|
| Children age 0–17 prescribed five (5) or more medications concomitantly               |                               |                                  |
| Children 0–17 with a dosage exceeding maximum guidelines based on FDA-approved labels |                               |                                  |
| Children under 1 year old prescribed a psychotropic drug                              |                               |                                  |

**Note:** Rates for foster and nonfoster children are comparable within the same state and the ratio of prescriptions to foster children to prescriptions to nonfoster children is comparable across states. However, prescription rates are not comparable across states because certain states covered more psychotropic drugs than other states. In addition, we excluded children whose prescriptions were not reported to CMS because they were covered by an HMO in the two states with both fee-for-service and HMO prescription coverage.

Source: GAO analysis of state Medicaid and foster care data.

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**Concomitant psychotropic drug prescriptions.**<sup>26</sup> Across the five states, the rate of children prescribed five or more psychotropic drugs concomitantly ranged from 0.11 to 1.33 percent among foster children compared with a lower 0.01 to 0.07 percent rate among nonfoster children. This translates to 1,752 children with such prescriptions in the five states—609 foster children and 1,143 nonfoster children. According to our experts, the use of five or more drugs at once is a high-risk practice. Our experts also said that no evidence supports the use of five or more psychotropic drugs in adults or children, and only limited evidence supports the use of even two drugs concomitantly in children. Increasing the number of drugs used concurrently increases the likelihood of adverse reactions and long-term side effects, such as high cholesterol or diabetes, and limits the ability to assess which of multiple drugs are related to a particular treatment goal.<sup>27</sup>

**Doses exceeding maximum levels in FDA-approved drug labels.** The rate of children prescribed medications exceeding maximum doses for the child's age, as cited in the Texas Utilization Parameters based on information in FDA-approved drug labels for the child's age ranged from 1.12 to 3.27 percent among foster children compared with a lower 0.16 to 0.56 percent rate among nonfoster children.<sup>28</sup> A total of 20,965 children in the five states had such a prescription—2,165 foster children and 18,800 nonfoster children. Of children prescribed drugs for which there was no FDA-recommended dose for their age, 0.34 to 1.52 percent of foster children and 0.05 to 0.16 percent of nonfoster children were prescribed dosages that exceeded the maximum standards published in the medical

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<sup>26</sup>In our analysis of rates of psychotropic prescriptions, we included stimulants (e.g., ADHD drugs), anti-anxiety drugs, antidepressants, antipsychotics, hypnotics, mood stabilizers, and medications containing combinations of these drug classes. Other psychotropic drugs, such as anticonvulsants and alpha agonists, may be used to treat both physical and mental health conditions. However, because they are more likely to be used for mental health indications when combined with another psychotropic drug, we included them in our concomitant analyses when combined with a second psychotropic drug.

<sup>27</sup>For example, see Zito et al, *Psychotropic Medication Patterns Among Youth in Foster Care*, *Pediatrics* 2008; Volume 121; 157-163.

<sup>28</sup>For this analysis, we used dosage guidelines developed by the state of Texas based on FDA-approved drug labels, where available, for 33 drugs. For additional information, see Heiligenstein, *Psychotropic Medication Utilization Parameters for Foster Children*, Office of the Commissioner, Texas Department of Family and Protective Services (Austin, Tex.: December 2010).

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literature. According to our experts, taking drugs at dosages exceeding levels recommended by the FDA and medical literature increases the potential for adverse side effects. Although there may be cases in which such doses are clinically justified, in general, there is a lack of research demonstrating that high dosages are more effective. In addition, our experts said that for some drugs, a higher dose may be less effective than the more moderate recommended dose.<sup>29</sup>

**Psychotropic prescriptions for infants.** The rate of children age under 1 year old prescribed a psychotropic drug ranged from 0.3 to 2.1 percent among foster children compared with a lower 0.1 to 1.2 percent rate among nonfoster children. This translates to 76 foster children and 3,765 nonfoster children under 1 year old in the five states—a total of 5,265 prescriptions.<sup>30</sup> Our experts said that there are no established mental health indications for the use of psychotropic drugs in infants, and providing them these drugs could result in serious adverse effects. According to our data, fewer than 10 infants in foster care and 22 nonfoster infants were prescribed clonidine—with dosages generally used in older children—which one of our experts said could result in significant sedation and potential cardiac problems including, on rare occasions, sudden death. Fewer than ten infants in foster care were prescribed an antidepressant or an antipsychotic, compared with 44 and 12 infants not in foster care, respectively. According to our experts, antidepressants and antipsychotics have significant potential side effects, including cardiovascular and metabolic problems. Anti-anxiety drugs such as antihistamines and benzodiazepines accounted for the vast majority of the prescriptions for infants. Our experts noted that these drugs could

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<sup>29</sup>According to one of our experts, the effect of psychotropic medications has not been proven to be safe or effective above the maximum recommended dose by an FDA review. At lower dosages, psychotropic medications generally show an increase in efficacy with an increase in dose, but this dose-response relationship changes as the dose increases. At higher dosages, increasing doses of medications are often accompanied by an increased risk in adverse effects with little or no added benefit.

<sup>30</sup>While the data we used for this analysis were generally reliable, the date of birth field was blank for some records. The number of foster infants, in particular, captured in the claims data may be underreported. It is also possible that a small number of Medicaid and foster care records may contain inaccurate personal data or prescription information likely resulting from data entry errors.

have been prescribed for nonmental health conditions.<sup>31</sup> For example, the antihistamines could be prescribed to treat allergies, itching, and skin conditions such as eczema, the benzodiazepines for seizures or as sedation for a medical procedure. While physicians may use their discretion to prescribe these drugs to infants, these nonmental health uses still carry the same risk of adverse effects, including, for antihistamines, diminished mental alertness and excitation in young children. According to our experts, these cases raise significant concerns because infants are at a stage in their development where they are potentially more vulnerable to the effect of psychotropic drugs. See table 2 for more information.

**Table 2: Children age 0-1 year old prescribed psychotropic drugs in five selected states<sup>a</sup>**

| <b>Drug category (subclass)</b>            | <b>Foster children</b> | <b>Nonfoster children</b> |
|--|------------------------|---------------------------|
| Anti-anxiety (antihistamines) <sup>b</sup> | 55                     | 3,454                     |
| Anti-anxiety (benzodiazepines)             | 17                     | 254                       |
| Other anti-anxiety drugs                   | 0                      | <10                       |
| ADHD drugs                                 | <10                    | 37                        |
| Antidepressants                            | <10                    | 44                        |
| Antipsychotics                             | <10                    | 12                        |
| Hypnotic                                   | 0                      | <10                       |
| Mood stabilizer                            | 0                      | <10                       |

Source: GAO analysis of state Medicaid and foster care data.

<sup>a</sup>Note: A total of 76 foster children and 3,765 nonfoster children, or 3,841 children age 0-1, were prescribed a psychotropic drug. The totals in the table above do not add up to 3,841 because some infants were prescribed more than one psychotropic drug.

<sup>b</sup>Of children prescribed antihistamines, 26 foster children and 2,169 nonfoster children had prescriptions covering fewer than 20 days. According to one of our experts, this more likely represents a non-mental health use, such as for allergies or rashes.

Claims data also raise concerns about patient adherence to prescribed drug regimens, which our experts noted as a patient safety matter. Although foster children as a group were 1.7 to 3.3 times more likely to have three or more gaps of 7 to 29 days between prescriptions than nonfoster children, this is likely related to their overall higher rates of

<sup>31</sup>Experts also noted that some of these prescriptions may have been written with the intention of treating an uninsured parent or sibling. It is not possible to determine from the data whether this was the case.

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psychotropic prescriptions. When comparing only those prescribed psychotropic drugs, nonfoster children were 1.2 to 2.0 times more likely to have three or more gaps than foster children, suggesting that adherence is higher among foster children. Frequent gaps of 7 or more days in prescription claims have a number of potential causes, including a parent or the caretaker's failure to fill prescriptions on behalf of a child in a timely manner or a lack of consistent access to care.<sup>32</sup> Gaps in drug claims do not indicate that the drugs as prescribed have potential health risks. However, nonadherence to drug regimens can pose significant risks to a patient, such as reduced efficacy from undertreatment, rebound of symptoms, and withdrawal symptoms. For example, the sudden discontinuation of benzodiazepines such as alprazolam can cause seizures<sup>33</sup> and the sudden discontinuation of SSRIs<sup>34</sup> such as paroxetine can cause a variety of problems, including dizziness, headaches, fatigue, and nausea.<sup>35</sup> Nonadherence to a drug regimen can cause the drug to appear ineffective even though it was not taken for a full trial. For example, antidepressants generally take 3 to 6 weeks to have a beneficial effect on the patient's symptoms.<sup>36</sup> Failure to take the antidepressant medications for a sufficient length of time may be interpreted as a lack of response to the treatment, which can result in the premature switch to or addition of other drugs. Table 3 provides more information on gaps in prescriptions for foster and nonfoster children by state.

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<sup>32</sup>Infrequent gaps may also be caused by a serious illness that prevents the patient from taking the medication as prescribed, or patients who choose to discontinue a medication because of side effects.

<sup>33</sup>G. Chouinard, *Issues in the clinical use of benzodiazepines: potency, withdrawal, and rebound*. J Clin Psychiatry. 2004; 65 Suppl 5:7-12.

<sup>34</sup>Selective serotonin reuptake inhibitors (SSRIs) are antidepressants.

<sup>35</sup>S. Hosenbocus, R. Chahal, *SSRIs and SNRIs: A review of the Discontinuation Syndrome in Children and Adolescents*. J Can Acad Child Adolesc Psychiatry. 2011 Feb; 20(1): 60-7.

<sup>36</sup>National Institute of Mental Health, *Mental Health Medications*, U.S. Department of Health and Human Services. (Bethesda, Md.: Revised 2008).

**Table 3: Percentage of Children Age 0-17 Prescribed a Psychotropic Drug with Three or More Gaps of 7-29 Days in Drug Claims in 5 States**

| State         | Percent of children who had three or more gaps in drug claims |                    | Percent of children prescribed a psychotropic drug who had three or more gaps in drug claims |                    |
|---------------|---|--------------------|--|--------------------|
|               | Foster Children   | Nonfoster Children | Foster Children  | Nonfoster Children |
| Florida       | 1.8   | 1.1                | 7.8  | 12.1               |
| Massachusetts | 3.4   | 1.8                | 8.4  | 16.4               |
| Michigan      | 1.7   | 0.9                | 7.9  | 11.3               |
| Oregon        | 1.6   | 0.5                | 7.7  | 9.5                |
| Texas         | 2.2   | 0.7                | 6.6  | 8.6                |

Source: GAO analysis of Medicaid and foster care data for Florida, Massachusetts, Michigan, Oregon, and Texas.

<sup>a</sup>Since we used both primary and secondary lists in our gaps analysis, the number of foster and nonfoster children prescribed a psychotropic drug is slightly higher than reported in our overall prescription rates, which were based on primary drugs only.

## Selected States' Psychotropic Drug Monitoring Programs Fall Short of AACAP-Best Principles Guidelines

Comparing the selected states' monitoring programs for psychotropic drugs provided to foster children with AACAP's guidelines indicates that, as of October 2011, each of the state programs falls short of providing comprehensive oversight as defined by AACAP. Though states are not required to follow these guidelines, the six states we examined had developed monitoring programs that satisfied some of AACAP's best principles guidelines to varying degrees. Such variation is not surprising given that states set their own oversight guidelines and have only recently been required, as a condition of receiving certain federal child welfare grants, to establish protocols for the appropriate use and monitoring of psychotropic drugs prescribed to foster children.<sup>37</sup>

HHS has provided limited guidance to the states on how to improve their control measures to monitor psychotropic drug prescriptions to foster children. Without formally endorsing specific oversight measures for states to implement, HHS conducts state reviews and provides other online resources, including the AACAP guidelines, to help states improve their programs. ACF performs Child and Family Services Reviews (CFSR) of states to ensure conformity with federal child welfare

<sup>37</sup>Child and Family Services Improvement and Innovation Act, Pub. L. No. 112-34, § 101(b)(2), 125 Stat. 369 (2011).

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requirements—which include provisions for safety, permanency, and family and child well-being—and to assist states as they enhance their capacity to help families achieve positive outcomes.<sup>38</sup> These reviews include the examination of a limited number of children’s case files, in part to determine whether the state foster care agency conducted assessments of children’s mental health needs and provided appropriate services to address those needs. However, these reviews are not designed to identify specific potential health risk indicators related to psychotropic medications, and since they occur every 2 to 5 years, states cannot rely on these reviews to actively monitor prescriptions. In addition, ACF operates technical assistance centers and provides online resources such as links to state guidance on psychotropic drug oversight, academic studies on psychotropic drugs, and recordings of teleconferences related to the oversight of psychotropic drugs.<sup>39</sup> While HHS makes a variety of resources available to states developing oversight programs for psychotropic drugs, it has not endorsed any specific guidance. In the absence of HHS-endorsed guidance, states have developed varied oversight programs that in some cases fall short of AACAP’s recommended guidelines.

The AACAP guidelines are arranged into four categories, including consent, oversight, consultation, and information sharing, that contain practices defined as minimal, recommended, or ideal. The following describes the extent to which the selected states’ monitoring programs cover these areas.

**Consent:** According to interviews and documentation provided by state Medicaid and foster care officials, all six selected states have

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<sup>38</sup>CFSRs, which occur on a regular and recurring basis in every state (generally every 2 to 5 years depending on the results of the prior review), are the central and most comprehensive component of federal efforts to determine state compliance with federal child welfare requirements. ACF also reviews states’ progress related to areas found not to be in substantial conformity with federal requirements based on the last CFSR, generally on an annual basis.

<sup>39</sup>In order to be eligible for certain federal child welfare grants, state child welfare agencies are required to develop a plan for ongoing oversight and coordination of health care services for foster children, including mental health, in coordination with the state Medicaid agency, pediatricians, other health care experts, and child welfare experts. See 42 U.S.C. § 622(b)(15). Among other things, the state plans must also include the oversight of prescription drugs, and how the agency actively consults and involves physicians and other professionals in assessing the health and well-being of children in foster care in determining appropriate medical treatment for the children.

implemented some practices consistent with AACAP guidelines for consent procedures, though in varying scope and application. According to AACAP, the consent process should be documented and monitored to ensure that caregivers are aware of relevant information, such as the child’s diagnosis, expected benefits and risks of treatments, common side effects, and potentially severe adverse events. Thus, states that do not incorporate consent procedures similar to AACAP’s guidelines may increase the likelihood that caregivers are not fully aware of the risks and benefits associated with the decision to medicate with psychotropic drugs, and may limit the caregiver’s ability to accurately assess and monitor the foster child’s reaction to the drugs. Table 4 lists AACAP’s guidelines relative to consent and illustrates the extent to which states have implemented those guidelines.

**Table 4: State Consent Laws and Policies Compared with AACAP’s Best Principles Guidelines**

| Guideline   |  | FL                    | MD                    | MA                    | MI                | OR                    | TX                |
|-------------|--|-----------------------|-----------------------|-----------------------|-------------------|-----------------------|-------------------|
| Minimal     | Identify the parties empowered to consent for psychotropic drug treatment for youth in state custody in a timely fashion   | Fully implemented     | Fully implemented     | Fully implemented     | Fully implemented | Fully implemented     | Fully implemented |
| Minimal     | Establish a mechanism to obtain assent for psychotropic medication management from minors when possible  | Fully implemented     | Fully implemented     | Not implemented       | Not implemented   | Not implemented       | Fully implemented |
| Recommended | Obtain simply written psycho-educational materials and medication information sheets to facilitate the consent process   | Fully implemented     | Partially implemented | Fully implemented     | Not implemented   | Fully implemented     | Fully implemented |
| Ideal       | Establish training requirements for child welfare, court personnel and/or foster parents to help them become more effective advocates for children in their custody <sup>1</sup> | Partially implemented | Partially implemented | Partially implemented | Not implemented   | Partially implemented | Fully implemented |

|   |                       |                         |
|---|-----------------------|-------------------------|
|  | Fully implemented     | <b>FL</b> Florida       |
|  | Partially implemented | <b>MD</b> Maryland      |
|  | Not implemented       | <b>MA</b> Massachusetts |
|   |                       | <b>MI</b> Michigan      |
|   |                       | <b>OR</b> Oregon        |
|   |                       | <b>TX</b> Texas         |

Source: GAO analysis of information collected through interviews with, and various documentation provided by, the selected states’ Medicaid and Foster Care officials, and the AACAP’s best principles guideline.

<sup>1</sup>AACAP Best Principles Guideline states this training should include the names and indications for use of commonly prescribed psychotropic medications, monitoring for medication effectiveness and side effects, and maintaining medication logs. Materials for this training should include a written “Guide to Psychotropic Medications” that includes many of the basic guidelines reviewed in the psychotropic medication training curriculum.

Florida and Michigan provide examples of how states vary in their approach to monitoring consent procedures used for psychotropic drugs prescribed to foster children. For example, Florida requires all prescribers

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to obtain a standardized written consent form from the parental or legal guardian, or a court order, before a psychotropic drug is administered. The consent form includes the diagnosis, dosage, target symptoms, drug risks and benefits, drug monitoring plan, alternative treatment options, and discussions about the treatment between the child and the parent or legal guardian. Florida law identifies who is authorized to give consent, and obtains assent for psychotropic drug management from minors when age and developmentally appropriate. Florida provides required training to caseworkers, but the names and indications for use of commonly prescribed psychotropic drugs are not included.

In contrast, Michigan has policies identifying who is authorized to give consent to foster children, but does not use a standardized consent form that can be used to help inform consent decisions. Instead, Michigan requires that caseworkers maintain in their files the consent forms used by individual prescribers, which likely vary in content and may thus vary in helpfulness to consent givers. Moreover, Michigan does not have training requirements in place to help caseworkers, court personnel, and foster parents become more effective advocates for children in their custody. Training for caseworkers is optional, but according to an agency official, the training was unavailable because no trainer had been hired as of September 2011. Michigan does not have policies for obtaining assent from minors when possible, thus meeting only one of AACAP's guidelines for consent procedures.

**Oversight procedures:** Each of the six states has developed some procedures similar to AACAP's guidelines for overseeing psychotropic drug prescriptions for foster children, as evidenced by interviews and documentation provided by state Medicaid and foster care officials.<sup>40</sup> According to one study, states that implement standards to improve oversight of the use of psychotropic drugs may create enhanced

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<sup>40</sup>Each of the six states reviewed performs a drug utilization review during the prescription claims process to promote patient safety, reduce costs, and prevent fraud and abuse as required by the Omnibus Budget Reconciliation Act (OBRA) of 1990 (Pub. L. No. 101-508, § 4401, 104 Stat. 1388, § 1388-143). States were encouraged by enhanced federal funding to design and install point-of-sale electronic claims management systems that interface with their Medicaid Management Information Systems (MMIS) operations. The annual report requirement is used to assess patient safety, provider prescribing habits and dollars saved by avoidance of problems such as drug-drug interactions, drug-disease interactions, therapeutic duplication, and overprescribing by providers. However, the extent to which states' DUR process included reviews of psychotropic drugs varied across our states and the DUR process is not focused on the foster child population specifically.

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continuity of care, increased placement stability, reduced need for psychiatric hospitalization, and decreased incidence of adverse drug reactions.<sup>41</sup> As such, states that do not incorporate oversight procedures similar to AACAP's recommendations limit their ability to identify the extent to which potentially risky prescribing is occurring in the foster care population. Table 5 lists AACAP's guidelines relative to oversight and illustrates the extent to which selected states have implemented those guidelines.

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<sup>41</sup>M. W. Naylor, et al, 2007. *Psychotropic Medication Management for Youth in State Care: Consent, Oversight, and Policy Considerations*, Child Welfare V 86, 5 (2007) p.175-192.

**Table 5: State Oversight Laws and Policies Compared with AACAP’s Best Principles Guidelines**

| Guideline |  | FL                    | MD                    | MA                    | MI                    | OR                    | TX                    |
|-----------|--|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| Minimal   | Establish guidelines for the use of psychotropic medications for children in state custody   | Partially implemented | Partially implemented | Partially implemented | Fully implemented     | Not implemented       | Fully implemented     |
| Ideal     | Oversight program includes an advisory committee to oversee a medication formulary and provide medication monitoring guidelines to practitioners who treat children in the child welfare system <sup>1</sup>   | Partially implemented | Partially implemented | Not implemented       | Partially implemented | Not implemented       | Partially implemented |
| Ideal     | Oversight program monitors the rate and types of psychotropic medication usage and the rate of adverse reactions among youth in state custody  | Partially implemented |
| Ideal     | Oversight program establishes a process to review non-standard, unusual, and/or experimental psychiatric interventions with children who are in state custody  | Partially implemented | Partially implemented | Partially implemented | Fully implemented     | Partially implemented | Fully implemented     |
| Ideal     | Oversight program collects and analyzes data and makes quarterly reports to the state or county child welfare agency regarding the rates and types of psychotropic medication use. Make this data available to clinicians in the state to improve the quality of care provided | Partially implemented | Partially implemented | Partially implemented | Not implemented       | Not implemented       | Fully implemented     |
| Ideal     | Maintain an ongoing record of diagnoses, height and weight, allergies, medical history, ongoing medical problem list, psychotropic medications, and adverse medication reactions that are easily available to treating clinicians 24 hours a day                               | Partially implemented | Fully implemented     | Partially implemented | Fully implemented     | Partially implemented | Partially implemented |

|   |                       |                         |
|---|-----------------------|-------------------------|
|  | Fully implemented     | <b>FL</b> Florida       |
|  | Partially implemented | <b>MD</b> Maryland      |
|  | Not implemented       | <b>MA</b> Massachusetts |
|   |                       | <b>MI</b> Michigan      |
|   |                       | <b>OR</b> Oregon        |
|   |                       | <b>TX</b> Texas         |

Source: GAO analysis of information collected through interviews with, and various documentation provided by, the selected states’ Medicaid and Foster Care officials, and the AACAP’s best principles guideline.

<sup>1</sup>AACAP describes advisory committees as composed of agency and community child and adolescent psychiatrists, pediatricians, other mental health providers, consulting clinical pharmacists, family advocates or parents, and state child advocates.

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Texas and Maryland provide examples of how states vary in their approach to oversight of psychotropic drug use among foster children. For example, the Texas Department of Family and Protective Services (DFPS) and the University of Texas at Austin College of Pharmacy assembled an advisory committee that included child and adolescent psychiatrists, psychologists, pediatricians, and other mental health professionals to develop psychotropic drug use parameters for foster children. These parameters are used to help identify cases requiring additional review. Factors that trigger additional reviews include dosages exceeding usual recommended levels, prescriptions for children of very young age, concomitant use of five or more psychotropic drugs, and prescriptions by a primary care provider lacking specialized training.<sup>42</sup> According to the Texas foster care agency's data analysis, after Texas released these guidelines in 2005, psychotropic drug use among Texas foster care children declined from almost 30 percent in fiscal year 2004 to less than 21 percent in fiscal year 2010. Texas also analyzes Medicaid claims data to monitor psychotropic drug prescriptions for foster children and to identify any unusual prescribing behaviors. Texas provides quarterly reports to child welfare officials on the use of psychotropic drugs among foster children and treating clinicians have access to a child's medical records on a 24-hour basis. However, the electronic health record system does not always capture the child's height, weight, and allergies, which is optional for prescribers to enter into the system. This information is helpful as a child's weight may be used to determine the recommended dose for some medications, while allergy information may be used to determine whether a child should take a particular medication. In addition, ongoing medical problems are not recorded in the electronic health record system and Texas does not measure the rate of adverse reactions at the macro level among youth in state custody.

Maryland fully applies only one of the six AACAP guidelines for oversight procedures and partially applies others. Maryland provides foster children in out-of-home placement with a "medical passport" that serves as a record of the child's previous and current medical file. Each topic included in AACAP's guidelines for maintaining ongoing medical records, including diagnoses, allergies, and medical history, is documented in the passport, and an additional copy of the passport is kept in the child's case record

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<sup>42</sup>Primary care provider prescriptions were not flagged when treating ADHD, uncomplicated depression, and uncomplicated anxiety disorders.

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and maintained electronically. However, Maryland has not produced any specific guidelines for the use of all psychotropic prescriptions among foster children, thus limiting the state's ability to identify potentially risky prescribing practices for the foster child population.<sup>43</sup> Without guidelines for psychotropic drugs, there are no criteria to help agency officials monitor the appropriateness of prescriptions. Moreover, Maryland does not review Medicaid claims data statewide specifically for foster children, and therefore does not produce quarterly reports to identify the rate and types of drugs used in the foster care population that could help identify and monitor prescribing trends. In addition, as stated earlier, Maryland's 2008 foster care data were found unreliable. Maryland officials told us that transitioning to a new records system in 2007 resulted in incorrect and missing data for foster children.

**Consultation program:** According to interviews and documentation provided by state Medicaid and foster care officials, five of the six states have implemented some of AACAP's guidelines for consultation, but only one of the six selected states has implemented a consultation program that ensures all consent givers and prescribers are able to seek advice from child and adolescent psychiatrists before making consent decisions for foster children. States that do not have a consultation program to help link consent givers and prescribers with child and adolescent psychiatrists may reduce the extent to which prescribers and consent givers are informed about the expected benefits and risks of treatments, alternative treatments, and the risks associated with no treatment. Table 6 lists the AACAP guidelines relative to consultation programs and illustrates the extent to which selected states have implemented those guidelines.

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<sup>43</sup>Beginning October 2011, the Maryland Medicaid Pharmacy Program (MMPP) implemented a peer-review authorization process to ensure the safe and effective use of antipsychotic medications in children. Claims for antipsychotic medications that are for children younger than the FDA-approved age require a Prior Authorization (PA) based on the peer-review assessment. The MMPP's Board-Certified child psychiatrist oversees the peer-review project. According to a state agency official, a child and adolescent psychiatrist who is faculty at Johns Hopkins University School of Medicine monitors all psychotropic medication use for children entering foster care in Baltimore City. However, this practice is not statewide.

**Table 6: State Consultation Programs Compared with AACAP's Best Principles Guidelines**

| Guideline   |  | FL                | MD                    | MA                    | MI              | OR                    | TX                    |
|-------------|--|-------------------|-----------------------|-----------------------|-----------------|-----------------------|-----------------------|
| Recommended | Design a consultation program administered by child and adolescent psychiatrists. This program provides consultation by child and adolescent psychiatrists to the persons or agency that is responsible for consenting for treatment with psychotropic medications   | Fully implemented | Not implemented       | Partially implemented | Not implemented | Partially implemented | Partially implemented |
| Recommended | The consultation program provides consultations by child and adolescent psychiatrists to, and at the request of, physicians treating this difficult patient population   | Fully implemented | Partially implemented | Fully implemented     | Not implemented | Not implemented       | Not implemented       |
| Recommended | The consultation program conducts face-to-face evaluations of youth by child and adolescent psychiatrists at the request of the child welfare agency, the juvenile court, or other state or county agencies empowered by law to consent for treatment with psychotropic medications when concerns have been raised about the pharmacological regimen | Not implemented   | Not implemented       | Fully implemented     | Not implemented | Not implemented       | Fully implemented     |



Source: GAO analysis of information collected through interviews with, and various documentation provided by, the selected states' Medicaid and Foster Care officials, and the AACAP's best principles guideline.

Massachusetts and Oregon provide examples of how states vary their approach in providing expert consultations to caregivers. For example, Massachusetts's foster care agency started an initiative to connect child welfare staff to Medicaid pharmacists who can provide information on medications and the foster child's drug history, including interactions between any current and proposed drugs. In addition, primary care physicians who treat children, including foster care children, also have access to the state-funded Massachusetts Child Psychiatry Access Project, a system of regional children's mental health consultation teams designed to help pediatricians find and consult with child psychiatrists. Massachusetts has six child psychiatrists who are available to provide consultations on a part-time basis to child welfare staff, but these

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consultations are not available for other consent givers such as foster parents. The foster care agency's consultation program also provides face-to-face evaluations of foster children at the request of consent givers concerned about a child's treatment.

In early 2009, Oregon put a consultation program in place to help consent givers make informed decisions. In 2010, Oregon's foster care agency shifted the responsibility for all consent decisions where the agency has legal custody or is the legal guardian of the child from foster parents to child welfare agency officials, who now have access to a child and adolescent psychiatrist and can seek consultations before making consent decisions. However, the consultation program does not conduct face-to-face evaluations of children—by a child and adolescent psychiatrist—at the request of consent givers, nor does it enable prescribing physicians to consult with child and adolescent psychiatrists. Oregon has plans for the development of the Oregon Psychiatric Access Line for Kids, which would allow primary care physicians and nurse practitioners to consult with child psychiatrists, but agency officials told us the program is not operational due to a lack of funding.

**Information sharing:** Four of the six selected states have created websites with information on psychotropic drugs for clinicians, foster parents, and other caregivers. Access to comprehensive information can help ensure that clinicians, foster parents, and other interested parties are fully informed about the use and management of psychotropic drugs. Table 7 lists AACAP's guidelines relative to information sharing and illustrates the extent to which selected states have implemented those guidelines.

**Table 7: State Information-sharing Laws and Policies Compared with AACAP’s Best Principles Guidelines**

| Guideline |   | FL                | MD              | MA                | MI              | OR                | TX                |
|-----------|---|-------------------|-----------------|-------------------|-----------------|-------------------|-------------------|
| Ideal     | Create a website to provide ready access for clinicians, foster parents, and other caregivers to pertinent policies and procedures governing psychotropic medication management | Fully implemented | Not implemented | Fully implemented | Not implemented | Fully implemented | Fully implemented |
| Ideal     | Website includes psycho-educational materials   | Fully implemented | Not implemented | Fully implemented | Not implemented | Fully implemented | Fully implemented |
| Ideal     | Website includes consent forms  | Fully implemented | Not implemented | Not implemented   | Not implemented | Fully implemented | Not implemented   |
| Ideal     | Website includes adverse effect rating forms  | Not implemented   | Not implemented | Not implemented   | Not implemented | Not implemented   | Not implemented   |
| Ideal     | Website includes reports on prescription patterns for psychotropic medications  | Not implemented   | Not implemented | Not implemented   | Not implemented | Not implemented   | Fully implemented |
| Ideal     | Website includes links to helpful, accurate, and ethical websites about child and adolescent psychiatric diagnoses and psychotropic medications                                 | Fully implemented | Not implemented | Not implemented   | Not implemented | Not implemented   | Fully implemented |

|   |                       |           |               |
|---|-----------------------|-----------|---------------|
|  | Fully implemented     | <b>FL</b> | Florida       |
|  | Partially implemented | <b>MD</b> | Maryland      |
|  | Not implemented       | <b>MA</b> | Massachusetts |
|   |                       | <b>MI</b> | Michigan      |
|   |                       | <b>OR</b> | Oregon        |
|   |                       | <b>TX</b> | Texas         |

Source: GAO analysis of information collected through interviews with, and various documentation provided by, the selected states’ Medicaid and Foster Care officials, and the AACAP’s best principles guideline.

For example, Florida’s foster care agency has partnered with the University of South Florida to implement Florida’s Center for the Advancement of Child Welfare Practice to provide needed information and support to Florida’s professional child welfare stakeholders.<sup>44</sup> The

<sup>44</sup>According to the Center’s website, its mission is to support and facilitate the identification, expansion, and transfer of expert knowledge and best practices in child welfare case practice, direct services, management, finances, policy, and organizational development to child welfare and child protection stakeholders throughout Florida.

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program's website is consistent with four of AACAP's six guidelines for information sharing. For example, the website includes policies and procedures governing psychotropic drug management, staff publications and educational materials about psychotropic drugs, consent forms, and links to other informative publications and news stories related to foster children and psychotropic drugs. However, the website does not provide reports on prescription patterns for psychotropic drugs or adverse effect rating forms.

In comparison, Oregon's foster care agency developed a website that includes information regarding psychotropic medication, but the website is not updated regularly to operate as an ongoing information resource. The website currently has information on state policies and procedures governing the use of psychotropic drugs and also contains web links to consent forms and a medication chart that can be used as a psychotropic medication reference tool. However, the website does not meet three of the six information-sharing guidelines, including those on posting adverse effect rating forms, reporting prescription patterns, and providing links to other informative websites. States with less accessibility to comprehensive information may limit the extent to which physicians, foster parents, and other interested parties are informed about the use and management of psychotropic drugs.

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## Conclusions

The higher rates of psychotropic drug prescriptions among foster children may be explained by their greater mental health needs and the challenges inherent to the foster care system. However, thousands of foster and nonfoster children in the five states we analyzed were found to have prescriptions that carry potential health risks. While doctors are permitted to prescribe these drugs under current laws, increasing the number of drugs used concurrently and exceeding the maximum recommended dosages for certain psychotropic drugs have been shown to increase the risk of adverse side effects in adults. Prescriptions for infants are also of concern, due to the potential for serious adverse effects even when these drugs are used for non-mental health purposes. Comprehensive oversight programs would help states identify these and other potential health risks and provide caregivers and prescribers with the information necessary to weigh drug risks and benefits. The recently enacted Child and Family Services Improvement and Innovation Act requires states to establish protocols for monitoring psychotropic drugs prescribed to foster children. Under the act, each state is authorized to develop its own monitoring protocols, but HHS-endorsed, nationwide guidelines for consent, oversight, consultation, and information sharing

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could help states close the oversight gaps we identified and increase protections for this vulnerable population.

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## Recommendation for Executive Action

In our draft report, we recommended that the Secretary of HHS evaluate our findings and consider endorsing guidance to state Medicaid and child welfare agencies on best practices for monitoring psychotropic drug prescriptions for foster children, including guidance that addresses, at minimum, informed consent, oversight, consultation, and information sharing.

We have received written comments on our draft report from HHS and relevant agencies in 6 states. In written comments, HHS agreed with our recommendation and provided technical comments, which we incorporated as appropriate. In written comments and exit conferences, staff from state Medicaid and foster care agencies provided comments on key facts from the report. Agency comments will be incorporated and addressed in a written report that will be issued in December 2011.

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Chairman Carper, Ranking Member Brown, and Members of the Subcommittee, this completes my prepared statement. I would be pleased to respond to any questions that you may have at this time.

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## GAO Contacts

For additional information about this testimony, please contact Gregory D. Kutz at (202) 512-6722 or [kutzg@gao.gov](mailto:kutzg@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement.

# Appendix I: Print-friendly version of figure 1 and figure 2

State:

**Florida (FL)**

**\$** Medicaid amount paid for psychotropic medications prescribed to foster and nonfoster children during 2008:

**\$64,358,968**



| Percentage of children prescribed psychotropic medication age: | Foster children | Nonfoster children | Ratio of foster to nonfoster children |
|--|-----------------|--------------------|---------------------------------------|
| 0–17 years old   | 22.0%           | 8.2%               | 2.7                                   |
| 13–17 years old  | 36.8%           | 11.9%              | 3.1                                   |
| 6–12 years old   | 31.2%           | 12.3%              | 2.5                                   |
| 0–5 years old  | 5.3%            | 3.3%               | 1.6                                   |

**Note:** Rates for foster and nonfoster children are comparable within the same state and the ratio of prescriptions to foster children to prescriptions to nonfoster children is comparable across states. However, prescription rates are not comparable across states because certain states covered more psychotropic drugs than other states. In addition, we excluded children whose prescriptions were not reported to CMS because they were covered by an HMO in the two states with both fee-for-service and HMO prescription coverage. Percentages and ratios are rounded to the nearest tenth, and therefore the reported ratio may be slightly different than the ratio of the rounded percentages.

Source: GAO analysis of state Medicaid and foster care data.

State:

**Massachusetts (MA)**

**\$** Medicaid amount paid for psychotropic medications prescribed to foster and nonfoster children during 2008:

**\$29,584,901**



| Percentage of children prescribed psychotropic medication age: | Foster children | Nonfoster children | Ratio of foster to nonfoster children |
|--|-----------------|--------------------|---------------------------------------|
| 0–17 years old   | 39.1%           | 10.2%              | 3.8                                   |
| 13–17 years old  | 53.4%           | 14.7%              | 3.6                                   |
| 6–12 years old   | 44.8%           | 12.1%              | 3.7                                   |
| 0–5 years old  | 4.9%            | 2.2%               | 2.2                                   |

**Note:** Rates for foster and nonfoster children are comparable within the same state and the ratio of prescriptions to foster children to prescriptions to nonfoster children is comparable across states. However, prescription rates are not comparable across states because certain states covered more psychotropic drugs than other states. In addition, we excluded children whose prescriptions were not reported to CMS because they were covered by an HMO in the two states with both fee-for-service and HMO prescription coverage. Percentages and ratios are rounded to the nearest tenth, and therefore the reported ratio may be slightly different than the ratio of the rounded percentages.

Source: GAO analysis of state Medicaid and foster care data.

State:

**Michigan (MI)**

**\$** Medicaid amount paid for psychotropic medications prescribed to foster and nonfoster children during 2008:

**\$72,749,858**



| Percentage of children prescribed psychotropic medication age: | Foster children | Nonfoster children | Ratio of foster to nonfoster children |
|--|-----------------|--------------------|---------------------------------------|
| 0–17 years old   | 21.0%           | 7.9%               | 2.7                                   |
| 13–17 years old  | 35.0%           | 13.1%              | 2.7                                   |
| 6–12 years old   | 26.7%           | 11.5%              | 2.3                                   |
| 0–5 years old  | 4.4%            | 1.1%               | 3.8                                   |

**Note:** Rates for foster and nonfoster children are comparable within the same state and the ratio of prescriptions to foster children to prescriptions to nonfoster children is comparable across states. However, prescription rates are not comparable across states because certain states covered more psychotropic drugs than other states. In addition, we excluded children whose prescriptions were not reported to CMS because they were covered by an HMO in the two states with both fee-for-service and HMO prescription coverage. Percentages and ratios are rounded to the nearest tenth, and therefore the reported ratio may be slightly different than the ratio of the rounded percentages.

Source: GAO analysis of state Medicaid and foster care data.

State:

Oregon (OR)

 Medicaid amount paid for psychotropic medications prescribed to foster and nonfoster children during 2008:

**\$14,326,756**



| Percentage of children prescribed psychotropic medication age: | Foster children | Nonfoster children | Ratio of foster to nonfoster children |
|--|-----------------|--------------------|---------------------------------------|
| 0–17 years old   | 19.7%           | 4.8%               | 4.1                                   |
| 13–17 years old  | 43.3%           | 12.0%              | 3.6                                   |
| 6–12 years old   | 23.4%           | 6.2%               | 3.8                                   |
| 0–5 years old  | 2.5%            | 0.6%               | 3.9                                   |

**Note:** Rates for foster and nonfoster children are comparable within the same state and the ratio of prescriptions to foster children to prescriptions to nonfoster children is comparable across states. However, prescription rates are not comparable across states because certain states covered more psychotropic drugs than other states. In addition, we excluded children whose prescriptions were not reported to CMS because they were covered by an HMO in the two states with both fee-for-service and HMO prescription coverage. Percentages and ratios are rounded to the nearest tenth, and therefore the reported ratio may be slightly different than the ratio of the rounded percentages.

Source: GAO analysis of state Medicaid and foster care data.

State:

**Texas (TX)**

**\$** Medicaid amount paid for psychotropic medications prescribed to foster and nonfoster children during 2008:

**\$194,952,105**



| Percentage of children prescribed psychotropic medication age: | Foster children | Nonfoster children | Ratio of foster to nonfoster children |
|--|-----------------|--------------------|---------------------------------------|
| 0–17 years old   | 32.2%           | 7.1%               | 4.5                                   |
| 13–17 years old  | 58.2%           | 11.4%              | 5.1                                   |
| 6–12 years old   | 45.8%           | 10.6%              | 4.3                                   |
| 0–5 years old  | 9.1%            | 3.1%               | 2.9                                   |

**Note:** Rates for foster and nonfoster children are comparable within the same state and the ratio of prescriptions to foster children to prescriptions to nonfoster children is comparable across states. However, prescription rates are not comparable across states because certain states covered more psychotropic drugs than other states. In addition, we excluded children whose prescriptions were not reported to CMS because they were covered by an HMO in the two states with both fee-for-service and HMO prescription coverage. Percentages and ratios are rounded to the nearest tenth, and therefore the reported ratio may be slightly different than the ratio of the rounded percentages.

Source: GAO analysis of state Medicaid and foster care data.

State:

**Florida (FL)**



|   | Percentage of foster children | Percentage of nonfoster children |
|---|-------------------------------|----------------------------------|
| Children age 0–17 prescribed five (5) or more medications concomitantly               | 0.11%                         | 0.03%                            |
| Children 0–17 with a dosage exceeding maximum guidelines based on FDA-approved labels | 1.50%                         | 0.44%                            |
| Children under 1 year old prescribed a psychotropic drug                              | 2.1%                          | 1.2%                             |

**Note:** Rates for foster and nonfoster children are comparable within the same state and the ratio of prescriptions to foster children to prescriptions to nonfoster children is comparable across states. However, prescription rates are not comparable across states because certain states covered more psychotropic drugs than other states. In addition, we excluded children whose prescriptions were not reported to CMS because they were covered by an HMO in the two states with both fee-for-service and HMO prescription coverage.

Source: GAO analysis of state Medicaid and foster care data.

State:

**Massachusetts (MA)**



|   | Percentage of foster children | Percentage of nonfoster children |
|---|-------------------------------|----------------------------------|
| Children age 0–17 prescribed five (5) or more medications concomitantly               | 1.33%                         | 0.07%                            |
| Children 0–17 with a dosage exceeding maximum guidelines based on FDA-approved labels | 2.21%                         | 0.56%                            |
| Children under 1 year old prescribed a psychotropic drug                              | 0.7%                          | 0.7%                             |

**Note:** Rates for foster and nonfoster children are comparable within the same state and the ratio of prescriptions to foster children to prescriptions to nonfoster children is comparable across states. However, prescription rates are not comparable across states because certain states covered more psychotropic drugs than other states. In addition, we excluded children whose prescriptions were not reported to CMS because they were covered by an HMO in the two states with both fee-for-service and HMO prescription coverage.

Source: GAO analysis of state Medicaid and foster care data.

State:

**Michigan (MI)**



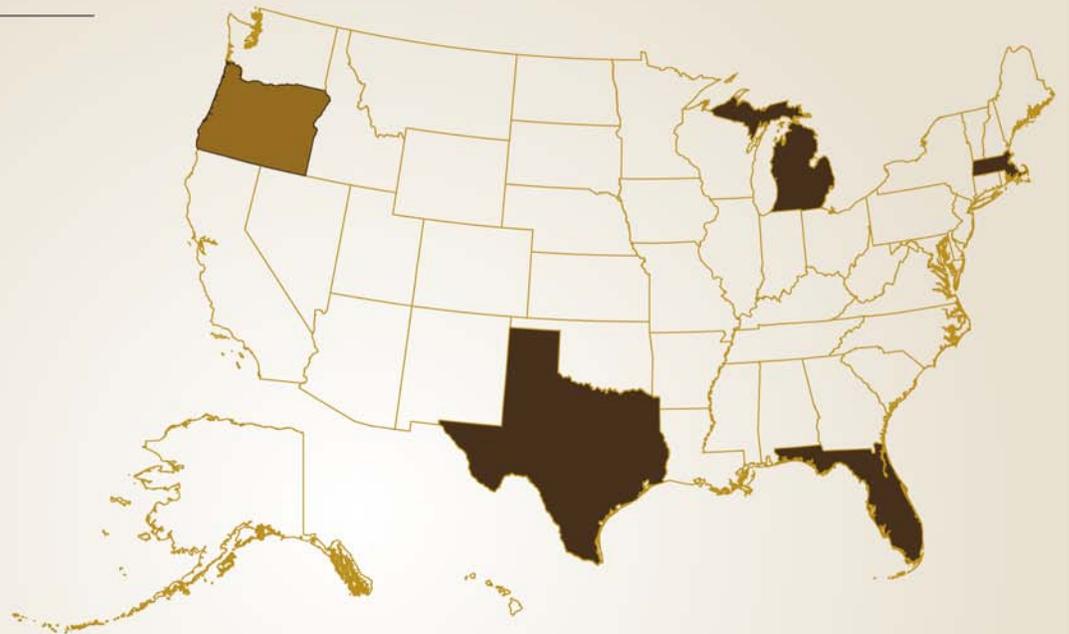
|   | Percentage of foster children | Percentage of nonfoster children |
|---|-------------------------------|----------------------------------|
| Children age 0–17 prescribed five (5) or more medications concomitantly               | <b>0.29%</b>                  | <b>0.02%</b>                     |
| Children 0–17 with a dosage exceeding maximum guidelines based on FDA-approved labels | <b>1.67%</b>                  | <b>0.49%</b>                     |
| Children under 1 year old prescribed a psychotropic drug                              | <b>1.5%</b>                   | <b>0.3%</b>                      |

**Note:** Rates for foster and nonfoster children are comparable within the same state and the ratio of prescriptions to foster children to prescriptions to nonfoster children is comparable across states. However, prescription rates are not comparable across states because certain states covered more psychotropic drugs than other states. In addition, we excluded children whose prescriptions were not reported to CMS because they were covered by an HMO in the two states with both fee-for-service and HMO prescription coverage.

Source: GAO analysis of state Medicaid and foster care data.

State:

**Oregon (OR)**



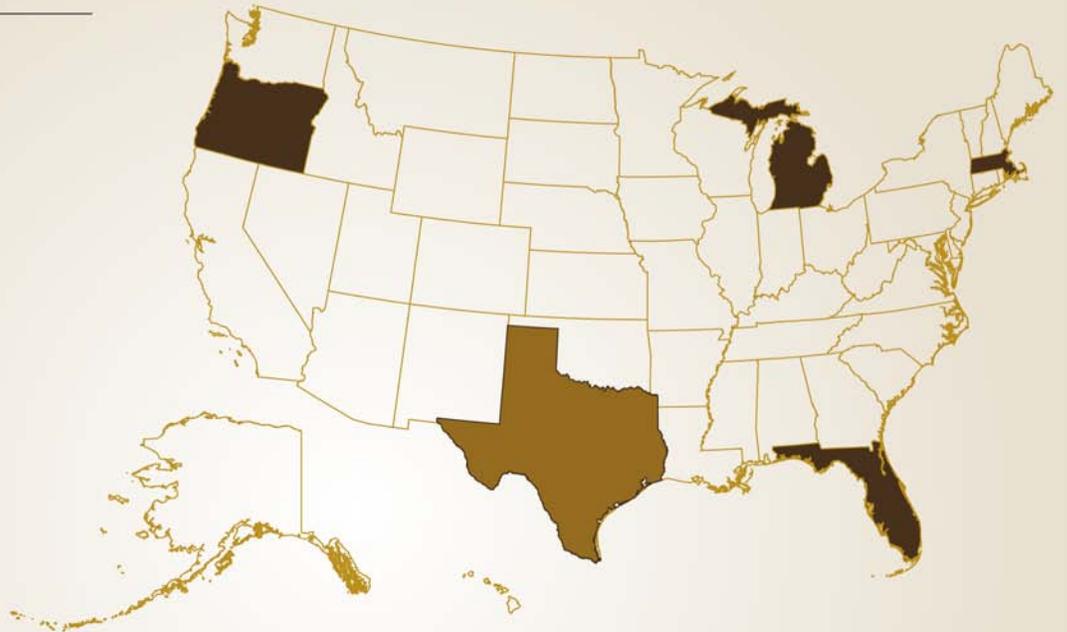
|   | Percentage of foster children | Percentage of nonfoster children |
|---|-------------------------------|----------------------------------|
| Children age 0–17 prescribed five (5) or more medications concomitantly               | <b>0.13%</b>                  | <b>0.01%</b>                     |
| Children 0–17 with a dosage exceeding maximum guidelines based on FDA-approved labels | <b>1.12%</b>                  | <b>0.16%</b>                     |
| Children under 1 year old prescribed a psychotropic drug                              | <b>0.3%</b>                   | <b>0.1%</b>                      |

**Note:** Rates for foster and nonfoster children are comparable within the same state and the ratio of prescriptions to foster children to prescriptions to nonfoster children is comparable across states. However, prescription rates are not comparable across states because certain states covered more psychotropic drugs than other states. In addition, we excluded children whose prescriptions were not reported to CMS because they were covered by an HMO in the two states with both fee-for-service and HMO prescription coverage.

Source: GAO analysis of state Medicaid and foster care data.

State:

**Texas (TX)**



|   | Percentage of foster children | Percentage of nonfoster children |
|---|-------------------------------|----------------------------------|
| Children age 0–17 prescribed five (5) or more medications concomitantly               | 1.05%                         | 0.02%                            |
| Children 0–17 with a dosage exceeding maximum guidelines based on FDA-approved labels | 3.27%                         | 0.37%                            |
| Children under 1 year old prescribed a psychotropic drug                              | 1.2%                          | 1.0%                             |

**Note:** Rates for foster and nonfoster children are comparable within the same state and the ratio of prescriptions to foster children to prescriptions to nonfoster children is comparable across states. However, prescription rates are not comparable across states because certain states covered more psychotropic drugs than other states. In addition, we excluded children whose prescriptions were not reported to CMS because they were covered by an HMO in the two states with both fee-for-service and HMO prescription coverage.

Source: GAO analysis of state Medicaid and foster care data.

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