Treatment of Pediatric Attention-Deficit/Hyperactivity Disorder: An Assessment of State Medicaid Policies

OSTLTS Generic Information Collection Request
OMB No. 0920-0879

Supporting Statement – Section A

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- **Goal of the study:** To collect information about the characteristics and implementation of state Medicaid policies that may impact the treatment of pediatric Attention-Deficit/ Hyperactivity Disorder (ADHD). The proposed project will serve as a pilot information collection to inform the development of a separate ICR to collect data on an annual basis in future years.

- **Intended use of the resulting data:** The resulting data from this information collection are intended to be used to:
  - Supplement information on policies regarding state Medicaid program prior authorization for ADHD medications prescribed to children.
  - Confirm whether each state has a prior-authorization policy for pediatric ADHD medication prescriptions, details of the policy, and the date of policy implementation.
  - Inform NCBDDD of Medicaid policies regarding behavioral health services delivery models of states.
  - Create a publicly available, interactive database that characterizes the ADHD medication prior authorization policies and behavioral health services delivery models for all U.S. states and D.C.
  - In conjunction with Medicaid claims data (MAX data), evaluate the impact of these policies on ADHD medication and behavior therapy treatment rates in young children.

- **Methods to be used to collect:** Information will be collected from an electronic questionnaire sent via email to respondents.

- **The subpopulation to be studied:** Respondents include 51 Medicaid Medical Directors from all 50 states and the District of Columbia.

- **How data will be analyzed:** Descriptive data will be summarized for each state and entered into a searchable online database available to the public.

Section A – Justification

1. Circumstances Making the Collection of Information Necessary

Background

This information collection is being conducted using the Generic Information Collection mechanism of the OSTLTS OMB Clearance Center (O2C2) – OMB No. 0920-0879. The respondent universe for this information collection aligns with that of the O2C2. Data will be collected from 51 (50 states and the District of Columbia) Medicaid Medical Directors acting in their official capacities.

This information collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241). This information collection falls under the essential public health service(s) of:

☐ 1. Monitoring health status to identify community health problems
☐ 2. Diagnosing and investigating health problems and health hazards in the community
☒ 3. Informing, educating, and empowering people about health issues
☐ 4. Mobilizing community partnerships to identify and solve health problems
☒ 5. Development of policies and plans that support individual and community health efforts
☐ 6. Enforcement of laws and regulations that protect health and ensure safety
☐ 7. Linking people to needed personal health services and assure the provision of health care when otherwise unavailable
☐ 8. Assuring a competent public health and personal health care workforce
☒ 9. Evaluating effectiveness, accessibility, and quality of personal and population-based health services
☐ 10. Research for new insights and innovative solutions to health problems [1]

As of 2011-12, 6.4 million, or 11% of school-aged children 4-17 years of age received an ADHD diagnosis, with the rates approximately 50% higher among children with public insurance.[2] Approximately 5.4 million U.S. school-aged children have a current ADHD diagnosis and 2.5 million are taking medication for ADHD treatment.[2] The prevalence of diagnosed ADHD has increased by 3-6% per year since 1997.[2]

The annual societal costs of childhood ADHD are estimated at $38–72 billion, including those associated with health care, education, juvenile justice, and loss of family productivity.[3] Childhood ADHD is associated with higher rates of unintentional injury, emergency room visits, peer problems, and academic failure.[4, 5, 6, 7, 8, 9] Long-term consequences include increased risk for incarceration, other psychiatric disorders, and earlier death by suicide.[10] Although medication treatment using methylphenidate has strong effects on the core symptoms of ADHD (hyperactivity, impulsivity, inattention),[11, 12] evidence-based parent- or teacher-administered behavior therapy has been associated with unique improvements in academic, social, and family functioning.[13, 14]
The Agency for Healthcare Research and Quality (AHRQ) has concluded that there is “high-strength evidence” that parent behavior training (PBT) is efficacious for the treatment of ADHD and disruptive behavioral disorders among preschoolers. AHRQ has also determined that PBT is more effective and has fewer—in fact no—adverse effects compared to methylphenidate alone for the treatment of preschoolers at risk for ADHD.[15, 16] Research on the use of ADHD medications with preschoolers has documented that preschoolers are much more likely than older children treated with these medications to experience negative health side effects, including emotional lability, appetite loss, trouble sleeping, stomachaches, social withdrawal, and lethargy.[17] Additionally, a recent study comparing behavioral and pharmacological treatments for pediatric ADHD determined that beginning ADHD treatment with behavioral therapy alone produced better outcomes, such as reduced classroom rules violations, than beginning treatment with medication.[18]

In 2007, the American Academy of Child and Adolescent Psychiatry (AACAP) published guidelines for the pharmacological treatment of children under age 6 years with various psychiatric disorders.[19] In these guidelines, the AACAP recommended that clinicians try behavioral therapy before prescribing medication to treat preschool aged children with ADHD.[19] In 2011, the American

Academy of Pediatrics (AAP) updated their previously published clinical practice guidelines with recommendations for the diagnosis and treatment of pediatric ADHD.[20] Those treatment recommendations vary by age. "For preschool-aged children (4–5 years of age), the primary care clinician should prescribe evidence-based parent and/or teacher-administered behavior therapy as the first line of treatment," followed by medication only if behavioral therapy fails to provide significant improvement in the child's functioning.[20] For children aged 6–11 years, the AAP recommends a combination of FDA-approved ADHD medication and behavioral therapy.[20] For children aged 12–18 years, the AAP recommends prescribing psychotropic medications, "preferably" in combination with behavior therapy.[20]

But, when best practice recommendations are compared to epidemiological statistics, it appears that there is a misalignment between current and best practice for pediatric ADHD treatment. Data from the 2009–2010 National Survey of Children with Special Health Care Needs suggest that clinical best practice guidelines for ADHD are not being followed. The results of this survey show that fewer than half of children under age 6 with diagnosed ADHD receive any behavioral therapy, and 25.4% of these children are being treated exclusively with medication.[21]

CDC's National Center on Birth Defects and Developmental Disabilities (NCBDDD) aims to protect and promote the health of babies, children, people with blood disorders, and people with disabilities. NCBDDD's Child Development Studies (CDS) team focuses on health and development during the early years of a child's life. The CDS team conducts research to learn more about healthy child development and to better understand certain specific conditions that affect children, including ADHD, Tourette syndrome, behavior disorders, and mood and anxiety disorders. Regarding ADHD, NCBDDD is working to align current practice and best practice to ensure toddlers and preschoolers (2-5 years of age) receive recommended behavioral therapy treatment for ADHD. NCBDDD uses this data to inform clinical and state programs and to evaluate the reasons for the misalignment between current clinical practice and best practices for the diagnosis and treatment of ADHD in young children. To help achieve the overarching goal for young children with ADHD to receive first-line treatment for the disorder, NCBDDD seeks to understand the barriers to the provision of ADHD best practices and evaluate model programs and policies that attempt to address these barriers. State-based policy evaluation, in particular, is used to identify how states can support the delivery of ADHD best practices, improve the ADHD services provided to young children, and drive down the long-term costs associated with ADHD.

NCBDDD has identified Medicaid prior-authorization policy interventions as a set of strategies that may control the use of ADHD medication among young patients diagnosed with ADHD and guide clinicians towards referral for behavior therapy. In order to better understand the current state of practice, NCBDDD has previously sought to research and disseminate findings on the impact of this policy intervention as well as the impact of related policies to determine their value for guiding clinicians towards use of first-line ADHD treatment among preschoolers with the disorder. As part of this approach, a research team consisting of three researchers, one from the CDC and two from Temple University's Policy Surveillance Program, has already conducted a preliminary cross-

sectional mapping environmental scan of state Medicaid pediatric ADHD medication prior-authorization policies as of November 1, 2015.

The team conducted an internet search for Medicaid prior-authorization policies involving the prescription of ADHD medications, stimulant medications, or psychotropic medications to children younger than 18 years old in the 51 state jurisdictions and Washington, D.C. The team reviewed prior-authorization forms, memoranda from state Medicaid directors to prescribers, drug utilization review board meeting notes, and state Preferred Drug Lists (PDLs). The team also reviewed literature on Medicaid behavioral health services carve-out policies (an insurance reimbursement arrangement where payment for Medicaid mental or behavioral health services are carved out of managed care contracts to either the Medicaid fee-for-service system or a specialized Behavioral Health Care Organization) for future use in understanding the relationship of prior authorization policies with medication and PBT prescription rates.

Based on this initial review, the team developed a coding scheme that incorporated the key features of prior-authorization policies and recorded these features in a database that will be publicly available on the lawatlas.org website. The team also continued to review states' prior-authorization policies to ensure all were coded as of November 1, 2015. The final number of state Medicaid prior authorization policies recorded was 27.

Based on this review, the team also identified several gaps in the available information. First, the finding of 27 states with a policy for managing pediatric ADHD medication prescriptions relies on the assumption that all Medicaid programs have made their policies regarding pediatric ADHD medication prescriptions publicly available on the Internet. Additionally, the coding methods described above rely on the assumption that the researchers can accurately characterize each state's Medicaid policies to reflect their use in practice. A targeted search of published literature and available grey sources did not provide any sufficient reports, and no nationwide collection and characterization of Medicaid prior-authorization policies has been previously done.

A second gap in the available information related to the provision of ADHD treatment services is the health delivery model for behavioral health services within Medicaid. State Medicaid programs have carved out the provision of behavioral health services to another agency (e.g., a behavioral health organization) or they have carved these services out of their managed care contracts to be paid for using a fee-for-service model. To date, there has been no systematic collection of state behavioral health services carve-out policies that is available to the public.

To address these gaps, a web-based assessment of the 51 (50 states and the District of Columbia) Medicaid programs is proposed. The purpose of this assessment is to collect information about the characteristics and implementation of state Medicaid policies that relate to pediatric ADHD treatment. This data collection effort is the first national-level attempt of its kind and will serve as a pilot information collection to inform the development of a separate ICR to collect these data on an annual basis in future years.

This information collection aims to learn more about the use of: 1) prior authorization policies by Medicaid programs to manage ADHD medication prescriptions to children; and 2) behavioral health services carve-out policies to manage PBT reimbursement. Additionally, the information collection will provide an opportunity to validate the findings of the previous literature review/environmental scan which found that 27 states held a policy for managing pediatric ADHD medication prescriptions.

Results from this information collection will be used to: 1) supplement the publicly available information on these policies, 2) confirm whether each state has a prior authorization policy for ADHD medications prescribed to children, the details of that policy, and the dates of policy implementation, 3) inform NCBDDD of Medicaid policies regarding behavioral health services delivery models of states, and 4) create a publicly available, interactive database that characterizes the ADHD medication prior authorization policies and behavioral health services delivery models for all U.S. states and D.C.. Additionally, the information will be used in conjunction with Medicaid claims data (MAX data) to evaluate the impact of such policies on ADHD medication and PBT rates in young children.

Overview of the Information Collection System

Information will be collected from a total of 51 (50 states and the District of Columbia) Medicaid Medical Directors, or their designee, via an electronic questionnaire (see **Attachment A—Instrument: Word version** and **Attachment B—Instrument: Adobe PDF version**) allowing respondents to complete and submit their responses electronically. The electronic instrument will be used to gather information on the characteristics and implementation of state Medicaid prior-authorization policies for medications prescribed to treat pediatric ADHD. The information collection instrument was developed using Adobe Acrobat Professional. This method was chosen allow respondents to complete and submit their responses electronically using widely available, free software (Adobe Acrobat), reducing overall burden.

The electronic PDF instrument will include prepopulated data specific to the respondent's state, as generated by the lawatlas.org website. The prepopulated data will include: 1) a copy of any prior-authorization policy the team has reviewed for the respondent's state; and 2) a copy of the key features of the state's prior-authorization policies as recorded by the research team in the lawatlas.org database. Each respondent will be asked a series of questions regarding the prepopulated data to confirm whether or not CDC has correctly characterized certain components of the state's Medicaid policies related to ADHD treatment. This delivery method will further reduce respondents' burden by eliminating the need to go back and forth between the instrument and external webpages or reference documents.

Upon completion of the instrument, respondents need only click a "submit" button that will deliver the completed assessment to a secure CDC email address without any further action by the respondent.

The assessment was designed to collect the minimum information necessary for the purposes of this project. The information collection instrument was pilot tested by 7 public health professionals. Feedback from this group was used to establish the estimated time required to complete the information collection instrument, refine questions as needed, and ensure accurate programming and skip patterns within the instrument.

Items of Information to be Collected

The electronic information collection instrument (see **Attachment A—Instrument: Word version** and **Attachment B—Instrument: Adobe PDF version**) will assess the characteristics and implementation of state Medicaid policies that relate to pediatric ADHD treatment.

The survey consists of a total of 15 questions. Question formats include dichotomous, multiple response, interval, and open-ended. Although the prepopulated information included will be tailored to each respondent, the questions regarding that information will be the same across all respondents. In an effort to minimize response burden, the instrument was designed with a particular focus on streamlining questions by limiting narrative or open-ended questions whenever possible. The instrument will collect information on the following:

- Characteristics of Medicaid policies requiring prior authorization for obtaining coverage for ADHD medications prescribed to children younger than 18, including:
    - Whether the Medicaid program has any such policy
    - Whether our team's characterization of a state's policy is correct
    - Specific characteristics of a Medicaid program's prior authorization policy
    - Implementation date and most recent update date for the policy

- Characteristics of Medicaid programs' behavioral health services carve-out policy, including:
    - Whether the Medicaid program's coverage for behavioral health services are currently carved in to a managed care organization or carved out to a fee for service model or a behavioral health organization.
    - Whether the Medicaid program's behavioral health services were ever carved out in the last five years.

- Respondent information related to their official duty including name, title, position, and contact information. This information will be collected only for the purpose of contacting the respondent upon his/her request or to clarify a respondent's answer. This information will be kept in a secure CDC file at all times, and the data will be de-identified for any reporting activities following the data collection.

2. Purpose and Use of the Information Collection

The purpose of this assessment is to collect information about the characteristics and implementation of state Medicaid policies that relate to pediatric ADHD treatment. Specifically, CDC would like to collect information on state use of prior-authorization and behavioral health carve-outs to support the delivery of recommended ADHD treatment.

This data collection effort is the first national-level attempt of its kind and will serve as a pilot information collection to inform the development of a separate ICR to collect these data on an annual basis in future years.

The resulting data from this information collection are intended to be used to:

- Supplement information on policies regarding state Medicaid program prior authorization for ADHD medications prescribed to children.
- Confirm whether each state has a prior-authorization policy for pediatric ADHD medication prescriptions, details of the policy, and the date of policy implementation.
- Inform NCBDDD of Medicaid policies regarding behavioral health services delivery models of states.
- Create a publicly available, interactive database that characterizes the ADHD medication prior authorization policies and behavioral health services delivery models for all U.S. states and D.C.
- In conjunction with Medicaid claims data (MAX data), evaluate the impact of these policies on ADHD medication and PBT rates in young children.

3. Use of Improved Information Technology and Burden Reduction

Information will be collected via an electronic questionnaire. This method was chosen to allow respondents to complete and submit their responses electronically, reducing the overall burden on respondents. The information collection instrument was designed to collect the minimum information necessary for the purposes of this project (i.e., limited to [15] questions). Furthermore, skip patterns were incorporated to allow for streamlining responses and the reduction of burden on respondents.

4. Efforts to Identify Duplication and Use of Similar Information

This information collection will be a new information collection regarding Medicaid policies for prior authorization for ADHD medication prescriptions for children and reimbursement for parent-administered behavior therapy. Prior to developing this information collection, a legal analyst in NCBDDD conducted a targeted literature review focused on Medicaid policies related to children with ADHD. In addition, two legal analysts, one from NCBDDD and one from Temple University, and

a CDC legal epidemiology assistant spent approximately forty hours reviewing publicly available documents from the Centers for Medicare and Medicaid Services (CMS) website, the National Association of Medicaid Directors website, and individual states' Medicaid websites as well as a general Internet search using Google and PubMed search engines. None of these searches resulted in any centralized report or source specifically documenting the ADHD prior-authorization information for the Medicaid programs in all states and the District of Columbia. Based on this review, it has been concluded that there is no other project that duplicates the proposed efforts.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

This request is for a one time information collection. There are no legal obstacles to reduce the burden. This information collection is a direct response to CDC's need to understand state-based efforts to manage pediatric treatment of ADHD. If no data are collected, CDC will be unable to:

- Analyze and understand how and to what extent Medicaid prior authorization policies for pediatric ADHD treatment affect ADHD medication prescription rates
- Analyze and understand how and to what extend Medicaid prior-authorization policies for pediatric ADHD treatment affect provider referrals for behavioral therapy as first-line treatment for pediatric ADHD.
- Produce scientifically rigorous data on the status of Medicaid prior-authorization policies across the country

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances with this information collection package. This request fully complies with the regulation 5 CFR 1320.5 and will be voluntary.

8.Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

This information collection is being conducted using the Generic Information Collection mechanism of the OSTLTS OMB Clearance Center (O2C2) – OMB No. 0920-0879. A 60-day Federal Register Notice was published in the Federal Register on May 16, 2014, Vol. 79, No. 95; pp. 28513. No comments were received.

CDC partners with professional STLT organizations, such as the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), and the National Association of Local Boards of Health (NALBOH) along with the National Center for Health Statistics (NCHS) to ensure that the collection requests under individual ICs are not in conflict with collections they have or will have in the field within the same timeframe.

9. Explanation of Any Payment or Gift to Respondents

CDC will not provide payments or gifts to respondents.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The Privacy Act does not apply to this information collection. STLT governmental staff will be speaking from their official roles. All information collected will be stored in a secure environment maintained by CDC. Although CDC will collect some individually identifiable information (IIF), used only for follow-up as needed, CDC will remove all IIF and use only the state name in the final dataset. No IIF will be distributed publicly.

This information collection is not research involving human subjects.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

No information will be collected that are of personal or sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

The estimate for burden hours is based on a pilot test of the information collection instrument by 7 public health professionals. In the pilot test, the average time to complete the instrument including time for reviewing instructions, gathering needed information and completing the instrument, was approximately 15 minutes (range: 10 to 20 minutes). For the purposes of estimating burden hours, the upper limit of this range (i.e., 20 minutes) is used.

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) Bureau of Labor Statistics for occupational employment for General and Operations Managers (http://www.bls.gov/oes/current/oes_nat.htm). Based on DOL data, an average hourly wage of $57.44 is estimated for all 51 respondents. Table A-12 shows estimated burden and cost information.

Table A-12: Estimated Annualized Burden Hours and Costs to Respondents

Information collection Instrument: Form Name	Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Medicaid ADHD Medication Prior-Authorization	State Medicaid Medical Program Director	50	1	20/60	17	$57.44	$976
Medicaid ADHD Medication Prior-Authorization	District of Columbia Medicaid Medical Program Director	1	1	20/60	1	$57.44	$57
	TOTALS	**51**	**1**		**18**		**$1,033**

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There will be no direct costs to the respondents other than their time to participate in each information collection.

14. Annualized Cost to the Government

There are no equipment or overhead costs. Contractors, however, are being used to support development of the assessment tool, data collection, and data analysis. The only cost to the federal government would be the salary of CDC staff and contractors. The total estimated cost to the federal government is $1631.00. Table A-14 describes how this cost estimate was calculated.

Table A-14: Estimated Annualized Cost to the Federal Government

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Average Cost
Lead Epidemiologist (GS-14)- Instrument development, response collection and storage	10	$54.35	$543.50
ORISE Fellow- Instrument development, pilot testing, clearance, instrument deployment, response collection and storage	30	$31.25	$937.50
Sub-contract (incl. 3 sub-contractors)- Policy Surveillance Program at Temple	5	N/A	$150.00

University; Instrument development			
Estimated Total Cost of Information Collection			**$1631.00**

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Once the 10-business day period information collection period has closed, data will be compiled, cleaned and stored in a secure Excel database maintained by the CDC. Descriptive analyses will be conducted to summarize data. Upon completion of the data analysis, CDC will use the de-identified data to:

- Supplement information on policies regarding state Medicaid program prior authorization for ADHD medications prescribed to children.
- Confirm whether each state has a prior-authorization policy for pediatric ADHD medication prescriptions, details of the policy, and the date of policy implementation.
- Inform NCBDDD of Medicaid policies regarding behavioral health services delivery models of states.
- Create a publicly available, interactive database that characterizes the ADHD medication prior authorization policies and behavioral health services delivery models for all U.S. states and D.C.
- In conjunction with Medicaid claims data (MAX data), evaluate the impact of these policies on ADHD medication and PBT rates in young children.

Results may also be submitted for publication in a scientific journal.

<u>Project Time Schedule</u>

- ✓ Design data collection instrument ..... (COMPLETE)
- ✓ Develop protocol, instructions, and analysis plan ..... (COMPLETE)
- ✓ Pilot test data collection instrument ..... (COMPLETE)
- ✓ Prepare OMB package ..... (COMPLETE)
- ✓ Submit OMB package ..... (COMPLETE)
- ❑ OMB approval ..... (TBD)
- ❑ Conduct assessment ..... (Assessment open 6 weeks)
- ❑ Code, quality control, and analyze data..... (4 weeks)
- ❑ Prepare reports ..... (6 weeks)
- ❑ Disseminate results/reports ..... (6 weeks)

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We are requesting no exemption.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

LIST OF ATTACHMENTS – Section A

A. Attachment A—Instrument: Adobe PDF version
B. Attachment B—Instrument: Word version

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