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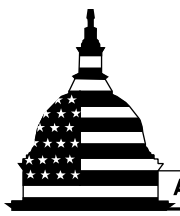
Report to Congressional Requesters

December 2012

CHILDREN'S MENTAL HEALTH

Concerns Remain about Appropriate Services for Children in Medicaid and Foster Care



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Accountability * Integrity * Reliability

GAO-13-15

December 2012

CHILDREN'S MENTAL HEALTH

Concerns Remain about Appropriate Services for Children in Medicaid and Foster Care

GAO Highlights

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Highlights of GAO-13-15, a report to congressional requesters

Why GAO Did This Study

Experts have concerns that children with mental health conditions do not always receive appropriate treatment, including concerns about appropriate use of psychotropic medications (which affect mood, thought, or behavior) and about access to psychosocial therapies (sessions with a mental health provider). These concerns may be compounded for low-income children in Medicaid and children in foster care (most of whom are covered by Medicaid)—populations who may be at higher risk of mental health conditions. Within HHS, CMS oversees Medicaid, and ACF supports state child welfare agencies that coordinate health care for foster children.

GAO was asked to provide information on children's mental health. This report examines (1) the use of psychotropic medications and other mental health services for children in Medicaid nationwide, and related CMS initiatives; (2) HHS information on the use of psychotropic medications and other mental health services for children in foster care nationwide, and related HHS initiatives; and (3) the amount HHS has invested in research on children's mental health.

GAO analyzed data from HHS's MEPS—a national household survey on use of medical services—from 2007 through 2009 for children covered by Medicaid and private insurance. GAO reviewed two recent ACF foster care reports with data from a national survey conducted during 2008 through 2011. GAO analyzed data from HHS agencies that conduct or fund research and interviewed HHS officials and children's mental health providers, researchers, and advocates.

View GAO-13-15. For more information, contact Katherine Iritani at (202) 512-7114 or iritanik@gao.gov.

What GAO Found

An annual average of 6.2 percent of noninstitutionalized children in Medicaid nationwide and 4.8 percent of privately insured children took one or more psychotropic medications, according to GAO's analysis of 2007-2009 data from the Department of Health and Human Services' (HHS) Medical Expenditure Panel Survey (MEPS). MEPS data also showed that children in Medicaid took antipsychotic medications (a type of psychotropic medication that can help some children but has a risk of serious side effects) at a relatively low rate—1.3 percent of children—but that the rate for children in Medicaid was over twice the rate for privately insured children, which was 0.5 percent. In addition, MEPS data showed that most children whose emotions or behavior, as reported by their parent or guardian, indicated a potential need for a mental health service did not receive any services within the same year. The Centers for Medicare & Medicaid Services (CMS) and many states have initiatives under way to help ensure that children receive appropriate mental health treatments. However, CMS's ability to monitor children's receipt of mental health services is limited because CMS does not collect information from states on whether children in Medicaid have received services for which they were referred. GAO recommended in 2011 that CMS identify options for collecting such data from state Medicaid programs. Findings in this report underscore the continued importance of CMS's monitoring of children's receipt of mental health services.

HHS's Administration for Children and Families (ACF) reported that 18 percent of foster children were taking psychotropic medications at the time they were surveyed, although utilization varied widely by the child's living arrangement. ACF also reported that 30 percent of foster children who may have needed mental health services did not receive them in the previous 12 months. HHS agencies are taking steps to promote appropriate mental health treatments for foster children, such as by sending information to states on psychotropic medication oversight practices.

HHS's National Institutes of Health spent an estimated $1.2 billion on over 1,200 children's mental health research projects during fiscal years 2008 through 2011. Most of the funding—$956 million—was awarded by the National Institute of Mental Health, with more research projects studying psychosocial therapies than psychotropic medications. Other HHS agencies spent about $16 million combined on children's mental health research during this period.

HHS reviewed a draft of this report and provided technical comments, which GAO incorporated as appropriate.

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Abbreviations

AACAP	American Academy of Child & Adolescent Psychiatry
ACF	Administration for Children and Families
ADHD	attention deficit hyperactivity disorder
AHRQ	Agency for Healthcare Research and Quality
BPCA	Best Pharmaceuticals for Children Act
CDC	Centers for Disease Control and Prevention
Child Improvement Act	Child and Family Services Improvement and Innovation Act
CHIP	State Children's Health Insurance Program
CMS	Centers for Medicare & Medicaid Services
EBT	evidence-based therapy
EPSDT	Early and Periodic Screening, Diagnostic, and Treatment
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
MEPS	Medical Expenditure Panel Survey
NICHD	Eunice Kennedy Shriver National Institute of Child Health & Human Development
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
NSCAW II	National Survey of Child and Adolescent Well-being II
PREA	Pediatric Research Equity Act
SAMHSA	Substance Abuse and Mental Health Services Administration

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Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

December 10, 2012

The Honorable Tom Harkin
Chairman
Committee on Health, Education, Labor, & Pensions
United States Senate

The Honorable Rosa DeLauro
The Honorable Lucille Roybal-Allard
House of Representatives

Children with mental health conditions are among the country's most vulnerable populations, and there are concerns about whether they have access to the most appropriate kind of care for their conditions. Early detection and treatment of childhood mental health conditions can improve a child's symptoms and reduce potentially detrimental effects on a child, such as difficulties with relationships, dropping out of school, and involvement with the juvenile justice system. Children with mental health conditions,[1] such as attention deficit hyperactivity disorder (ADHD) or depression, can be treated with psychosocial therapies (sessions with a provider designed to reduce symptoms and improve functioning); psychotropic medication (medications that affect mood, thought, or behavior); or a combination of both. Many of these children, however, lack access to the treatments they need to help them manage or overcome their emotional or behavioral problems.[2] In addition, child mental health advocates, providers, and researchers have expressed concern about the increase in the prescribing of psychotropic medications for children, in part because there is limited evidence available regarding short- and long-term safety and efficacy for some types of medications,

[1]In this report, the term "mental health condition" includes all mental, emotional, and behavioral disorders that are included in the Diagnostic and Statistical Manual of Mental Disorders, with the exception of pervasive developmental disabilities (such as autism) and substance use disorders, which we excluded from our study. Examples of disorders that are included are attention deficit hyperactivity disorder (ADHD); anxiety disorders, including post-traumatic stress disorder; mood disorders, including depression and bipolar disorder; schizophrenia; and eating disorders.

[2]According to data from the Department of Health and Human Services' (HHS) 2007 National Survey of Children's Health, about 40 percent of children ages 2 through 17 who needed treatment from a mental health professional did not receive it during the previous year.

particularly for combinations of medications. Mental health experts are especially concerned about the recent increase in prescribing of antipsychotic medications—psychotropic medications developed to treat conditions such as schizophrenia and bipolar disorder—in part because these medications can cause very serious side effects, such as rapid weight gain and the development of diabetes.

Concerns about access to appropriate mental health services and the increased prescribing of psychotropic medications may be compounded for children in Medicaid, the State Children's Health Insurance Program (CHIP),[3] and foster care—children who may be at higher risk of mental health conditions than other children.[4] Children in foster care, most of whom are eligible for Medicaid, are an especially vulnerable population because often they have been subjected to traumatic experiences involving abuse or neglect and they may suffer from multiple, serious mental health conditions.[5] Although state Medicaid programs are generally required to cover services to screen children for mental health problems and to provide treatment for any identified conditions, we previously reported that it can be difficult for physicians to find mental health specialists to whom they can refer children in Medicaid.[6] Concerns for children in Medicaid and CHIP are also related to studies that have shown that publicly insured children are prescribed psychotropic

[3]Medicaid is a federal-state program for certain categories of low-income children, families, and individuals. CHIP is also a federal-state program and provides health care coverage to children living in families whose incomes exceed the eligibility requirements for Medicaid. In 2010, there were an estimated 42 million children enrolled in Medicaid and CHIP.

[4]Data from the Centers for Disease Control and Prevention's National Health Interview Survey showed that a higher proportion of children in Medicaid and CHIP had difficulties in emotion, concentration, or behavior than privately insured children—about 8 percent versus 4 percent, respectively, during 2001 through 2007. The Administration for Children and Families' National Survey of Child and Adolescent Wellbeing II estimated that about 32 percent of children in foster homes had a behavior problem during 2008 through 2009.

[5]In 2010, about 408,000 children were in foster care. This estimate includes children who may live with relatives informally; such children are not included in the definition of foster care we used in this report. See U.S. Department of Health and Human Services, Children's Bureau, *Foster Care Statistics 2010* (Washington, D.C.: 2012).

[6]GAO, *Medicaid and CHIP: Most Physicians Serve Covered Children but Have Difficulty Referring Them for Specialty Care,* GAO-11-624 (Washington, D.C.: June 30, 2011).

medications at higher rates than privately insured children.[7] We reported in 2011 that children in foster care take these medications at higher rates than other children in Medicaid, and we recommended that HHS consider issuing guidance to state Medicaid and child welfare agencies on best practices for monitoring psychotropic medication prescriptions for foster children.[8]

Several agencies in the Department of Health and Human Services (HHS) have responsibilities related to children's mental health. The Centers for Medicare & Medicaid Services (CMS) oversees, and jointly finances with the states, the Medicaid and CHIP programs, which provide health coverage for low-income children.[9] State Medicaid programs are required by federal law to provide coverage for certain health services, which may include mental health services, for most children through the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit.[10] The Administration for Children and Families (ACF) provides funding for and oversees states' child welfare programs, which are responsible for monitoring and coordinating mental health services for foster children, among other things. The Substance Abuse and Mental Health Services Administration (SAMHSA) works to increase the quality and availability of mental health treatments, such as by awarding grants that support the development of community-based services for children with mental health conditions, including children in foster care. Other HHS agencies, including the National Institutes of Health (NIH), Food and Drug Administration (FDA), Agency for Healthcare Research and Quality (AHRQ), and Centers for Disease Control and Prevention (CDC),

[7]See, for example, A. Martin et al., "Use of Multiple Psychotropic Drugs by Medicaid-Insured and Privately Insured Children," *Psychiatric Services*, vol. 53, no. 12 (2002).

[8]We recommended that HHS 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. See GAO, *Foster Children: HHS Guidance Could Help States Improve Oversight of Psychotropic Prescriptions*, GAO-12-201 (Washington, D.C.: Dec. 14, 2011).

[9]States may administer their CHIP programs as expansions of their Medicaid programs, as standalone CHIP programs, or as a combination.

[10]While states must also provide EPSDT services to CHIP children who are enrolled as part of an expansion of their state's Medicaid program, CHIP children who are enrolled under a separate CHIP plan are not entitled to EPSDT services.

conduct, fund, or review research that seeks to expand the knowledge of children's mental health conditions and treatments.

Because of your interest in children's access to appropriate mental health treatments, you asked us to provide information on mental health services, including medications, for children in Medicaid, CHIP, and foster care nationwide and on the federal investment in children's mental health research. This report examines (1) the use of psychotropic medications and other mental health services by children nationwide in Medicaid and CHIP, and related CMS initiatives; (2) HHS information on the use of psychotropic medications and other mental health services by foster children nationwide, and related HHS initiatives; and (3) the amount HHS has invested in research to study children's mental health conditions and treatments.

To examine the use of psychotropic medications and other mental health services by children in Medicaid and CHIP, we analyzed nationwide data from the Medical Expenditure Panel Survey (MEPS) from 2007 through 2009.[11] We included children ages 0 through 20 who were enrolled in Medicaid or CHIP for at least 10 months in a calendar year, excluding children in foster care.[12] Because MEPS does not differentiate between children in Medicaid and children in CHIP, we could not report on these programs separately. For the purposes of this report, we used the term Medicaid to refer to both Medicaid and CHIP. We analyzed MEPS data for privately insured children as a point of comparison.[13] Specifically, we examined annual rates of psychotropic medication use, numbers and types of medications taken,[14] and utilization of office-based mental health services, such as visits to a psychiatrist or psychologist. We also examined receipt of mental health services by children who had a

[11]MEPS is a nationally representative household survey conducted by AHRQ that collects information on individuals' use of medical services by setting and provider type. Specifically, we examined children's use of psychotropic medications, mental health-related office visits, and therapy visits. We pooled 3 years of data to obtain a sample size large enough to conduct our analyses.

[12]State Medicaid programs generally cover children under 21 years of age.

[13]We included children who were enrolled in private insurance for at least 10 months in a calendar year.

[14]MEPS reports on all medications taken in a calendar year but does not provide information on whether medications were taken concomitantly—that is, in combination with other medications.

potential mental health need. To identify children with a potential mental health need, MEPS employs a standardized psychometric scale designed to measure emotional and behavioral impairment.[15] Using this scale, we identified the percentage of children whose emotions or behavior, as reported by their parents, indicated a potential need for mental health services.[16] This measure does not indicate the level of treatment a child might require; rather, it identifies the percentage of children whose emotions or behavior indicated a need for, at a minimum, a mental health evaluation. Estimates using MEPS may be conservative because the survey excludes children in institutional settings, such as psychiatric hospitals, who are likely to be high utilizers of psychotropic medications and mental health services. In addition, MEPS relies on self-reporting by parents for utilization of medications and services, which may be understated because parents may be reluctant to report such information due to the stigma that can be associated with mental health conditions.[17] We reviewed the MEPS survey instruments and methodology and determined that the data were sufficiently reliable for our purposes. (See app. I for more information about the methodology we used to analyze MEPS data.) We also reviewed relevant literature on children's mental health and interviewed CMS officials and state mental health program directors to learn about their efforts to monitor prescribing of psychotropic medications and to increase access to mental health services among children.

[15]The psychometric scale is known as the Columbia Impairment Scale and consists of 13 questions designed to assess emotional distress and behavioral impairment. The maximum score is 52, and children who score 16 or higher are considered to have a potential mental health need. Parents of children ages 5 through 17 are asked to rate on a scale of 0 to 4 (0 being no problem and 4 being a very big problem) how much of a problem their child has in several areas, including getting along with family members, being involved in activities, and behaving at school. The scale is considered to be valid and reliable for use in surveys. See H. R. Bird et al., "The Columbia Impairment Scale (CIS): Pilot Findings on a Measure of Global Impairment for Children and Adolescents," *International Journal of Methods in Psychiatric Research,* vol. 3, no. 3 (1993).

[16]The preferred respondent for the interview is the person, 18 years or older, who is most knowledgeable about the family's health care and who is keeping records about health care use and expenses. For the purposes of this report, we consider this person to be the child's parent or guardian, although this may not always be the case.

[17]See, S. Zuvekas, "Prescription Drugs and the Changing Patterns of Treatment for Mental Disorders, 1996-2001," *Health Affairs*, vol. 24, no. 1 (2005).

To examine HHS information on the use of psychotropic medications and other mental health services by foster children nationwide, we reviewed two reports published by ACF. Both reports presented the results of the National Survey of Child and Adolescent Well-being II (NSCAW II), a nationally representative longitudinal survey of children ages 0 through 19 who were in contact with the child welfare system.[18] The NSCAW II surveys occurred in multiple phases during 2008 through 2011. One report, published in November 2011, summarized NSCAW II data collected during phase 1, from March 2008 through September 2009.[19] The second ACF report was a research brief on the use of psychotropic medication by children in contact with the child welfare system, which was published in 2012 and used NSCAW II data collected during phase 2, from October 2009 through January 2011.[20] The survey collected information on children who either lived in out-of-home foster care placements or remained in the care of their parents or relatives.[21] For this report, we considered children in foster care to be those who lived in out-of-home foster care placements—that is, in nonrelative foster homes—formal kin care,[22] group homes, or residential treatment centers.[23] We reported ACF's estimates of foster children's use of psychotropic

[18]According to ACF, the child welfare system is a group of government services designed to promote the well-being of children, including foster children. Contact with the child welfare system can stem from reports of possible child abuse or neglect and from requests by families for help protecting their children.

[19]H. Ringeisen et al., *NSCAW II Baseline Report: Children's Services*, OPRE Report #2011-27f (Washington, D.C.: Office of Planning, Research and Evaluation, Administration for Children and Families, U.S. Department of Health and Human Services, 2011).

[20]L.F. Stambaugh et al., *Psychotropic Medication Use by Children in Child Welfare*, OPRE Report #2012-33 (Washington, D.C.: Office of Planning, Research and Evaluation, Administration for Children and Families, U.S. Department of Health and Human Services, 2012).

[21]Child welfare systems can arrange for children to live with relatives, foster families, adoptive families, or other permanent placements when the child is not safe at home.

[22]Formal kin care is a living arrangement where the child is placed under legal custody of the state, but in physical custody of a relative.

[23]Group homes and residential treatment centers provide structured 24-hour care in a group setting to children with physical or behavioral needs. Residential treatment centers are inpatient facilities other than a hospital that provide specialized services to children, such as psychiatric services.

medications and of receipt of mental health services by foster children.[24] ACF's reports identified children with a potential mental health need by selecting children whose scores were above a certain level on one of five standardized psychometric scales that were used in NSCAW II and were designed to measure emotional or behavioral problems. These scales were the Child Behavior Checklist, which is based on caregiver reports; the Youth Self-Report; the Teacher's Report Form; the Children's Depression Inventory; and the Trauma Symptom Checklist for Children.[25] Questions in these scales were asked of the child, caregiver, or teacher, depending on the scale.[26] We reviewed ACF's report on psychotropic medication use to examine the extent to which the children ACF identified as having a potential mental health need received any mental health services within the past 12 months (or since the start of the child's living arrangement, if less than 12 months).[27] We also interviewed officials from ACF, AHRQ, and SAMHSA and representatives of provider organizations and mental health and child welfare advocacy groups to obtain information on the challenges foster children face in receiving appropriate mental health treatments.[28] Finally, to examine related HHS initiatives, we reviewed HHS documents and interviewed agency officials to obtain information about HHS's activities to help states promote appropriate use of mental health treatments for foster children.

[24]The survey asked caregivers about the child's receipt of mental health services in the previous 12 months or since the start of the living arrangement, if less than 12 months. Mental health services, which ACF refers to as specialty mental health services in OPRE Report #2012-33, include treatments received at an outpatient drug or alcohol clinic, mental health center, community health center, therapeutic nursery, hospital psychiatric unit, detox unit, inpatient unit, hospital emergency room, residential treatment center, group home, or school-based setting. Mental health services can also be received from a private mental health professional or family doctor, or during in-home counseling or crisis services.

[25]According to ACF, these scales are reliable assessments of children's behavioral and emotional problems.

[26]The Youth Self-Report, Children's Depression Inventory, and Trauma Symptom Checklist for Children were all asked of the child.

[27]Stambaugh et al., OPRE Report #2012-33, 6.

[28]We spoke with, among other organizations, the American Academy of Child & Adolescent Psychiatry, the American Academy of Pediatrics, the American Psychological Association, the National Association of Social Workers, and the Child Welfare League of America.

To describe HHS's investment in research to study children's mental health conditions and treatments, we requested data on research activities and interviewed officials from selected HHS agencies that conduct or sponsor children's mental health research: NIH, FDA, AHRQ, and CDC.[29] We asked each agency for a list of research projects[30] that were conducted internally by agency staff or conducted by external researchers and were funded by the agency for all or part of fiscal years 2008 through 2011.[31] We used the following inclusion and exclusion criteria for our analysis:

- Include projects that tested children, as well as projects that tested both children and adults, such as family studies.[32]
- Exclude research involving animals, projects that primarily studied substance abuse or pervasive developmental disorders such as autism, and large-scale surveys examining the prevalence of mental health conditions or mental health service utilization.[33]
- Exclude grants that did not specifically fund research, such as grants supporting student training or scientific conferences.

[29]We also spoke with officials from CMS, ACF, and SAMHSA, who told us that these agencies do not conduct or sponsor children's mental health research meeting our criteria.

[30]For the purposes of this report, we use the term "research projects" to encompass both internally conducted studies and external grants, contracts, and cooperative agreements.

[31]We included projects that began before fiscal year 2008 or extended past fiscal year 2011. NIH, AHRQ, and CDC were able to provide grant funding information on an annual basis, but FDA did not provide information broken down by fiscal year for their research projects, so some of the funding attributed to FDA may have been spent before or after our fiscal year 2008 through 2011 time frame.

[32]Agencies differed in their definition of a child. For example, NIH defines child as 0 to 20 years of age, while FDA defines child as 0 to 16.

[33]AHRQ and CDC sponsor large household surveys that have questions that address children's mental health, but these surveys also cover topics other than mental health conditions in children. We excluded these surveys from our analysis due to the difficulty of determining how much of the overall survey funding was directed toward developing, testing, and fielding the specific questions on children's mental health. Similarly, we did not include NIH's National Children's Study, a large prospective study of the effects of environment on children's health. However, individual grants and contracts awarded by NIH may have used survey methodology, and we did not attempt to exclude these during analysis.

NIH was unable to provide an agency-wide estimate of spending on children's mental health research projects that met our criteria. Therefore we requested data individually from the two institutes at NIH that, according to agency officials, sponsor and conduct most of the children's mental health research—the National Institute of Mental Health (NIMH) and the Eunice Kennedy Shriver National Institute of Child Health & Human Development (NICHD). We assessed the reliability of data from NIMH and NICHD by selecting a sample of research projects from each to determine whether they met our criteria. When some research projects in the NIMH sample appeared not to meet our criteria, we examined the primary research focus identified for each project. We then systematically excluded all projects with a primary research focus that did not appear to meet our criteria, such as schizophrenia in adults. On the basis of our review of the NIMH and NICHD samples, we determined that the data were sufficiently reliable for the purposes of our report. Because other institutes and centers at NIH may also have sponsored children's mental health research, we have likely underestimated NIH's total investment. We also determined that data from FDA, AHRQ, and CDC were sufficiently reliable for our purposes. We also spoke with officials from HHS agencies, representatives from provider and mental health advocacy groups, and researchers to better understand research needs in children's mental health.

We conducted this performance audit from November 2011 to December 2012 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.

Background

Children with mental health conditions can be treated with psychotropic medications, psychosocial therapies, or a combination of both.

Psychotropic Medications

Psychotropic medications can be very effective in treating children with mental health conditions, but they may also produce side effects, some of which can be serious. For example, according to the American Academy of Child & Adolescent Psychiatry (AACAP), medications used to treat ADHD can reduce symptoms such as hyperactivity in children, as well as improve their attention and increase their ability to get along with others. These medications have been widely tested in children and are generally

considered safe; however, ADHD medications have also been associated with side effects ranging from mild to serious, such as sleeplessness, loss of appetite, tics, agitation, hallucinations, liver problems, and suicidal thoughts.

Research has shown that foster children take psychotropic medications at much higher rates than other children covered by Medicaid. For example, we previously reported that while about 5 to 10 percent of nonfoster children in five states' Medicaid programs took a psychotropic medication in 2008, rates among children in foster care were about 20 to 39 percent.[34] The use of five or more medications concomitantly (that is, at the same time), while rare, was also higher among children in foster care.[35] We reported that several factors may have contributed to the higher utilization rates among foster children, such as the increased prevalence and greater severity of mental health conditions among these children.

Studies have shown that rates of psychotropic medication use among all children have increased. For example, one study found that the percentage of children's doctor visits involving psychotropic medications increased by 75 percent from 1996 to 2007—from 6 percent to about 11 percent.[36] Among these visits, those involving two or more medications rose from about 14 percent to about 20 percent.[37] Experts have identified a number of potential factors that could account for the increased use of psychotropic medications. For example, AACAP's guidelines on the use of psychotropic medications for children identified explanations such as the expanding evidence base demonstrating the efficacy of these medications for children[38] and the efforts of

[34]See, GAO-12-201. This analysis was based on fee-for-service Medicaid drug claims.

[35]Concomitant use of five or more medications ranged from 0.13 to 1.33 percent in foster children in the five states, compared with 0.01 to 0.07 in nonfoster children. See GAO-12-201.

[36]J. S. Comer, M. Olfson, and R. Mojtabai, "National Trends in Child and Adolescent Psychotropic Polypharmacy in Office-Based Practice, 1996-2007," *Journal of the American Academy of Child & Adolescent Psychiatry*, vol. 49, no. 10 (2010).

[37]The study also found that visits that were paid for by a public insurance program, such as Medicaid, were more likely to involve a prescription for multiple medications than were visits paid for by private insurance.

[38]However, AACAP noted that there is a lack of research on the efficacy of taking multiple psychotropic medications concomitantly.

pharmaceutical companies to market drugs to prescribers and consumers.[39]

Children's use of antipsychotic medications has also increased in recent years. For example, a recent analysis by a large pharmacy benefit manager[40] found that use of antipsychotics among insured children ages 10 through 19 increased from about 0.5 percent in 2001 to about 1 percent in 2010.[41] Some studies have indicated that antipsychotic medications are increasingly being prescribed for off-label purposes—that is, prescribed for conditions and in populations that are not included in FDA-approved labels.[42] For example, one study found that in 2004, almost 75 percent of children enrolled in Medicaid who were taking antipsychotic medications had mental health conditions other than those included in the drugs' labels, most commonly ADHD. Although doctors may prescribe drugs off-label, the Congressional Research Service has noted that such prescribing may increase the risk of children receiving ineffective medications, receiving dosages that are too high or too low, or experiencing side effects that are unique to children.[43] While antipsychotics can be effective medications for some children, their side effects can be very serious and include increases in cholesterol, rapid weight gain, and the development of diabetes or irreversible movement disorders. Mental health researchers and others have stated that there is a need for further research on the safety and effectiveness of antipsychotics for children, particularly the long-term effects.

[39]J. Walkup et al., "Practice Parameter on the Use of Psychotropic Medication in Children and Adolescents," *Journal of the American Academy of Child & Adolescent Psychiatry*, vol. 48, no. 9 (2009).

[40]Pharmacy benefit managers are firms that administer prescription drug benefits on behalf of health insurance plans.

[41]This estimate of antipsychotic use is specific to second-generation antipsychotics, also known as atypical antipsychotics. Second-generation antipsychotics have largely replaced first-generation antipsychotics in the past two decades. See *America's State of Mind Report* (Medco Health Solutions, Inc. 2011).

[42]See S. Crystal et al., "Broadened Use of Atypical Antipsychotics: Safety, Effectiveness, and Policy Challenges," *Health Affairs*, vol. 28, no. 5 (2009).

[43]Congressional Research Service, *FDA's Authority to Ensure That Drugs Prescribed to Children Are Safe and Effective* (Washington, D.C.: June 25, 2012).

Furthermore, some studies found that the prescribing of antipsychotics was higher among publicly insured children than among privately insured children, and even higher among foster children. One study found that children enrolled in Medicaid were prescribed antipsychotic medications at over four times the rate of children with private insurance in 2004.[44] In addition, AHRQ funded a study of antipsychotic prescribing based on Medicaid claims from 13 states, which found that utilization of antipsychotics in 2007 was much higher among foster children than among nonfoster children in Medicaid—12.4 percent on average versus 1.4 percent, respectively.[45] Prescribing of antipsychotics is a concern for CMS and state Medicaid programs not only because of safety issues, but also because these medications are costly. They represented the single largest drug expenditure category for Medicaid in 2007—over $2.8 billion.[46]

One reason for particular concern about growing use of antipsychotics and other psychotropic medications in children is that manufacturers do not always test medications for use in children. Manufacturers are responsible for conducting clinical trials and demonstrating their products' safety and efficacy to FDA, which is responsible for making decisions about whether and how medications can be marketed for children and for ensuring that manufacturers incorporate information from pediatric clinical trials into medication labels when required. However, because children are a small part of the overall population and physicians can prescribe medications off-label to children even if the medications have been tested only in adults, manufacturers may lack economic incentives to conduct

[44]S. Crystal et al., "Broadened Use of Atypical Antipsychotics."

[45]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 (Rutgers, New Jersey: July 2010).

Another recent AHRQ-funded analysis of prescribing rates for foster children using Medicaid claims from 48 states found that 11.8 percent of foster children used antipsychotics in 2007. See, D. Rubin et al., "Interstate Variation in Trends of Psychotropic Medication Use among Medicaid-Enrolled Children in Foster Care," *Children and Youth Services Review*, vol. 34 (2012).

[46]This total applies only to Medicaid enrollees who were not dually eligible for Medicare. See J. Verdier, A. Bagchi, and D. Esposito, *Prescription Drug Use and Cost among Medicaid Beneficiaries with Disabilities and Chronic Illnesses*, a report prepared for the Centers for Medicare & Medicaid Services (September 2011).

trials with children. According to a recent analysis by FDA scientists, fewer than half of all medications were adequately labeled for pediatric use in 2009.[47] The Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA)[48] address testing of medications in children by authorizing FDA to provide incentives for or require manufacturers to conduct pediatric studies in certain circumstances.[49] (For more information on BPCA and PREA and label changes for psychotropic medications resulting from these laws, see app. III.)

Psychosocial Therapies

Psychosocial therapies are mental health treatments that generally involve sessions with a mental health professional that are designed to reduce patients' emotional or behavioral symptoms. Such therapies may be used instead of, or in combination with, psychotropic medications to treat children with mental health conditions.[50] Psychosocial therapies that have been shown to be effective in treating mental health conditions may be referred to as evidence-based therapies (EBT). While there is no standard definition of what constitutes "evidence-based," some federal agencies and provider organizations evaluate and compile information on available therapies. For example, SAMHSA maintains the National Registry of Evidence-based Programs and Practices, a list of treatments that have been assessed by independent evaluators and rated on the

[47]Labeling was considered adequate if it stated that the drug was approved for pediatric use or that the drug had been studied in children, or if the label included safety, efficacy, or dosing information for all pediatric age groups as appropriate. See A. Sachs et al., "Pediatric Information in Drug Product Labeling," *Journal of the American Medical Association*, vol. 307, no. 18 (2012).

[48]For BPCA, see 21 U.S.C. § 355a and 42 U.S.C. § 284m. For PREA, see 21 U.S.C. §§ 355c, 355d.

[49]Under BPCA, manufacturers may opt to receive an additional 6 months of exclusive marketing for a medication from FDA in exchange for conducting pediatric studies. Under PREA, subject to certain exceptions, manufacturers must conduct pediatric studies before a medication can be marketed.

[50]Several large, federally funded studies have demonstrated that treatment with a combination of a psychosocial therapy and a psychotropic medication can be more effective than either treatment is alone for certain conditions. For example, NIMH funded a large multi-site study that found that treating children with anxiety with both an antidepressant medication and cognitive behavioral therapy was superior to either medication or therapy alone. See J. Walkup et al., "Cognitive behavioral therapy, sertraline, or a combination in childhood anxiety," *New England Journal of Medicine*, vol. 359, no. 26 (2008).

strength of the evidence showing their effectiveness. Provider organizations may also make recommendations to providers on which treatments to use. For example, AACAP publishes practice parameters that contain recommendations for treating specific disorders, with each recommendation labeled to indicate the strength of the evidence underlying it.

Although psychosocial therapies may be effective for many children, the Institute of Medicine and others have reported that a shortage of mental health providers in general is a major factor affecting access to services, especially for children.[51] Furthermore, finding a mental health professional who has been trained to provide a specific EBT can be a challenge because training in EBTs is not uniformly required in medical and professional schools.[52]

Foster Care

Children enter foster care when they have been removed from their parents or guardians and placed under the responsibility of a state child welfare agency, often because of maltreatment at home. Removal from the home can occur for multiple reasons, including parental violence, substance abuse, severe depression, or incarceration. According to ACF, 46 percent of children investigated by child welfare services came to a state's attention primarily because of a report of neglect, and 27 percent had experienced physical abuse as the most serious form of recorded maltreatment.[53] Other children are referred when their own behaviors or conditions are beyond the control of their families or they pose a threat to themselves or the community. Children in foster care can experience traumatic stress due to maltreatment experienced at home as well as the

[51]Institute of Medicine of the National Academies, Committee on Crossing the Quality Chasm: Adaptation to Mental Health and Addictive Disorders, *Improving the Quality of Health Care for Mental and Substance-Use Conditions: Quality Chasm Series* (Washington, D.C.: 2006).

[52]A 2006 survey of graduate programs in psychology, psychiatry, and social work found that although programs offered electives in EBTs, few programs required students to do both coursework and supervised clinical work in EBTs. See M. Weissman et al., "National Survey of Psychotherapy Training in Psychiatry, Psychology, and Social Work," *Archives of General Psychiatry*, vol. 63 (2006).

[53]See National Survey of Child and Adolescent Well-being (NSCAW), *No. 7: Special Health Care Needs among Children in Child Welfare* (Washington, D.C.: Office of Planning, Research and Evaluation, Administration for Children and Families, U.S. Department of Health and Human Services).

trauma of being removed from their homes. Trauma significantly increases the risk of mental health problems, difficulties with social relationships and behavior, physical illness, and poor school performance. Furthermore, child mental health experts have stated that the traumatic stress symptoms foster children may experience are often the same as symptoms that can indicate other mental health conditions, which may lead to misdiagnosis and inappropriate treatments.

When children are taken into foster care, the state's child welfare agency becomes responsible for determining where the child should live and providing the child with needed supports. The agency may place the foster child in the home of a relative, with unrelated foster parents, or in a group home or residential treatment center, depending on the child's needs. The agency is responsible for arranging needed services, including mental health services.[54] Federal officials, providers, and child and mental health advocacy groups have identified several factors that create challenges for foster children in receiving appropriate mental health services. Foster children can experience frequent changes in their living placements, which can lead to a lack of continuity in mental health care, and new providers may not have the medical history of the patient.[55] This lack of stability can lead to treatment disruptions and can increase the number of medications prescribed. Coordinating mental health care for foster children may be difficult for both the medical provider and the case worker because multiple people are making decisions on the child's behalf. In addition, caseworkers in child welfare agencies may have large caseloads, making it difficult for them to ensure that foster children's mental health needs are being met.

As a condition of receiving federal child welfare grant funding, state child welfare agencies must annually submit plans to ACF that, among other things, address the mental and other health needs of foster children. In 2011, the Child and Family Services Improvement and Innovation Act (Child Improvement Act) required states, as part of these plans, to identify protocols for monitoring foster children's use of psychotropic medications

[54]Most foster children are eligible for Medicaid, which generally entitles them to needed health services under EPSDT, including mental health services.

[55]ACF reported that foster children moved an average of 1.6 times in an 18-month period and that some children changed placements as many as 12 times in that same period. See Stambaugh et al., OPRE Report #2012-33, 2.

and to address how emotional trauma associated with children's maltreatment and removal from their home will be monitored and treated.[56] As part of their June 2012 Annual Progress and Service Reports to ACF, states provided information on their plans for monitoring psychotropic medication prescribing and treatment of emotional trauma for foster children. Prior to the Child Improvement Act, many states had already implemented policies and practices regarding prescribing psychotropic medications for foster children, such as issuing written guidelines for prescribers, collecting data to monitor prescribing, requiring informed consent from relevant parties before filling a prescription, and requiring consultation with a mental health specialist for prescriptions exceeding certain dosage thresholds.[57]

Children in Medicaid Took Psychotropic Medications at a Higher Rate Than Those with Private Insurance, and Most Children in Medicaid with a Potential Mental Health Need Did Not Receive Services

On average, 6.2 percent of noninstitutionalized children in Medicaid nationwide took psychotropic medications during a calendar year from 2007 through 2009, and 21 percent of those children took an antipsychotic medication. The estimates for privately insured children were lower. About 14 percent of children in Medicaid had a potential need for mental health services, and over two-thirds of them did not receive any services. CMS and states have made efforts to ensure that children receive appropriate mental health services, but CMS's ability to monitor their receipt of services for which they were referred is limited because CMS does not collect information from states on whether children in Medicaid have received services for which they were referred.

[56]Pub. L. No. 112-34, §§ 101(b)(1), (2), 125 Stat. 369 (2011) (codified at 42 U.S.C. §§ 622(b)(15)(A)(ii), (v)).

[57]According to a 2010 Tufts University study, 26 states had written guidelines on the use of psychotropic medications among foster children and 13 states were developing them at that time. See *Multi-State Study on Psychotropic Medication Oversight in Foster Care* (Boston, Mass.: Tufts Clinical and Translational Science Institute, September 2010.). We previously reviewed six states and reported that, although states are not required to follow best principle guidelines published by AACAP, none of them had monitoring programs that met all of these guidelines on monitoring psychotropic medication prescriptions for children. See GAO-12-201.

About 6 Percent of Children in Medicaid Took Psychotropic Medications, and They Were over Twice as Likely as Privately Insured Children to Take an Antipsychotic

Our analysis of MEPS data from 2007 through 2009 found that, on average, 6.2 percent of children in Medicaid nationwide—those who were not in institutions or in foster care and were ages 0 through 20—took at least one psychotropic medication during a calendar year.[58] The comparable rate for privately insured children was lower—4.8 percent.[59] The utilization rate was over twice as high for boys as for girls in Medicaid—8.4 percent versus 3.9 percent.[60] There is a higher prevalence among boys of certain mental health disorders for which psychotropic medications are prescribed,[61] which is one possible explanation for this difference. Among children in Medicaid who took psychotropic medications, utilization was highest among youth ages 18 through 20—12.7 percent—and lowest among children under age 5—less than 1 percent. Utilization rates for privately insured children were highest among children ages 12 through 17—7.5 percent. (See app. III for more-detailed information on children who took psychotropic medications.)

[58]For purposes of this report, we refer to children in Medicaid and CHIP as children in Medicaid, because the MEPS data do not distinguish between children in Medicaid and CHIP.

These estimates of medication use may be lower than other estimates because MEPS excludes children living in institutional settings and because the survey relies on self-reporting by parents, whose information on the utilization of medications and services may be understated due to the stigma that can be associated with mental health conditions. In addition, these estimates may be lower because we excluded from our analysis children with developmental disorders such as autism, and such children may be taking psychotropic medications. However, some children with autism take medications for other mental health conditions. These children would likely have been included in our analysis. Finally, these estimates do not include foster children, whom we excluded from this analysis. We previously reported that rates of psychotropic medication usage by children in Medicaid ranged from 5 percent to 10 percent across five states, on the basis of an analysis of fee-for-service claims. See GAO-12-201.

[59]The difference between children in Medicaid and privately insured children was statistically significant.

[60]For privately insured children, utilization was also higher among boys than girls—6.3 percent versus 3.2 percent, respectively.

[61]For example, the prevalence of ADHD may be as much as six times higher among prepubescent boys than among girls, and the prevalence of schizophrenia in adolescents is estimated to be twice as high among boys. See J. Seida et al., *First- and Second-Generation Antipsychotics for Children and Young Adults*. Comparative Effectiveness Review No. 39. AHRQ Publication No. 11(12)-EHC077-EF (Rockville, Md.: Agency for Healthcare Research and Quality, 2012).

Nationwide, almost half of children in Medicaid who took psychotropic medications took multiple psychotropic medications in a 1-year period. Specifically, our analysis found that 28 percent of the children in Medicaid who took psychotropic medications took two medications within a year, and 16 percent took three or more. Among privately insured children who took psychotropic medications, 22 percent took two medications within a year, and 11 percent took three or more.[62] This finding may reflect concomitant use of multiple medications—that is, medications taken in combination—or providers prescribing different drugs over time to find one that works best for the child.

The most common types of psychotropic medications taken by children were ADHD medications, antidepressants, and antipsychotics. We found that, of children who took psychotropic medications, about three-fourths took ADHD medications. According to a recent analysis by FDA officials, utilization of ADHD medications increased 46 percent from 2002 to 2010, and methylphenidate, a stimulant used to treat ADHD, was the most commonly prescribed medication for adolescents ages 12 through 17.[63] Antidepressants were the second most common type of medication taken—about one-fourth of the children in Medicaid and one-third of privately insured children who were taking psychotropic medication took an antidepressant. (See table 1.)

[62]Estimates were not significantly different between Medicaid and private insurance. Because MEPS does not allow for analysis of concomitant medication use, we do not know whether medications taken in the same year were taken concurrently or sequentially. Sequential use is not uncommon because different medications or dosages might be tried before one is found that works for a particular child.

[63]G. Chai et al., "Trends of Outpatient Prescription Drug Utilization in US Children, 2002-2010," *Pediatrics*, vol. 130, no. 1 (2012).

Table 1: Most Common Types of Psychotropic Medications Taken by Children Covered by Medicaid or Private Insurance, Ages 0-20, 2007-2009

Percentage of children who took the type of medication among children who took any psychotropic medication		
Type of medication	**Medicaid**	**Private insurance**
ADHD medication	78%	74%
Antidepressant	24	33
Antipsychotic[a]	21	10

Source: GAO analysis of HHS data.

Notes: Data are from the Medical Expenditure Panel Survey. The percentages do not sum to 100 because children can take multiple medications. Differences between children covered by Medicaid and those covered by private insurance were not statistically significant, unless otherwise noted. Percentages represent estimated average annual rates.

[a]The difference between children in Medicaid and privately insured children was statistically significant.

Our analysis also found that children in Medicaid were over twice as likely as privately insured children to take an antipsychotic medication. Overall, about 1.3 percent of children in Medicaid and 0.5 percent of privately insured children took antipsychotics.[64] Regardless of whether children were covered by Medicaid or private insurance, the majority of children who took an antipsychotic were males ages 6 through 17.

Our analysis also found that many children who took psychotropic medication did not receive other mental health services during the same year. Most children who took psychotropic medication did not receive psychosocial therapy or counseling in the same year—61 percent of Medicaid children and 66 percent of privately insured children.[65] While not all children would necessarily benefit from both medication and therapy, AACAP has stated that medication alone is rarely adequate treatment for children with complex mental health needs.[66] Furthermore, 26 percent of Medicaid children and 30 percent of privately insured children who took psychotropic medication did not have any mental health-related office

[64]This difference was statistically significant.

[65]Differences between children in Medicaid and those with private insurance were not statistically significant.

[66]See *The Mental Health Needs of Children in Foster Care*, accessed September 7, 2012, http://www.aacap.org/cs/2011_press_releases/the_mental_health_needs_of_children_in_foster_care.

visits in the same year.[67] This finding suggests that they did not have a medication-management follow-up visit, which pediatric provider organizations recommend. For example, guidelines from the American Academy of Pediatrics state that physicians consider follow-up visits every 3 to 6 months for children taking ADHD medications to monitor the child's behavior and medication side effects.

About 14 Percent of Children in Medicaid Had a Potential Mental Health Need, but Most Did Not Receive Mental Health Services

Our analysis of national survey data from 2007 through 2009 indicated that 14 percent of noninstitutionalized children in Medicaid and 9 percent of noninstitutionalized privately insured children had a potential mental health need.[68] As described earlier, these estimates of potential mental health need are based on a broad measure of a child's emotional or behavioral impairment, as reported by parents.[69] One possible explanation for the higher level of potential mental health need among Medicaid children could be the lower average family incomes of children enrolled in Medicaid compared to those of children with private insurance. Some studies have found that low income is associated with an increased prevalence of mental health conditions.[70]

Our analysis also indicated that most children with a potential mental health need did not receive mental health services, regardless of their insurance type. For example, over 80 percent of children with a potential need, whether covered by Medicaid or private insurance, did not receive any psychosocial therapy, and over 70 percent did not have any mental health office visits. (See table 2.) While it is not possible to assess which services a child may need on the basis of survey data, our analysis indicates that most children whose parents indicated a significant level of

[67]Differences between children in Medicaid and those with private insurance were not statistically significant.

[68]This difference was statistically significant. Estimates of potential mental health need apply only to children ages 5 through 17 because MEPS asks questions from the Columbia Impairment Scale only of parents of children in this age range.

[69]Parents were asked to rate how much of a problem their child has in several areas, including getting along with family members, being involved in activities, and behaving at school. Most children—80 percent—who were considered to have emotional or behavioral impairment had scores ranging from 16 to 26. The highest possible score is 52.

[70]See, for example, J. Sareen et al., "Relationship between Household Income and Mental Disorders: Findings from a Population-Based Longitudinal Study," *Archives of General Psychiatry*, vol. 68, no. 4 (2011).

behavioral impairment did not even receive a mental health evaluation. Even when a child received at least one mental health service, it is not possible to know whether his or her mental health needs were fully met.

Table 2: Percentages of Children with a Potential Mental Health Need Who Did Not Receive Certain Mental Health Services in a Calendar Year, by Medicaid or Private Insurance Coverage, 2007-2009

Service	Medicaid	Private insurance
No mental health office visits	72%	75%
No psychosocial therapy	82	83
No psychotropic medications	69	75
No mental health office visits or medications	65	69

Source: GAO analysis of HHS data.

Notes: Data are from the Medical Expenditure Panel Survey. Children were ages 5-17. Differences between children covered by Medicaid and those covered by private insurance were not statistically significant. Percentages represent estimated average annual rates.

Children were considered to have a potential mental health need if they scored 16 or above on the Columbia Impairment Scale, a psychometric scale used by MEPS that is designed to measure emotional and behavioral impairment.

About one-fourth of all children with a potential mental health need had a mental health office visit. Among Medicaid children who had mental health office visits, about 40 percent saw a psychiatrist and 30 percent saw a pediatrician at least once in a calendar year. (See table 3.) Just over half of children with any mental health office visits received psychosocial therapy, which suggests that nearly half of all mental health office visits involved another type of service, such as diagnostic assessment or medication management. Among children in Medicaid with at least one mental health office visit, the average number of visits in a year was about seven.[71]

[71]The average number of visits per year for privately insured children was about six. This difference was not statistically significant. Overall, 5.6 percent of all children in Medicaid and 4.5 percent of privately insured children had a mental health office visit in a calendar year. The difference between the two groups was not statistically significant.

Table 3: Types of Providers Seen by Children Ages 0-20 Who Had One or More Mental Health Office Visits, by Medicaid and Private Insurance Coverage, 2007-2009

Percentage		
Type of provider seen	**Medicaid**	**Private insurance**
Mental health specialist		
Psychiatrist	40%	38%
Psychologist	20	24
Social worker	6	8
Nonspecialist		
Pediatrician	30	25
Family physician	11	12

Source: GAO analysis of HHS data.

Notes: Data are from the Medical Expenditure Panel Survey. Differences between children covered by Medicaid and those covered by private insurance were not statistically significant.

Percentages add to more than 100 because children could have multiple office visits with different types of providers.

Numbers presented are estimates. Percentages represent the proportion of children with at least one visit to the provider type in a calendar year and do not reflect whether a child had multiple visits with a particular provider type.

CMS and States Have Made Efforts to Ensure That Children Receive Appropriate Mental Health Services, but CMS's Ability to Monitor Children's Receipt of Services Is Limited

CMS has initiated activities to help ensure that children in Medicaid receive appropriate mental health services. For example, CMS has begun working with states to improve their monitoring of the prescribing of psychotropic medications, and in August 2012 the agency issued an Informational Bulletin to states titled, "Collaborative Efforts and Technical Assistance Resources to Strengthen the Management of Psychotropic Medications for Vulnerable Populations." The bulletin provided a link to additional information on the CMS website that discusses practices some states have employed to enhance the ability of their Drug Utilization Review programs to monitor psychotropic medication prescribing, such as using Drug Utilization Reviews to identify and contact providers whose prescribing patterns vary significantly from recommended standards of care for children.[72] In addition, through its voluntary Pediatric Quality Measures Program, CMS is working with states to collect data on three

[72]See http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Drug-Utilization-Review.html (accessed Sept. 10, 2012).

quality measures related to mental health, including receipt of follow-up care for children prescribed ADHD medication.

CMS has also begun working with states to improve access to mental health services through the EPSDT benefit. Most children in Medicaid are entitled to services under EPSDT, which covers regular checkups and screenings as well as treatment services. Children found to have mental health needs at a screening are generally entitled to treatment services to address those needs, whether or not the services are typically covered under the Medicaid program in the child's state. According to CMS, its National EPSDT Improvement Workgroup has a Behavioral Health Subgroup that is developing an action plan to determine steps CMS can take to work with states to promote access to effective mental health care for children through EPSDT. The agency also told us it plans to issue an Informational Bulletin on children's behavioral health screening, referral, and treatment, which it will disseminate to state Medicaid agencies and others in early 2013.

As required under federal law, states annually submit data to CMS on the provision of services under EPSDT, such as the number of children referred for additional services as a result of checkups and screenings.[73] These data may include referrals for mental health services for children found to have mental health needs during screenings. We previously reported that CMS does not impose requirements beyond this federal law and, accordingly, does not collect information from states on whether children received the services for which they were referred, which limits CMS's ability to monitor whether children in Medicaid are receiving the services they need.[74] We recommended that CMS work with states to identify options for collecting such information. CMS officials told us that the agency had contracted for a study examining options for collecting data from state Medicaid programs on EPSDT referrals; the study concluded that states were unlikely to be able to produce accurate information on referred services using existing data sources. The officials also said that, as of September 2012, CMS was in the process of identifying alternative approaches for collecting data on children's receipt of treatment services, such as analyzing national survey data. However,

[73]42 U.S.C. § 1396a(a)(43).

[74]GAO, *Medicaid and CHIP: Reports for Monitoring Children's Health Care Services Need Improvement*, GAO-11-293R (Washington, D.C.: Apr. 5, 2011).

the alternatives currently under consideration would not produce the data from all states that would enable CMS to monitor at the state level children's receipt of treatment services for which they were referred through Medicaid.

States have also made efforts to increase children's access to mental health services. Because many children receive mental health services from nonspecialists, 28 states have programs to facilitate consultation between primary care providers and child psychiatrists. For example, under Washington state's Second Opinions program, psychiatrists review Medicaid psychotropic prescriptions that exceed certain safety thresholds—such as dose or use of combinations of medications—and provide a second opinion to the prescribing physician. An evaluation of Washington's Second Opinions program and its Partnership Access Line—the state's voluntary program for physicians seeking child psychiatry consultations—found that such consultations are cost-effective and that they have resulted in an increase in referrals for psychosocial therapy and a decrease in prescribing of antipsychotic medications.[75] Similarly, Massachusetts's program, the Massachusetts Child Psychiatry Access Program, has been found to increase the ability of primary care providers to treat or refer their patients with mental health needs.[76] In a survey of primary care providers participating in the Massachusetts program, 63 percent reported that they were usually able to meet the needs of their psychiatric patients, an increase from only 8 percent of providers before they enrolled in the program.

Some states have also begun to integrate mental health services into primary care settings in an effort to increase access to mental health services. For example, through the "State Option to Provide Health Homes for Enrollees with Chronic Conditions," authorized under the Patient Protection and Affordable Care Act, states have the option to implement person-centered health care delivery systems, known as

[75]According to a program official, Washington's psychotropic monitoring programs have been associated with an 8.6 percent decrease in the number of children in Medicaid who took an antipsychotic from 2007 to 2010, and a cost savings to the state of about $300,000 per month.

[76]According to an evaluation of the Massachusetts program, primary care providers contacted the program with diagnostic questions, with requests for assistance in identifying local referrals and resources, and for consultation regarding medication.

health homes.[77] Health homes, which are designated providers that render comprehensive services for individuals with chronic conditions, must address mental health and substance abuse treatment needs. According to CMS, a number of states are developing proposals to establish health homes as part of their Medicaid programs, and CMS is providing technical assistance to these states.

Nearly One-Fifth of Foster Children Took Psychotropic Medications, and Nearly One-Third of Foster Children Who May Have Needed Mental Health Services Did Not Receive Them

ACF reported that 18 percent of foster children ages 1 through 19 took psychotropic medications. In addition, ACF found that 30 percent of foster children with a potential mental health need did not receive mental health services in a 12-month period. HHS is taking several steps to promote appropriate mental health treatment for foster children.

ACF Reported That 18 Percent of Foster Children Took Psychotropic Medications

ACF reported that 18 percent of foster children were taking one or more psychotropic medications at the time they were surveyed, although utilization varied widely by living arrangement.[78] ACF reported that foster children who lived in group homes or residential treatment centers had much higher rates of psychotropic medication use than foster children

[77]42 U.S.C. 1396w-4.

[78]In the survey, caregivers were asked whether the child was currently taking a psychotropic medication. Estimates for foster children refer to those who lived in nonrelative foster homes, formal kin care, group homes, or residential treatment centers, unless otherwise noted. Estimates of medication utilization are based on NSCAW II phase 2 data (collected during October 2009 through January 2011). Stambaugh et al., OPRE Report #2012-33, 3.

living in nonrelative foster homes or formal kin care[79]—48 percent versus 14 percent and 12 percent, respectively.[80] The higher utilization rate among children living in group homes or residential treatment centers may be related to these children having higher rates of potential mental health need—about 69 percent had a potential mental health need compared to about 44 percent of children living in nonrelative foster homes.[81] Another study found that child welfare workers were more likely to place children with behavior problems in a group living arrangement than with a foster family.[82]

In addition to reporting on overall use of psychotropic medications, ACF reported on concomitant use of psychotropic medications and on the use of antipsychotics by foster children. Among foster children who took psychotropic medication, ACF reported that 13 percent took three or more psychotropic medications concomitantly.[83] In addition, ACF reported that 6.4 percent of foster children took an antipsychotic medication and that the majority were ages 6 through 11.[84]

[79]Based on data that ACF reported, about 50 percent of foster children lived in nonrelative foster homes, 41 percent lived in formal kin care arrangements, and 9 percent lived in group homes or residential treatment centers. Stambaugh et al., OPRE Report #2012-33, 2.

[80]Differences in medication utilization by living arrangement are statistically significant and are based on NSCAW II phase 1 data (collected during March 2008 through September 2009). Ringeisen et al., OPRE Report #2011-27f, 45-46.

[81]ACF reported that differences in potential mental health need by living arrangement among children ages 11 through 17 are statistically significant and are based on NSCAW II phase 1 data (collected during March 2008 through September 2009). Ringeisen et al., OPRE Report #2011-27f, 34-35.

[82]M. E. Courtney, "Correlates of Social Worker Decisions to Seek Treatment-Oriented Out-of-Home Care," *Children and Youth Services Review,* vol. 20, no. 4, (1998).

[83]Estimates of concomitant use are based on NSCAW II phase 2 data (collected during October 2009 through January 2011). This estimate does not include children in formal kin care. Less than 1 percent of children in formal kin care were taking three or more medications at the time of the survey. Stambaugh et al., OPRE Report #2012-33, 4.

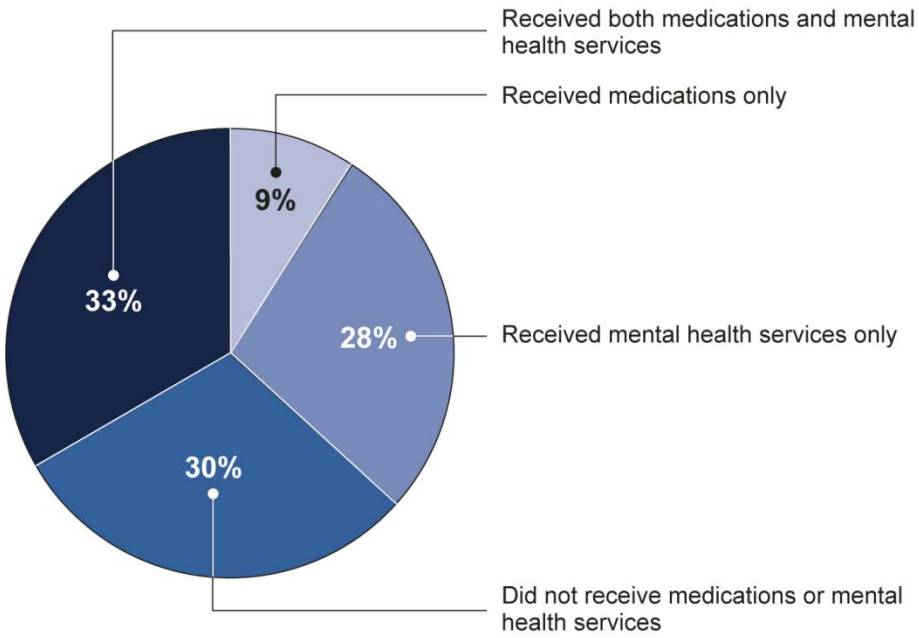
[84]Estimates of antipsychotic use are based on NSCAW II phase 2 data (collected during October 2009 through January 2011). This estimate does not include children in formal kin care. About 5 percent of children in formal kin care were taking an antipsychotic medication at the time of the survey. Stambaugh et al., OPRE Report #2012-33, 4.

ACF Reported That 30 Percent of Foster Children with a Potential Mental Health Need Did Not Receive Mental Health Services

ACF reported that 30 percent of foster children with a potential mental health need had not received any mental health services within the previous 12 months or since the start of the child's living arrangement, if less than 12 months.[85] (See fig. 1.) Although 70 percent of foster children with a potential mental health need received at least one mental health service, it is not possible to know the extent to which the child's mental health needs were met.

[85]In the survey, caregivers were asked to report about the child's mental health service use within 12 months or since the start of the child's living arrangement, if less than 12 months. Estimates of children with a potential mental health need who had not received mental health services are based on NSCAW II phase 2 data (collected during October 2009 through January 2011). Stambaugh et al., OPRE Report #2012-33, 6.

Figure 1: Receipt of Mental Health Services by Foster Children with a Potential Mental Health Need, Ages 1-19



Source: ACF.

Notes: ACF analysis is based on NSCAW II phase 2 data (collected during October 2009 through January 2011). See L.F. Stambaugh et al., *Psychotropic Medication Use by Children in Child Welfare*, OPRE Report #2012-33, (Washington, D.C.: Office of Planning, Research and Evaluation, Administration for Children and Families, U.S. Department of Health and Human Services, 2012). Children with a potential mental health need were considered to be those who scored above a certain level on one of five standardized psychometric scales used in NSCAW II to measure a child's emotional or behavioral problems.

For the survey, caregivers reported the child's receipt of mental health services in the previous 12 months or since the start of the living arrangement, if less than 12 months. Mental health services, which ACF refers to as specialty mental health services in OPRE Report #2012-33, include treatments received at an outpatient drug or alcohol clinic, mental health center, community health center, therapeutic nursery, hospital psychiatric unit, detox unit, inpatient unit, hospital emergency room, residential treatment center, group home, or school-based setting. Mental health services can also be received from a private mental health professional or family doctor, or during in-home counseling or crisis services.

HHS Has Provided Information to States on Use of Psychotropic Medications and Other Mental Health Services for Foster Children

In response to concerns related to the prescribing of psychotropic medications for foster children, HHS convened an interagency workgroup on the use of psychotropic medications for foster children in summer 2011. Led by ACF, the workgroup also has representatives from CMS, SAMHSA, NIH, AHRQ, and FDA. The workgroup developed a plan to expand the use of evidence-based screening, diagnosis, and interventions; strengthen the oversight and monitoring of psychotropic medications; and expand the overall knowledge and evidence base regarding medications and psychosocial treatments for foster children with mental health or trauma-related needs. The primary activity of the workgroup is to meet regularly to share information about individual and joint agency activities related to foster children's mental health. For example, the workgroup convened a meeting in September 2011 with researchers to increase federal staff's knowledge about psychotropic medication use among foster children, their mental health needs, the extent to which best practices on state oversight and monitoring of psychotropic medications exist, and future data needs. On the basis of the efforts of the workgroup, HHS has identified several areas where more research is needed, including clinical trials related to foster children's use of psychotropic medications, studies on differences between trauma and mental health diagnoses, and studies on EBTs for foster children.

Three member agencies of the workgroup—ACF, CMS, and SAMHSA—have collaborated on certain activities regarding use of psychotropic medications among foster children. In November 2011, the three agencies sent a joint letter to state Medicaid directors, mental health authorities, and child welfare directors. This letter contained information on the three agencies' activities and resources that aim to improve the mental health and well-being of foster children, such as ACF's Child Welfare Information Gateway website and SAMHSA's National Traumatic Stress Initiative grants. These agencies also jointly held several webinars to disseminate this information. In addition, they hosted a summit in August 2012 for state child welfare, Medicaid, and mental health agencies to help states develop psychotropic drug oversight practices and to facilitate interagency coordination for foster children. ACF is also working with CMS to develop quality measures specific to foster children as part of CMS's Pediatric Quality Measures Program.

In addition to participating in the workgroup, ACF is working with states to build the capacity of child welfare agencies to effectively respond to the complex needs of foster children. For example, in addition to overseeing the NSCAW surveys, ACF took the following actions:

- ACF issued a Program Instruction to help states implement the new requirements in the Child Improvement Act. In the Program Instruction, ACF described five components that state child welfare agencies should include in their plans to monitor psychotropic medications.[86] In addition, the instructions provided guidelines to states on treating and monitoring children experiencing emotional trauma, another requirement of the law. As of August 2012, ACF officials told us that all states had submitted their plans as required by the Child Improvement Act and the agency was reviewing them.

- ACF published two Information Memoranda for state child welfare agencies—one on promoting social and emotional well-being for children in child welfare and one on best practices in state psychotropic drug oversight.

- ACF has provided information about psychotropic medication prescribing and monitoring on its Child Welfare Information Gateway—a website that provides resources for child welfare agencies.[87]

SAMHSA has provided funding, guidance, and information to states and others to increase appropriate mental health services among foster children. For example:

- For its fiscal year 2012 National Child Traumatic Stress Initiative grants, SAMHSA placed a specific emphasis on child welfare. The initiative supports services for children experiencing trauma-related behavioral health problems and places a strong focus on using evidence-based psychosocial therapies.

[86]ACF identified the following five areas that the psychotropic medication protocols must address: (1) screening, assessment, and treatment planning mechanisms; (2) shared decision making and communication among the prescriber, the child, caregivers, other health care providers, and the child welfare worker; (3) effective medication monitoring at both the patient and the agency-wide level; (4) availability of child and adolescent psychiatrists for consultation; and (5) mechanisms for sharing accurate and up-to-date information related to psychotropic medications with clinicians, child welfare staff, and consumers. See Administration for Children and Families, U.S. Department of Health and Human Services, *Program Instruction*, ACYF-CB-PI-12-05 (Washington, D.C.: Apr. 11, 2012), 13.

[87]See http://www.childwelfare.gov.

- SAMHSA worked with AACAP to develop guidance for service providers and agency leaders on the use of psychotropic medications among children, including foster children. Through its Systems of Care grants, SAMHSA has also provided funding for foster children's mental health services; the agency reported in 2011 that 22 of its grantees had a child welfare focus or a partnership with a child welfare organization.

- The 2012 SAMHSA-sponsored National Children's Mental Health Awareness Day event had a special focus on foster children, and SAMHSA is planning a meeting in January 2013 titled "Improving Outcomes for African American Males in Foster Care."

NIH Spent an Estimated $1.2 Billion on Children's Mental Health Research during Fiscal Years 2008 through 2011

NIH spent about $1.2 billion on research projects related to children's mental health; NIMH was responsible for most of this funding, with the rest being spent by NICHD. Other HHS agencies—FDA, AHRQ, and CDC—spent an estimated $16 million on external research projects related to children's mental health.

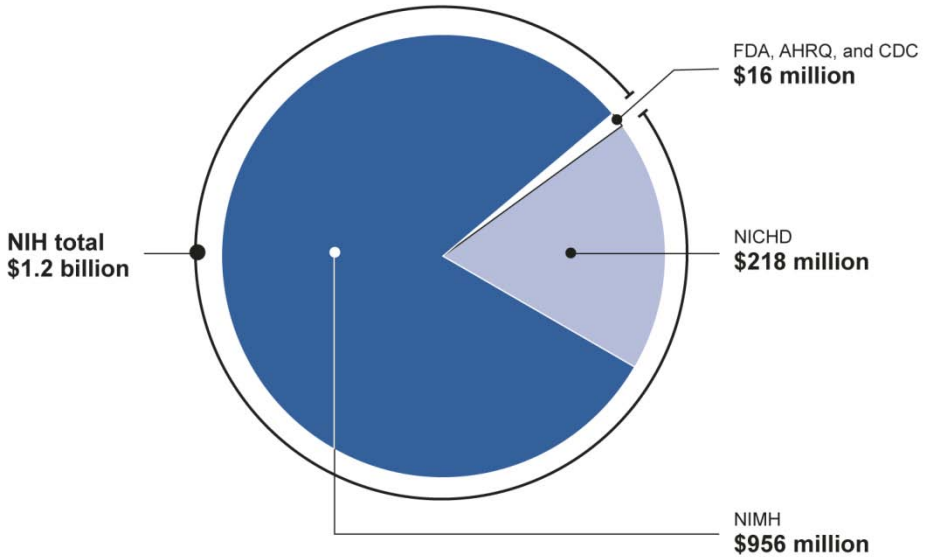
Most NIH Funding for Children's Mental Health Research Was Spent by NIMH

During fiscal years 2008 through 2011, NIH spent about $1.2 billion to support over 1,200 children's mental health research projects, most of which were supported by NIMH.[88] NIMH accounted for 81 percent—about $956 million—of NIH's funding for children's mental health research. (See fig. 2.) NIMH's $956 million (which represented about 18 percent of NIMH's total research budget in fiscal years 2008 through 2011)

[88]We use the term "spent" to refer to funds actually expended or provided to the recipient of a grant or cooperative agreement, to a contractor, or to agency scientists conducting research internally. Recipients of grants and cooperative agreements draw down funds either as an advance or as a reimbursement for costs incurred in accordance with the terms of the grant or cooperative agreement. Contractors receive funds as payment for goods and services provided under a contract. Intramural research expenditures include funding for salaries and research resources for agency scientists. Totals reported here represent the amount expended for projects during fiscal years 2008 through 2011 and do not reflect total amounts for all of the projects over their lifetimes. For example, for a project funded for 5 years starting in 2008, we included only the amount expended for the first 4 years (i.e., through 2011).

supported slightly over 900 research projects related to mental health in children ages 18 or younger.[89] The most-commonly studied mental health conditions were ADHD, major depression, and bipolar disorder. Nearly all of the projects (97 percent) were conducted externally under grants and contracts, with expenditures of about $861 million.[90] The remaining research projects, for which NIMH spent about $95 million, were conducted internally by NIMH scientists. For example, NIMH scientists used brain imaging techniques to examine how brain development in children with ADHD differed from typical brain development in children.

Figure 2: HHS Expenditures for Children's Mental Health Research, Fiscal Years 2008 through 2011



Source: GAO analysis of HHS data.

Note: According to NIH officials, NIMH and NICHD conduct and fund most of the NIH research on children's mental health. Additional NIH institutes and centers may have also sponsored children's mental health research, but NIH was unable to provide data from these other institutes and centers that met our criteria.

[89]Although NIH defines a child as 0 to 20 years of age, NIMH was able to identify studies that specifically included children 0 to 18, so we have reported numbers for this age range.

[90]Of the $861 million expended for extramural grants and contracts during this period, about $59 million (7 percent) was from appropriations made by the American Recovery and Reinvestment Act.

About half of NIMH-sponsored research projects (482) examined mental health treatments for children, with more projects studying psychosocial therapies than psychotropic medications. (See table 4.) Of the 482 treatment research projects, 325 involved testing psychosocial therapies. For example, one project tested the effect of therapies such as parent training and skill building on preventing negative outcomes such as substance use and school truancy in middle-school-aged girls in foster care. Psychotropic medication studies accounted for 137 of the 482 research projects.[91] For example, one project tested the effect of an antidepressant medication on brain activity in children with anxiety disorders, with the goal of better understanding how the medication works. NIMH also funded 66 research projects that tested the effects of combinations of treatments, such as two medications or a medication and a psychosocial therapy. For example, one project tested the effect of parent training—a psychosocial treatment—with and without the addition of a stimulant (or of a stimulant and an antipsychotic medication) on children with a disruptive behavior disorder in combination with ADHD and severe aggression. NIMH officials told us that the agency does not have quotas for the kinds of treatment studies it funds and encourages grant applications from researchers for both psychosocial and psychotropic treatment studies. However, officials noted that NIMH expects to fund more projects examining psychosocial therapies than projects that test medications because researchers may perceive psychosocial therapies to be less risky for children and not all psychotropic medications are approved for pediatric use.

[91]Treatment types do not add to 482 because a project could test both psychosocial therapies and psychotropic medications, or neither of these.

Table 4: National Institute of Mental Health Research Projects on Children's Mental Health, by Topic, Fiscal Years 2008 through 2011

Topic	Number of research projects	Expenditures (dollars in millions)[a]
Mental health treatment[b]	482	$458
Psychosocial therapies	325	268
Psychotropic medications	137	155
Combination[c]	66	62
Other than treatment[d]	425	498
Total	**907**	**$956**

Source: GAO analysis of NIMH data.

[a]These expenditure amounts refer to funds actually provided to the recipient of a grant or cooperative agreement, to a contractor, or to agency scientists conducting research internally. These amounts are the sum of NIMH spending on an annual basis during fiscal years 2008 through 2011.

[b]Numbers and expenditure amounts for treatment research project types do not add to mental health treatment total because projects can include more than one type of treatment.

[c]These research projects tested the effects of combinations of treatments, such as of two medications or a medication and a psychosocial therapy.

[d]These research projects did not examine the effects of a treatment such as a psychotropic medication or psychosocial therapy.

NICHD spent about $218 million to sponsor 324 research projects related to mental health in children in fiscal years 2008 through 2011.[92] Almost all projects (98 percent) were conducted externally under grants and contracts, with expenditures of about $195 million. NICHD's own scientists conducted the remaining research projects, for which NICHD spent about $23 million. Of the 324 research projects, 72 focused on mental health conditions, such as depression and ADHD.[93] For example, NICHD sponsored one study that examined the effectiveness of a mood stabilizing psychotropic medication—lithium—in children ages 7 to 17 with bipolar disorder.

[92]NICHD-sponsored research projects include children ages 0 to 20.

[93]Research projects that did not study mental health conditions may have studied children who were developing typically. For example, one project looked at the development of socially appropriate behavior in children ages 0 to 4 and how it related to factors such as the child's temperament and relationships with caregivers. Other research project types included studies of children with genetic conditions such as spina bifida.

NIMH and NICHD collectively spent about $309 million during this period to support almost 350 research projects that examined children's mental health in minority and health disparity populations.[94] NIMH sponsored 297 such projects, with expenditures of about $283 million, and NICHD spent about $26 million to sponsor 50 projects. For example, NIMH sponsored a study of Latino adolescents with depression that tested the effectiveness of a psychosocial therapy—cognitive behavioral therapy—with and without an additional educational component for parents.

NIMH and NICHD also funded translational research,[95] which tests treatments in real world settings and identifies effective strategies for implementing them in communities.[96] For example, NICHD sponsored a research project that evaluated the effectiveness of a psychosocial therapy for girls with post-traumatic stress disorder and concurrent substance abuse disorders who were involved with the juvenile justice system. The study examined ways to adapt the treatment for this population, and the researchers planned to use the study as a model to adapt other EBTs for children involved in the juvenile justice and child welfare systems.

[94]NIH defines a health disparity population as one that experiences a greater burden of illness when compared to the general population. Racial and ethnic minorities, persons with low socioeconomic status, and persons who live in rural areas are considered health disparity populations.

[95]The data NIMH and NICHD provided did not identify which projects were translational, so it was not possible to determine the total number of projects or how much was spent on this research.

[96]Providers we spoke with said that translational studies are important because treatments are often developed and tested under highly controlled conditions, and therefore it is unclear whether the treatments will work with different conditions or populations.

Other HHS Agencies Spent an Estimated $16 Million on Children's Mental Health Research Projects

Together, FDA, AHRQ, and CDC spent about $16 million on research projects on children's mental health in fiscal years 2008 through 2011. FDA spent about $4.5 million on four external research projects on the safety and effectiveness of psychotropic medications for children.[97] For example, FDA cosponsored a study with AHRQ that examined serious cardiovascular events such as heart attack and stroke among children taking ADHD medications. In addition, at the end of fiscal year 2011, FDA awarded a contract for about $6 million for a study on antipsychotic medications and the risk of type 2 diabetes in children; this study is currently under way.[98]

AHRQ spent about $8.6 million to fund five external research projects related to children's mental health in fiscal years 2008 through 2011.[99] Consistent with the agency's focus on improving outcomes by encouraging the use of evidence to make health care decisions, two of the five research projects AHRQ supported compared outcomes of using different mental health treatments. For example, one AHRQ-sponsored project compared outcomes of using various antipsychotic medications to treat children with ADHD who were enrolled in Medicaid, including children in foster care.[100] Child mental health experts we spoke with highlighted the need for more research that compares different psychotropic medications. For example, one federal official noted that all antidepressant medications bear the same "black box" warning describing

[97]FDA provided expenditure data on contracts for which the performance period overlapped fiscal years 2008 through 2011. FDA did not provide a breakdown of expenditures by fiscal year, so some of the $4.5 million reported here may have been spent before or after fiscal years 2008 through 2011.

[98]We did not include this contract in our total for FDA because it overlapped our time frame by only 1 month (September 2011).

[99]Of the $8.6 million in expenditures, about $1.2 million (14 percent) was from appropriations made by the American Recovery and Reinvestment Act. AHRQ also spent about $2 million on the project it cosponsored with FDA on cardiovascular effects of ADHD medications. However, because AHRQ spent these funds prior to the time frame examined in this report, we have not included that amount in AHRQ's total.

[100]In addition to sponsoring new studies that compare treatments for mental health conditions, AHRQ also funds systematic reviews of existing studies on available treatments. For example, AHRQ recently sponsored a review of the use of antipsychotic medications for children; the review stated that for most conditions there was limited evidence to determine which were safer or more efficacious. See J. Seida et al., *First- and Second-Generation Antipsychotics for Children and Young Adults*.

the potential for increases in suicidal thinking in children[101] but that there is limited information about whether any antidepressants are safer or more effective for children than other antidepressants.

CDC spent about $2.7 million on two external research projects during fiscal years 2008 through 2011, one on ADHD and the other on Tourette Syndrome and other tic disorders. The ADHD project examined topics including the prevalence of ADHD, the prevalence of ADHD in combination with other mental health conditions, and children's utilization of psychosocial and medication treatments. The project on tic disorders also looked at children's utilization of different kinds of treatments, as well as their school performance, social relationships, and factors associated with poorer functioning. Both projects were designed to include a diverse sample of children with the aim of detecting differences due to sex or race/ethnicity. For example, the ADHD study oversampled girls and included large samples of Black, Latino, and American Indian children.

Concluding Observations

Mental health conditions such as ADHD, depression, and bipolar disorder can have debilitating effects on a child's life, and early detection and treatment of childhood mental health conditions can improve children's outcomes into the future. While some children receive highly effective mental health treatments, our findings suggest that many children, including some in Medicaid and in foster care, may not be receiving appropriate treatment. Our analysis of national survey data indicates that concerns raised by providers, children's advocates, and others about potentially inappropriate prescribing of psychotropic drugs for some children and a lack of needed mental health services for some children may be warranted. Antipsychotic medications are of particular concern in light of the very serious side effects they can have for children, the limited understanding of their long-term effects, and their high cost. Children in Medicaid and in foster care are prescribed these medications at higher rates than other children. Furthermore, most children in Medicaid and many children in foster care with potential mental health needs do not receive mental health services that could help them. Differing rates of medication among the groups of children do not necessarily represent a problem, because potential factors beyond the scope of this review could

[101]A black box warning is the strongest warning an FDA-approved product can carry and may describe, for example, an adverse reaction that is so severe that it is essential that it be considered when evaluating the risks and benefits of a medication.

help explain the differences. Nonetheless, these findings do suggest that the recent federal and state initiatives to improve monitoring and oversight are appropriate, and that continued assessment of the prescribing of psychotropic medications to vulnerable populations and of the receipt of mental health services is important. Initiatives such as CMS's National EPSDT Improvement Workgroup and plans to help states improve their monitoring efforts, as well as the ACF-led interagency workgroup on the use of psychotropic medications for foster children, have the potential to help ensure that vulnerable children in Medicaid and foster care have access to effective mental health treatments that are appropriate for their mental health conditions. We recommended in 2011 that CMS identify options to collect information from states on whether children in Medicaid receive the services for which they are referred through their EPSDT-mandated screenings and check-ups, which would include referrals for specialty care such as mental health services. CMS has begun to explore options to address this recommendation, but it has not yet identified ways to systematically collect such data from state Medicaid programs. We continue to believe this recommendation is valid, and our findings in this report underscore the importance of HHS's monitoring the receipt of needed referral and treatment services, including those for mental health, by children in Medicaid.

Agency Comments

HHS did not comment on our findings but provided technical comments, which we incorporated as appropriate.

As arranged with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days after its issuance date. At that time, we will send copies of this report to the Secretary of Health and Human Services and other interested parties. In addition, the report will be available at no charge on the GAO website at http://www.gao.gov.

If you or your staff members have any questions, please contact me at (202) 512-7114 or iritanik@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Major contributors to this report are listed in appendix IV.

Katherine Iritani
Director, Health Care

Appendix I: Methodology Used to Analyze the Medical Expenditure Panel Survey

To provide information on the use of psychotropic medications and other mental health services by children covered by Medicaid, the Children's Health Insurance Program (CHIP), and private insurance, we analyzed nationwide data from the Medical Expenditure Panel Survey (MEPS) from 2007 through 2009. MEPS is a nationally representative survey of families, medical providers, and employers across the United States administered by the Agency for Healthcare Research and Quality (AHRQ). MEPS collects self-reported information on individuals' demographics, health and insurance status, and use of medical services by setting and provider type, among other things.[1] Specifically, we examined the use of psychotropic medications[2] and mental health-related office visits, therapy visits, and behavioral impairment. We pooled 3 years of data to obtain a sample size large enough to conduct our analyses, and reported average annual estimates.[3] To conduct our analysis, we constructed two cohorts of children who were insured for at least 10 months in 2007, 2008, or 2009—those who were enrolled in Medicaid or CHIP[4] and those covered by private insurance. We included children ages 0 through 20 and excluded children in foster care from our analysis.[5] In total, the sample Medicaid/CHIP cohort had 11,224 children, and the sample private insurance cohort had 11,639 children.

To develop the list of psychotropic medications used in the analysis, we compiled a list based on a list published by the National Institute of Mental Health as well as prescription drug lists from six state Medicaid programs. We then refined the list on the basis of input from two contracted child psychiatrists with clinical and research experience in the

[1]The preferred respondent for the interview is the person, 18 years or older, who is most knowledgeable about the family's health care and who is keeping records about health care use and expenses. For the purposes of this report, we consider this person to be the child's parent or guardian, although this may not always be the case.

[2]MEPS reports on all medications taken in a calendar year, but does not provide information on whether medications were taken concomitantly—that is, in combination with other medications.

[3]We did not report on utilization of mental health-related inpatient, outpatient, and emergency room visits because the numbers of cases were too low to conduct further analyses.

[4]Because MEPS does not differentiate between children in Medicaid and children in CHIP in the survey, we could not report on these programs separately. For the purposes of this report, we used the term Medicaid to refer to both Medicaid and CHIP.

[5]State Medicaid programs generally cover children under 21 years of age.

prescription of psychotropic medications to children.[6] (See table 5.) In our estimates of psychotropic medication utilization, we included only those instances when a medication was associated with a mental health condition (diagnosis codes 293-298, 300-302, 306-314 from the *International Classification of Diseases*, Ninth Revision, Clinical Modification) as the reason for the prescription, because some psychotropic medications can be used for non-mental-health purposes. Similarly, we identified office visits that included a mental health diagnosis code as the reason for the visit. Among the mental health-related visits, we also identified those visits during which the child was reported by the parent or guardian to have received psychotherapy or counseling.

[6]This list of psychotropic drugs was initially developed for use in a recent GAO report. For more information about the methodology used to develop the list of psychotropic medications, see GAO, *Foster Children: HHS Guidance Could Help States Improve Oversight of Psychotropic Prescriptions*, GAO-12-201 (Washington, D.C.: Dec. 14, 2011).

Table 5: Psychotropic Medications Used in the MEPS Analysis

Type of psychotropic medication	Medication ingredient
Attention deficit hyperactivity disorder (ADHD) medication	Amphetamine aspartate, amphetamine sulfate, dextroamphetamine saccharate, dextroamphetamine sulfate[a]
ADHD medication	Atomoxetine hydrochloride
ADHD medication	Clonidine
ADHD medication	Dexmethylphenidate hydrochloride
ADHD medication	Dextroamphetamine sulfate
ADHD medication	Guanfacine hydrochloride
ADHD medication	Lisdexamfetamine dimesylate
ADHD medication	Methamphetamine
ADHD medication	Methylphenidate hydrochloride
ADHD medication	Pemoline
Antianxiety	Alprazolam
Antianxiety	Buspirone hydrochloride
Antianxiety	Chlordiazepoxide hydrochloride
Antianxiety	Clonazepam
Antianxiety	Clorazepate dipotassium
Antianxiety	Diazepam
Antianxiety	Diphenhydramine hydrochloride
Antianxiety	Hydroxyzine
Antianxiety	Lorazepam
Antianxiety	Meprobamate
Antianxiety	Oxazepam
Antianxiety	Prazosin hydrochloride
Antianxiety	Propranolol hydrochloride
Antianxiety	Quazepam
Anticonvulsant	Carbamazepine
Anticonvulsant	Divalproex sodium
Anticonvulsant	Gabapentin
Anticonvulsant	Lamotrigine
Anticonvulsant	Oxcarbazepine
Anticonvulsant	Topiramate
Anticonvulsant	Valproate sodium
Anticonvulsant	Valproic acid
Antidepressant	Amitriptyline hydrochloride
Antidepressant	Amoxapine
Antidepressant	Bupropion hydrochloride

Type of psychotropic medication	Medication ingredient
Antidepressant	Citalopram hydrobromide
Antidepressant	Clomipramine hydrochloride
Antidepressant	Desipramine hydrochloride
Antidepressant	Desvenlafaxine succinate
Antidepressant	Doxepin hydrochloride
Antidepressant	Duloxetine hydrochloride
Antidepressant	Escitalopram oxalate
Antidepressant	Fluoxetine hydrochloride
Antidepressant	Fluvoxamine maleate
Antidepressant	Imipramine
Antidepressant	Isocarboxazid
Antidepressant	Maprotiline hydrochloride
Antidepressant	Mirtazapine
Antidepressant	Nefazodone hydrochloride
Antidepressant	Nortriptyline hydrochloride
Antidepressant	Paroxetine
Antidepressant	Phenelzine sulfate
Antidepressant	Protriptyline hydrochloride
Antidepressant	Selegiline
Antidepressant	Sertraline hydrochloride
Antidepressant	Tranylcypromine sulfate
Antidepressant	Trazodone hydrochloride
Antidepressant	Trimipramine maleate
Antidepressant	Venlafaxine
Antienuretic	Desmopressin acetate
Antiparkinson	Amantadine hydrochloride
Antiparkinson	Benztropine mesylate
Antiparkinson	Trihexyphenidyl hydrochloride
Antipsychotic	Aripiprazole
Antipsychotic	Chlorpromazine
Antipsychotic	Clozapine
Antipsychotic	Droperidol
Antipsychotic	Fluphenazine
Antipsychotic	Haloperidol
Antipsychotic	Loxapine
Antipsychotic	Mesoridazine besylate
Antipsychotic	Molindone hydrochloride

Type of psychotropic medication	Medication ingredient
Antipsychotic	Olanzapine
Antipsychotic	Paliperidone
Antipsychotic	Perphenazine
Antipsychotic	Pimozide
Antipsychotic	Quetiapine fumarate
Antipsychotic	Risperidone
Antipsychotic	Thioridazine
Antipsychotic	Thiothixene
Antipsychotic	Trifluoperazine hydrochloride
Antipsychotic	Ziprasidone
Combination antianxiety and antidepressant	Amitriptyline and chlordiazepoxide
Combination antipsychotic and antidepressant	Amitriptyline and perphenazine
Combination antipsychotic and antidepressant	Olanzapine and fluoxetine hydrochloride
Hypnotic	Estazolam
Hypnotic	Eszopiclone
Hypnotic	Flurazepam hydrochloride
Hypnotic	Midazolam hydrochloride
Hypnotic	Ramelteon
Hypnotic	Temazepam
Hypnotic	Triazolam
Hypnotic	Zaleplon
Hypnotic	Zolpidem tartrate
Mood stabilizer	Lithium
Sleep aid	Melatonin

Source: GAO.

[a]Amphetamine aspartate, amphetamine sulfate, dextroamphetamine saccharate, and dextroamphetamine sulfate are medications indicated for treatment of ADHD and were considered a single ingredient for the purposes of our review.

We also used MEPS to examine the receipt of mental health services by those children who were considered to have a potential mental health need. To estimate potential mental health need, we measured the percentage of children in each cohort whose score on a standardized psychometric scale designed to measure mental health impairment indicated a potential need for a mental health service. The psychometric scale, known as the Columbia Impairment Scale, consists of 13 questions and was developed such that children who scored a 16 or higher (out of a possible maximum score of 52) were considered to have emotional or behavioral impairment. As part of the MEPS survey, parents of children ages 5 through 17 were asked to rate on a scale of 0 to 4 (0 being no

problem and 4 being a very big problem) how much of a problem their child has in several areas, including getting along with family members, being involved in activities, and behaving well at school. This measure of emotional or behavioral impairment does not indicate the level of treatment a child might require; rather it identifies the percentage of children whose emotions or behavior indicated a need for, at a minimum, a mental health evaluation.[7]

Estimates of utilization rates for medication and other mental health services from MEPS may be conservative, because the survey excludes children who live in institutional settings, who are likely to be high utilizers of psychotropic medications and mental health services. In addition, MEPS relies on self-reporting by parents on their child's utilization of medications and services, which may be understated because parents may be reluctant to report such information due to the stigma that can be associated with mental health conditions.[8] These estimates may also be lower because we excluded from our analysis children with developmental disorders such as autism, and such children may be taking psychotropic medications. However, some children with autism take medications for other mental health conditions and these children would likely have been included in our analysis. Finally, these estimates do not include foster children, whom we excluded from this analysis. We reviewed the MEPS survey instruments and methodology and determined that the data were sufficiently reliable for our purposes.

[7]The scale is considered to be valid and reliable for use in surveys. See H. R. Bird et al., "The Columbia Impairment Scale (CIS): Pilot Findings on a Measure of Global Impairment for Children and Adolescents," *International Journal of Methods in Psychiatric Research,* vol. 3, no. 3 (1993).

[8]See S. Zuvekas., "Prescription Drugs and the Changing Patterns of Treatment for Mental Disorders, 1996-2001," *Health Affairs,* vol. 24, no. 1 (2005).

Appendix II: Food and Drug Administration Reviews of Psychotropic Drug Label Changes for Children

The Food and Drug Administration (FDA) is responsible for reviewing the results of pediatric studies conducted under two related laws—the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA). BPCA is a program under which manufacturers may receive an additional 6 months of market exclusivity in exchange for conducting pediatric studies.[1] Under PREA, subject to certain exceptions, drug manufacturers must conduct pediatric studies before a drug can be marketed.[2] FDA is responsible for reviewing the results of pediatric studies submitted under BPCA and PREA and ensuring manufacturers incorporate new information on pediatric use into medication labels when required. During fiscal years 2008 through 2011, 168 label changes resulted from studies conducted under these laws, 16 of which were for psychotropic medications. For example, the label for Invega, an atypical antipsychotic medication, was changed to indicate that it is safe and effective for the treatment of schizophrenia in children as young as age 12. (See table 6 for information on all 16 label changes.) In addition to reviewing label changes related to BPCA and PREA, in 2009 FDA began working with manufacturers to change the labels of all atypical antipsychotics to more clearly present data on their metabolic risks for children, which an FDA official said will help prescribers in selecting medications for their patients.[3]

[1]21 U.S.C. 355a, 42 U.S.C. 284m. Before marketing a new drug and before making certain changes to a previously approved drug, manufacturers must apply to FDA for approval. Once approval is granted, manufacturers may have protection from certain types of competition for a specified time frame based on patents listed for and exclusivity obtained for the drug. FDA may request pediatric studies from manufacturers that have applications approved or pending. If the manufacturer conducts the studies that FDA has requested and does so in accordance with generally accepted scientific principles and protocols, FDA will award 6 months of pediatric exclusivity, which attaches to existing patent and exclusivity protection for the drug.

[2]21 U.S.C. §§ 355c, 355d. When submitting a new drug application, drug manufacturers must conduct assessments of safety and efficacy for all relevant pediatric populations and to support dosing instructions. FDA may also require manufacturers that have already received approval to market a drug to conduct these assessments in certain circumstances, including if the FDA has determined that the product is used for a substantial number of pediatric patients for the labeled indications and the absence of adequate labeling could pose significant risks to pediatric patients.

[3]As of August 2012, 7 of 13 atypical antipsychotics had undergone label changes and the remaining 6 were pending review by FDA. FDA officials said they anticipate that all label changes will be finalized by early 2013.

Table 6: Label Changes for Psychotropic Medications Resulting from the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA) during Fiscal Years 2008 through 2011

Medication	Medication type	Date of changes	Label change(s)[a]	BPCA or PREA[b]
Abilify	Antipsychotic	Oct. 29, 2007	Extended use for the treatment of schizophrenia from adults to children as young as age 13; added information on dosing and safety	BPCA
		Feb. 27, 2008	Extended use for the treatment of bipolar disorder from adults to children as young as age 10; added information on dosing and safety	Both
		Nov. 19, 2009	Approved marketing for the treatment of irritability associated with autism in children as young as age 6; added information on dosing and safety	PREA
Daytrana	Stimulant (attention deficit hyperactivity disorder (ADHD))	Dec. 14, 2009	Added safety information regarding skin reactions	PREA
		Jun. 29, 2010	Extended use for the treatment of ADHD from children 6 to 12 to children ages 13 to 17; added information on safety	PREA
Depakote ER Depakote Sprinkles	Anticonvulsant mood stabilizer	Mar. 24, 2008	Added statements that efficacy was not established for the treatment of bipolar disorder in children ages 10 to 17 or for the prevention of migraine in children ages 12 to 17 and additional safety information	Both
Focalin XR	Stimulant (ADHD)	Oct. 23, 2009	Added information on dosing	PREA
Intuniv	Nonstimulant (ADHD)	Sept. 2, 2009	Approved marketing for the treatment of ADHD in children as young as age 6; added information on dosing and safety	PREA
		Feb. 25, 2011	Approved marketing for the treatment of ADHD in combination with stimulant ADHD medication for children as young as age 6; added information on safety	PREA
Invega	Antipsychotic	Apr. 6, 2011	Extended use for the treatment of schizophrenia from adults to children as young as age 12; added information on dosing and safety	Both
Kapvay Extended Release Tablets	Nonstimulant (ADHD)	Sept. 28, 2010	Approved marketing for the treatment of ADHD alone and in combination with stimulant ADHD medication for children as young as age 6; added information on safety	PREA
Lexapro	Antidepressant	Mar. 19, 2009	Approved marketing for the treatment of major depression in children as young as age 12; added information on dosing and safety	BPCA

Medication	Medication type	Date of changes	Label change(s)[a]	BPCA or PREA[b]
Seroquel	Antipsychotic	Dec. 2, 2009	Extended use for the treatment of schizophrenia from adults to children as young as age 13 and treatment of bipolar disorder to children as young as age 10; added information on dosing and safety	Both
Vyvanse Capsules	Stimulant (ADHD)	Nov. 10, 2010	Extended use for the treatment of ADHD from adults and children 6 to 12 to children ages 13 to 17; added information on safety	PREA
Zyprexa	Antipsychotic	Aug. 14, 2008	Added statement that safety and effectiveness were not established for children and additional safety information	BPCA
		Dec. 4, 2009	Extended use for the treatment of schizophrenia and bipolar disorder from adults to children as young as age 13; added information on dosing and safety	BPCA

Source: GAO analysis of Food and Drug Administration (FDA) information.

Notes: For BPCA, see 21 U.S.C. § 355a and 42 U.S.C. § 284m. For PREA, see 21 U.S.C. §§ 355c, 355d.

[a]This column contains a summary of key changes to the label and does not include all changes that were made.

[b]This column indicates whether drug manufacturers voluntarily submitted pediatric studies under BPCA or were required by FDA to submit studies under PREA. Drug manufacturers can submit studies to satisfy both laws; for example, if FDA requires a company to conduct studies under PREA, the manufacturer can request that the studies fulfill BPCA requirements to be awarded an additional 6 months of market exclusivity.

Appendix III: Results of the Medical Expenditure Panel Survey Analysis

Tables 7 and 8 provide estimates of children's utilization of psychotropic medications and other mental health services, based on our analysis of MEPS data.

Table 7: Utilization of Psychotropic Medications and Other Mental Health Services by Children Covered by Medicaid and Private Insurance, 2007-2009

Percentage of children (standard error)		
Characteristic	**Medicaid**	**Private insurance**
Use of psychotropic medications		
Percentage of all children	6.2% (0.4)	4.8%* (0.3)
Sex		
Males	8.4 (0.7)	6.3* (0.5)
Females	3.9 (0.4)	3.2 (0.4)
Age		
0-5 years	0.6 (0.2)[a]	0.1(0.1)[a]
6-11 years	8.6 (0.9)	4.8* (0.6)
12-17 years	8.4 (0.8)	7.5 (0.7)
18-20 years	12.7 (1.8)	6.6* (0.8)
Information on children taking psychotropic medications[b]		
Number of medications taken		
One medication	56.3 (2.9)	67.0 (3.0)
Two medications	28.0 (2.6)	22.2 (2.3)
Three or more medications	15.7 (2.1)	10.7 (1.9)
Types of medications taken		
Attention deficit hyperactivity disorder (ADHD) medication	78.4 (2.4)	73.5 (2.4)
Antidepressant	23.5 (2.7)	32.7 (2.8)
Antipsychotic	21.1 (2.6)	9.9* (2.1)
Receipt of other mental health services		
Mental health office visit	73.5 (2.6)	70.3 (2.5)
Psychotherapy	39.1 (2.8)	33.9 (3.1)
Information on children who had a mental health office visit[c]		
Took a psychotropic medication	81.0 (2.3)	73.8 (2.8)
Office visit included psychotherapy	54.5 (2.9)	52.1 (3.5)
Type of provider seen		
Psychiatrist	40.0 (3.4)	37.9 (3.4)
Psychologist	19.6 (2.2)	24 (3.0)
Social worker	6.4 (1.6)	8.3 (1.7)
Pediatrician	30.1 (3.1)	24.6 (2.4)

Percentage of children (standard error)		
Characteristic	**Medicaid**	**Private insurance**
Family practice physician	11.2 (1.9)	11.6 (2.2)
Receipt of mental health services by children with a potential mental health need		
Percentage of children with a potential mental health need	13.5 (0.7)	8.7* (0.5)
Utilization of mental health services among children with a mental health need		
No mental health office visits	71.7 (2.1)	75.4 (2.2)
No psychosocial therapy	82.4 (1.9)	83.2 (2.0)
No psychotropic medications	69.4 (2.0)	75.2 (2.4)
No office visits or medications	65.4 (2.2)	69.3 (2.5)

Legend: Asterisk indicates a statistically significant difference from children in Medicaid at the 99 percent confidence level.

Source: GAO analysis of Department of Health and Human Services data.

Notes: Data are from the Medical Expenditure Panel Survey. Numbers in parentheses are the standard errors—a measure of variation around the estimate. Children were ages 0 through 20 and had at least 10 months of coverage by either Medicaid or private insurance in a calendar year.

[a]The relative standard error is greater than or equal to 30 percent. Relative standard error is the proportion of the standard error divided by the estimate itself.

[b]Information below pertains only to children who took psychotropic medications.

[c]Information below pertains only to children who had a mental health office visit.

Table 8: Use of Psychotropic Medications and Other Mental Health Services by Children Covered by Medicaid and Private Insurance, by Age Group, 2007-2009

Percentage of children (standard error)

	Age group			
Characteristic	**0-5 years**	**6-11 years**	**12-17 years**	**18-20 years**
Use of psychotropic medications				
Use of one medication				
Medicaid	0.5 (0.2)[a]	4.6 (0.6)	4.8 (0.6)	7.1 (1.3)
Private insurance	0.1 (0.1)[a]	2.6 (0.4)	5.5 (0.5)	4.7 (0.6)
Use of two medications				
Medicaid	0.1 (0.1)[a]	2.7 (0.4)	2.0 (0.4)	3.6 (1.0)
Private insurance	—	1.5 (0.3)	1.4 (0.3)	1.2 (0.3)
Use of three or more medications				
Medicaid	—	1.3 (0.3)	1.5 (0.3)	2.0 (0.7)[a]
Private insurance	—	0.7 (0.2)[a]	0.6 (0.2)	0.8 (0.3)[a]
Types of medications taken				
ADHD medications				
Medicaid	0.2 (0.1)[a]	2.6 (0.3)	1.7 (0.2)	0.3 (0.1)
Private insurance	—	1.4* (0.2)	1.7 (0.2)	0.4 (0.1)
Antidepressants				
Medicaid	—	0.3 (0.1)	0.6 (0.1)	0.6 (0.1)
Private insurance	—	0.3 (0.1)[a]	0.7 (0.1)	0.6 (0.1)
Antipsychotics				
Medicaid	—	0.6 (0.1)	0.5 (0.1)	0.2 (0.1)
Private insurance	—	0.1* (0.1)[a]	0.2 (0.1)	—
Children with a potential mental health need[b]				
Medicaid	6.4 (1.2)	12.3 (0.9)	16.2 (1.1)	N/A
Private insurance	4.2 (1.1)	7.8* (0.6)	9.8* (0.6)	N/A
Receipt of Mental Health Services by Children with a Potential Mental Health Need[b]				
No mental health office visits				
Medicaid	88.2 (6.0)	65.7 (3.2)	76.3 (2.8)	N/A
Private insurance	—	75.4 (3.6)	75.2 (2.6)	N/A
No psychosocial therapy				
Medicaid	90.4 (5.5)	80.4 (3.0)	83.5 (2.6)	N/A
Private insurance	—	82.6 (3.4)	82.9 (2.3)	N/A
No psychotropic medications				
Medicaid	91.2 (5.3)	61.7 (3.4)	74.7 (2.6)	N/A
Private insurance	—	78.5* (3.8)	72.0 (3.2)	N/A

Percentage of children (standard error)				
	Age group			
Characteristic	**0-5 years**	**6-11 years**	**12-17 years**	**18-20 years**
No office visits or medications				
Medicaid	88.2 (6.0)	58.8 (3.5)	69.9 (2.9)	N/A
Private insurance	—	70.7 (4.1)	67.3 (3.2)	N/A

Legend: Asterisk indicates a statistically significant difference from privately insured children at the 99 percent confidence level. Dashes indicate the sample size was too small to produce a reliable estimate. N/A = not applicable.

Source: GAO analysis of Department of Health and Human Services data.

Notes: Data are from the Medical Expenditure Panel Survey. Numbers in parentheses are the standard errors—a measure of variation around the estimate. Children were ages 0 through 20 and had at least 10 months of coverage by either Medicaid or private insurance in a calendar year.

[a]The relative standard error is greater than or equal to 30 percent. Relative standard error is the proportion of the standard error divided by the estimate itself.

[b]Children were considered to have a potential mental health need if they scored 16 or above on the Columbia Impairment Scale, a psychometric scale used by MEPS that is designed to measure emotional and behavioral impairment. The scale was only administered for children ages 5 through 17; thus the estimates for children ages 18 through 20 were not applicable (N/A).

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

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Staff Acknowledgments

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