

# *Symposium: Children’s Health, Mental Health, and the Law*

## Fostering Transparency: A Preliminary Review of “Policy” Governing Psychotropic Medications in Foster Care

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*In light of increasing national attention on the high rates of prescribing psychotropic medication for children in foster care, and related new federal requirements for state reporting to the federal government, we analyzed child welfare agency laws, policies, and regulations in sixteen states. Our analysis revealed that states with monitoring policies in place tend to use informal guidance or underdeveloped policy statements that were likely not subject to public notice or comment, and afforded little, if any, opportunity for redress. This Article argues that, given the new federal requirements related to psychotropic medications and children in foster care, the state policy-making process must become more transparent to ensure broad public input and recourse in the case of non-compliance.*

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## INTRODUCTION

Psychotropic medications<sup>1</sup> are prescribed to approximately one in five of the over 400,000 children in foster care in the United States, based on regional Medicaid claims analyses<sup>2</sup>—about ten times more than children in the general population.<sup>3</sup> This prescribing disparity persists despite media attention to and policy makers' interest in the issue.<sup>4</sup>

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1. Psychotropic medications, also sometimes called psychiatric or psychotherapeutic medications, refer to a broad category of medications that “treat mental disorders.” NAT'L INST. OF MENTAL HEALTH, U.S. DEP'T OF HEALTH & HUMAN SERVS., MENTAL HEALTH MEDICATIONS 1 (2010). However, individual state agencies, legislatures, or courts may separately define psychotropic medications in either broader or more limited terms.

2. CHILDREN'S BUREAU, U.S. DEP'T OF HEALTH & HUMAN SERVS., FOSTER CARE STATISTICS 2012, at 1 (2013). Studies estimate that somewhere between thirteen to thirty-seven percent of children in foster care have been prescribed psychotropic medication. Estimates vary widely between different studies. Ramesh Raghavan et al., *Interstate Variations in Psychotropic Medication Use Among a National Sample of Children in the Child Welfare System*, 15 CHILD MALTREATMENT 121, 121 (2010).

3. Although the rates of medication for children in foster care vary widely, all studies agree that children in foster care are prescribed psychotropic medications at much higher rates than children in the general population, or even other children on Medicaid. Mark Olsson et al., *National Trends in the Use of Psychotropic Medications by Children*, 41 J. AM. ACAD. CHILD & ADOLESCENT PSYCHIATRY 514, 514-21 (2002).

4. A. Rachel Camp, *A Mistreated Epidemic: State and Federal Failure to Adequately Regulate Psychotropic Medications Prescribed to Children in Foster Care*, 83 TEMP. L. REV. 369, 373-75 (2011). Camp lists increasing media coverage as one of two key drivers for increasing state regulation of psychotropic medications. *Id.* at 374. “[G]rowing media coverage of high profile cases involving

Identifying the type of monitoring policies put in place by state child welfare agencies to address this issue may be critical to understanding the lack of progress.

Burgeoning concern about the high rates of psychotropics prescribed to children in foster care led the federal government to act.<sup>5</sup> In 2006, the Government Accountability Office (“GAO”) issued a report documenting the challenges facing child welfare systems, and noted that one in three states identified the use of psychotropic medications in their foster care population as among their most pressing issues to address over the next five years.<sup>6</sup> In 2008, the federal government responded through several provisions in the Fostering Connections to Success and Increasing Adoptions Act (“FCA”),<sup>7</sup> which requires states to set up a healthcare coordination and oversight plan for children in foster care.<sup>8</sup>

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children in foster care receiving psychotropic medications at . . . extremely high rates . . . has helped to raise awareness of the issue.” *Id.* (citations omitted). Overall, the rates of psychotropic medications remain high among children in foster care. See David Rubin et al., *Interstate Variation in Trends of Psychotropic Medication Use Among Medicaid-Enrolled Children in Foster Care*, 34 CHILD. & YOUTH SERVICES REV. 1492, 1496–97 (2012). However, some sub-populations have experienced stabilization in prescription rates. See Vilawan Chirdkiatgumchai et al., *National Trends in Psychotropic Medication Use in Young Children: 1994–2009*, 132 PEDIATRICS 615, 615–18 (2013) (discussing how rates of prescribing for very young children stabilized in the late 2000s).

5. Although this Article’s focus is psychotropic medication rates for children in foster care, the federal government has displayed broad concern about high rates of psychotropic medication prescribed to all children. For example, to rein in the high usage rates of psychotropic medications, the U.S. Department of Justice (“DOJ”) recently settled a suit against Johnson and Johnson (“J&J”) in which the DOJ alleged that J&J promoted the use of Risperdal, a psychotropic medication, to treat children with behavioral problems, even though it was only approved by the FDA for the treatment of schizophrenia, and even though they knew that Risperdal increased the risk of developing diabetes. Katie Thomas, *J&J to Pay \$2.2 Billion in Risperdal Settlement*, N.Y. TIMES, Nov. 5, 2013, at B1; Tom Wilemon, *Study: Antipsychotic Drugs Put Kids at Diabetes Risk*, USA TODAY (Aug. 22, 2013), <http://www.usatoday.com/story/news/nation/2013/08/21/antipsychotic-drugs-kids-diabetes/2682925/>.

6. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-07-75, CHILD WELFARE: IMPROVING SOCIAL SERVICE PROGRAM, TRAINING, AND TECHNICAL ASSISTANCE INFORMATION WOULD HELP ADDRESS LONGSTANDING SERVICE-LEVEL AND WORKFORCE CHALLENGES 19 fig.7 (2006).

7. Fostering Connections to Success and Increasing Adoptions Act of 2008, Pub. L. No. 110-351, § 205, 122 Stat. 3949, 3961 (codified as amended in scattered sections of 42 U.S.C.).

8. The healthcare coordination and oversight plan must be developed “in consultation with pediatricians, other experts in health care, and experts in and recipients of child welfare services . . . for the ongoing oversight and coordination of health care services for any child in a foster care placement, which shall ensure a coordinated strategy to identify and respond to the health care needs of children in foster care placements, including mental health and dental health needs.” 42 U.S.C. § 622(b)(15)(A). In 2012, the Administration for Children identified five areas related to psychotropic medication that must be included in states’ Oversight Plan, which is part of their Annual Progress and Services Report. Specifically, and in coordination with the State Medicaid Agency, the Oversight Plan must outline the “oversight of prescription medicines, including protocols for the appropriate use and monitoring of psychotropic medications” including information on: (1) “[c]omprehensive and coordinated screening, assessment, and treatment planning mechanisms;” (2) “[i]nformed and shared decision-making (consent and assent) and methods for on-going communication between . . . key stakeholders;” (3) “[e]ffective medication monitoring at both the client and agency level;” (4) “[a]vailability of mental health expertise and consultation . . . (at both the agency and individual

The FCA increased oversight of children in foster care, which was reinforced through provisions of the Child and Family Services Improvement and Innovation Act of 2011 (“CFSIIA”).<sup>9</sup> CFSIIA requires state child welfare agencies to develop a plan for the oversight of prescription medication, which must include protocols “for the appropriate use and monitoring of psychotropic medications.”<sup>10</sup>

Several academic studies reported that by 2010, the majority of state child welfare agencies had or were developing policies related to the oversight of psychotropic medications for children in foster care.<sup>11</sup> These studies examined the extent to which states were implementing monitoring policies related to psychotropic drugs and children in foster care. None of these studies identified their findings on a state-by-state basis, however, which made it difficult to identify the substance and scope of each policy. Moreover, the studies relied predominately on information from “key informants” at state agencies. These “key informants” included state child welfare and related agency staff, medical or mental health directors, foster care administrators, and other state mental health professionals and policymakers.<sup>12</sup> Further adding to the difficulty of identifying the substance and scope of the oversight provisions, the “policies” reported in these studies included not only self-reporting by agencies but also information obtained directly from the “key informants.”<sup>13</sup>

This Article builds on the existing literature by comprehensively investigating the types of monitoring policies enacted by several states. We define monitoring policies in two ways. First, as pre-authorization policies, which require “physicians to obtain preapproval in order for a patient to receive coverage for nonpreferred, and typically more

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case level”); and (5) “[m]echanisms for . . . sharing accurate and up-to-date information . . . related to . . . psychotropics . . . to clinicians, child welfare staff, and consumers.” CHILDREN’S BUREAU, U.S. DEP’T OF HEALTH & HUMAN SERVS., LOG No. ACYF-CB-IM-12-03, INFORMATION MEMORANDUM 12-13 (2012) [hereinafter INFORMATION MEMORANDUM 12-03].

9. Child and Family Services Improvement and Innovation Act of 2011, Pub. L. No. 112-34, § 101(b)(2), 125 Stat. 369.

10. *Id.* at 369.

11. *See, e.g.*, LAUREL K. LESLIE ET AL., TUFTS CLINICAL & TRANSLATIONAL SCI. INST., MULTI-STATE STUDY ON PSYCHOTROPIC MEDICATION OVERSIGHT IN FOSTER CARE I, 4-5 (2010); Thomas I. Mackie et al., *Psychotropic Medication Oversight for Youth in Foster Care: A National Perspective on State Child Welfare Policy and Practice Guidelines*, 33 CHILD. & YOUTH SERVICES REV. 2213, 2216-18 (2011).

12. LESLIE ET AL., *supra* note 11, at 3; *see also* MEDICAID MED. DIRS. LEARNING NETWORK & RUTGERS CTR. FOR EDUC. & RESEARCH ON MENTAL HEALTH THERAPEUTICS, ANTIPSYCHOTIC MEDICATION USE IN MEDICAID CHILDREN AND ADOLESCENTS: REPORT AND RESOURCE GUIDE FROM A 16-STATE STUDY 13 (2010).

13. LESLIE ET AL., *supra* note 11, at 3. Relying on information provided by “key informants” can be problematic since they often share or report their personal perspective only, and thus may not truly represent the agency. *See, e.g.*, Paula L. Grubb et al., *Workplace Bullying: What Organizations Are Saying*, 8 EMP. RTS. & EMP. POL’Y J. 407, 422 (2004) (discussing the research limitations of “key informant” interviewing).

expensive, medications.”<sup>14</sup> In some instances, pre-authorization may require court approval.<sup>15</sup> Second, as “red flag” policies, which identify “[p]atterns that may signal that factors other than clinical need are impacting the prescription of psychotropic medications,”<sup>16</sup> and therefore typically trigger a secondary review. Red flags identified by experts include the use of psychotropic medications for young children, unusually high dosage levels, and multiple medications prescribed simultaneously.<sup>17</sup> Better monitoring by state child welfare agencies could, in theory, show that the disparity in prescription rates for children in foster care is somehow justified.

Unfortunately, monitoring is a second-order problem for policymakers concerned about high rates of psychotropic medication prescription because analyzing monitoring policies is not directly related to curbing rates of prescription rates. More effective monitoring is necessary to understand whether and in what circumstances overprescribing occurs and the development of policies that effectively address the root causes of overprescribing.

This Article makes three contributions to further the development and understanding of monitoring policies related to the use of psychotropic medications for children in foster care. First, it shows that informal policies are the primary tools used by states to monitor psychotropic medications and children in foster care—a choice that should be revisited. “Formal policies” either take the form of statutes, laws enacted by the legislature, or agency rulemaking, legislative rules promulgated by an administrative agency, and are legally binding.<sup>18</sup> In contrast, “informal policies” are non-binding in nature and are typically established through guidance documents, also commonly referred to as non-legislative, interpretive rules, or policy statements.<sup>19</sup> Although states vary considerably in terms of how they define these guidance documents, and whether and under what circumstances a notice and comment period occurs, the majority of states do not require notice or comment before the issuance of guidance documents.<sup>20</sup> This is consistent with the 2010 Model State Administrative Procedure Act (“MSAPA”).<sup>21</sup>

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14. Christine Y. Lu et al., *Association Between Prior Authorization for Medications and Health Service Use by Medicaid Patients with Bipolar Disorder*, 62 *PSYCHIATRIC SERVICES* 186, 186 (2011).

15. *See, e.g.*, CAL. CODE REGS. tit. 22, § 89475 (2014) (prohibiting caregivers from compelling children in California foster care to take psychotropic medication without prior authorization in the form of a court order).

16. INFORMATION MEMORANDUM 12-03, *supra* note 8, at 8.

17. *See* LESLIE ET AL., *supra* note 11, at 7 tbl.1.

18. Ronald M. Levin, *Rulemaking Under the 2010 Model State Administrative Procedure Act*, 20 *WIDENER L.J.* 855, 859–61 (2011).

19. *Id.* at 856.

20. Rulemaking by federal agencies is subject to a single federal statute called the Administrative Procedure Act (“APA”). *See* 5 U.S.C. §§ 551–559 (2006). The federal APA does not govern states;

In our review, we could not locate many of the monitoring policies reported in the foregoing studies, suggesting the policies are not available in public databases or on the agencies' websites, and were likely based on internal agency memorandum or were simply an articulation of state norms.

Second, this Article catalogues and analyzes state policies, to the extent that they exist, related to the use of psychotropics in foster care. We show that the existing policies are underdeveloped and fail to consider much of the monitoring criteria that experts and state agencies have identified as essential to protecting children.<sup>22</sup> Finally, although this Article does not settle the ongoing debate about the uses and abuses of informal policies, we agree with scholars who argue that the benefits of, and need for, more transparency increase with the severity of a rule's potential effects.<sup>23</sup> Thus, policies that materially limit individual liberty rights—such as the prescribing of psychotropic medications—should be more formal, consistent with “rule of law” values.<sup>24</sup>

By “rule of law,” this Article refers to the legal processes for the creation and enforcement of, or challenges to, the formal or informal policies of a governmental agency.<sup>25</sup> In this context, a rule of law approach would examine whether the policies were formal or informal, and by extension, whether they were readily available and potentially known to all stakeholders involved in the decisionmaking process. Here,

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rather each state adopts its own APA equivalent. *See* Appendix B for a table of states reviewed in this Article, their definitions of formal and informal policies, and whether notice and comment is required prior to the issuance of guidance documents. Note that four of the sixteen states reviewed require some form of notice and comment for guidance documents, though we identified relevant monitoring policies in only two of those four.

21. *See* MODEL STATE ADMIN. PROCEDURE ACT § 311(e) (2010). Under the MSAPA, an agency may issue a guidance document without using rulemaking procedures, however, agencies must follow other procedural obligations. *Id.* (requiring agencies to, among other things, maintain and publish an index of all of its effective guidance documents).

22. *See infra* Part II.B for a discussion of these underdeveloped policies that do not consider factors essential to protecting children, including: the use of psychotropic medication in young children, the dosage level, and whether multiple medications are prescribed simultaneously. LESLIE ET AL., *supra* note 11, at 7 tbl.1.

23. For example, if an agency regulation seeks to deny liberty or property, the Due Process Clause and all of its protections will be implicated. *See, e.g.*, U.S. CONST. amend. XIV, § 1 (“[N]or shall any State deprive any person of life, liberty, or property, without due process of law . . . .”); Mark Seidenfeld, *Substituting Substantive for Procedural Review of Guidance Documents*, 90 TEX. L. REV. 331, 339 n.43 (2011) (noting that whenever liberty or property is limited by an agency order, the formalities and protections of the Due Process Clause are implicated). *Cf.* Sarah Jane Hughes, *A Case for Regulating Cyberpayments*, 51 ADMIN. L. REV. 809, 832 (1999) (noting that transparency is even more important where consumers must evaluate competing choices and risks).

24. Thomas O. Sargentich, *The Future of Administrative Law*, 104 HARV. L. REV. 769, 774 (1991) (book review) [hereinafter Sargentich, *Future of Administrative Law*].

25. *See infra* Part III for a detailed discussion of this “rule of law” approach to policymaking and the need for transparency in the rulemaking process.

stakeholders include caseworkers, parents, foster parents, and youth. Moreover, most child welfare systems rely on external medical personnel and health systems to provide health and behavioral care.<sup>26</sup> Increased transparency surrounding the development and implementation of these policies would promote efficiency and uniformity among and across providers. Policies pertaining to the use of psychotropic medications for children in state custody affect the liberty and well being of children, the majority of whom cannot consent or object to the use of these medications.<sup>27</sup> Therefore, this Article concludes that states should consider adopting formal policies consistent with rule of law values, especially to the extent that informal policies are not resulting in targeted changes in prescribing rates.

This Article proceeds in four Parts. Part I reviews the child welfare system and specific healthcare challenges for children in the system, focusing on psychotropic medications. Part II examines federal and state actions intended to increase oversight of psychotropic medications; it also reviews the development of federal and state requirements, where overall action has been slow and difficult to document. Part III summarizes the principles of transparency and discusses the rule of law approach to policymaking. Finally, Part IV applies rule of law principles to policymaking related to psychotropic medications and children in foster care, and argues that greater transparency is needed.

## I. BACKGROUND: CHILDREN IN CHILD WELFARE SYSTEMS

“Child welfare systems” are the agencies responsible for a child’s health and well-being when the child is removed from the care of their parent or legal guardian as the result of abuse or neglect.<sup>28</sup> For the

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26. See Camp, *supra* note 4, at 397–401 (describing the consent process and some of the fragmentation and administrative issues with obtaining healthcare for children in foster care).

27. Some states allow youth to consent for medical treatment before the age of 18. See, e.g., 55 PA. CODE § 3680.52(6) (2013) (“[A] child who is 14 years of age or older shall consent to mental health treatment, including the administration of psychotropic medication.”).

28. The federal law in effect in 2003 defined “child abuse and neglect” as meeting a minimal standard of “any recent act or failure to act on the part of a parent or caretaker, which results in death, serious physical or emotional harm, sexual abuse or exploitation, or an act or failure to act which presents an imminent risk of serious harm.” Child Abuse Prevention and Treatment and Adoption Reform Act, 42 U.S.C. § 5106g(2) (2003); see Gerard F. Glynn, *The Child’s Representation Under CAPTA: It Is Time for Enforcement*, 6 NEV. L.J. 1250, 1250–53 (2006) (providing background and overview of Child Abuse Prevention and Treatment and Adoption Reform Act (“CAPTA”)). CAPTA was first passed in 1974 to permit states to allocate federal funds toward combatting child abuse. Caroline T. Trost, *Chilling Child Abuse Reporting: Rethinking the CAPTA Amendments*, 51 VAND. L. REV. 183, 192 (1998). Under two doctrines—*parens patriae* and the “best interest of the child” standard—the responsibility of the state in protecting children has evolved. See *id.* at 190, 191 & nn. 38–39, 194–200 (discussing both standards and the history of the state’s role in child abuse enforcement). Child abuse and neglect are defined by state law, although states accepting federal funding to combat child abuse and neglect must meet the federal benchmark as defined in CAPTA.

purposes of this Article, ‘children in foster care’ refers to children in out-of-home placements within child welfare systems.<sup>29</sup> This Part describes some of the key organizational features of child welfare systems, the behavioral needs of the children for whom they care, and current trends in psychotropic medication usage by children in foster care.

#### A. STATE CHILD WELFARE SYSTEMS AND THE PROBLEM OF FRAGMENTATION

Although state welfare agencies are responsible for ensuring that children in their care obtain healthcare, including psychotropic medications, they also face challenges for effectively delivering care.<sup>30</sup> For example, state child welfare system structures differ in organizational design, resulting in widespread variation in how policies are implemented.<sup>31</sup> Under recent federal legislation,<sup>32</sup> child welfare agencies are responsible for implementing new state protocols directed at

ADMIN. FOR CHILDREN & FAMILIES, U.S. DEP’T OF HEALTH & HUMAN SERVS., *State Definitions of Child Abuse and Neglect*, CHILD WELFARE INFO. GATEWAY, <https://www.childwelfare.gov/can/defining/state.cfm> (last visited Aug. 1, 2014). States then enforce their child abuse statutes through their respective Child Protective Services (“CPS”), unique agencies designed with the purpose of preserving the family unit when possible. See ADMIN. FOR CHILDREN & FAMILIES, U.S. DEP’T OF HEALTH & HUMAN SERVS., *Family Reunification*, CHILD WELFARE INFO. GATEWAY, <https://www.childwelfare.gov/permanency/reunification> (last visited Aug. 1, 2014). Concomitant or separate civil and/or criminal liability may attach to the CPS investigation. ADMIN. FOR CHILDREN & FAMILIES, U.S. DEP’T OF HEALTH & HUMAN SERVS., *The Court System and Child Abuse and Neglect*, CHILD WELFARE INFO. GATEWAY, [https://www.childwelfare.gov/pubs/usermanuals/courts\\_92/courtsc.cfm](https://www.childwelfare.gov/pubs/usermanuals/courts_92/courtsc.cfm) (last visited Aug. 1, 2014).

29. Children in “out-of-home placement” have been removed from their home by the child welfare system as a result of parental abuse or neglect. Children are subsequently placed in either an institutionalized care setting or with a foster family. See Michael Wald, *State Intervention on Behalf of “Neglected” Children: A Search for Realistic Standards*, 27 STAN. L. REV. 985, 989 n.21 (1975) (discussing out-of-home placement as a potentially coercive aspect of foster care).

30. Laws passed to improve oversight of psychotropic medications have focused on child welfare agencies as responsible for monitoring progress (to be discussed *infra* Part II) and, when necessary, collaborating with other agencies such as Medicaid. In regard to implementing the FCA, “[s]tate and Tribal agencies are required to develop a plan for ongoing oversight and coordination of health care services for children in foster care, including mental health and dental health needs, in coordination with the State Medicaid agency, pediatricians, general practitioners, and specialists.” CHILDREN’S BUREAU, U.S. DEP’T OF HEALTH & HUMAN SERVS., LOG NO. ACYF-CB-PI-10-11, PROGRAM INSTRUCTION 21 (2010) [hereinafter PROGRAM INSTRUCTIONS 10-11].

31. Child welfare agencies provide services through fundamentally different approaches, depending on whether they are supervised at the state or county level (also known as being county-administered or state-administered). See Rebecca Wells, *Managing Child Welfare Agencies: What Do We Know About What Works?*, 28 CHILD. & YOUTH SERVICES REV. 1181, 1186 (2006) (discussing different types of child welfare systems and characteristics that matter for administering services). In addition, child welfare systems may be administered either directly through state or county services, or through a contractor. *Id.* County administered states—California, Colorado, Minnesota, New York, North Carolina, North Dakota, Pennsylvania, Ohio, and Virginia—also have some of the largest populations of children in the system. Three other states—Maryland, Nevada, and Wisconsin—are considered to have a hybrid administration. CHILDREN’S BUREAU, U.S. DEP’T OF HEALTH & HUMAN SERVS., STATE VS. COUNTY ADMINISTRATION OF CHILD WELFARE SERVICES 1–2 (2012).

32. See *supra* notes 7–10 and accompanying text for a discussion of federal law mandating that child welfare agencies implement new state protocols for improving healthcare for children in foster care.



improving healthcare for children in foster care, though the actual process for getting healthcare to such children involves many additional players and is highly fragmented.

The involvement of both Medicaid and managed care organizations (“MCOs”) is essential to the effective oversight of psychotropic medication use by children in foster care.<sup>33</sup> Typically, children in foster care receive their health insurance through Medicaid.<sup>34</sup> As such, each state’s Medicaid agency plays an integral role in setting policies and overseeing the healthcare of children in foster care.<sup>35</sup> Although Medicaid is a federal program that entitles children covered by it to certain diagnostic and screening treatments<sup>36</sup> along with other care, many of the coverage details are left to the discretion of the individual states, such as the type of non-pharmacological therapeutic interventions reimbursed through Medicaid. In states that use private insurance companies, or “payers,” to provide Medicaid,<sup>37</sup> the Medicaid agency contracts with the private payers (typically MCOs).<sup>38</sup>

Children in the child welfare system often experience inconsistency in access and treatment from physical health and behavioral health

33. In some instances, children in foster care have their medical care paid for directly through the Medicaid agency in a system known as Fee For Service. *See, e.g.,* MELINDA DUTTON ET AL., MEDICAID MANAGED CARE FOR CHILDREN IN FOSTER CARE 11 (2013), *available at* <http://www.uhfnyc.org/assets/1072> (identifying Medicaid “fee for service” reimbursement as an option for foster care agencies in New York). However, as of 2010, thirty-five states had adopted Medicaid managed care programs for their foster care populations. KAMALA D. ALLEN ET AL., MEDICAID AND CHILDREN IN FOSTER CARE 3 (2013), *available at* <http://childwelfaresparc.files.wordpress.com/2013/03/medicaid-and-children-in-foster-care.pdf>. Managed care organizations (MCOs) are a type of health insurance organization. *Managed Care*, MEDLINEPLUS, <http://www.nlm.nih.gov/medlineplus/managedcare.html> (last visited Aug. 1, 2014). MCOs have contracts with healthcare providers and medical facilities to provide care for members at reduced costs and include health maintenance organizations (“HMOs”) and preferred provider organizations (“PPOs”). *Id.* For more information about MCOs, see Barry R. Furrow, *Managed Care Organizations and Patient Injury: Rethinking Liability*, 31 GA. L. REV. 419, 421–27 (1997).

34. KAMALA D. ALLEN & TAYLOR HENDRICKS, CTR. FOR HEALTH CARE STRATEGIES, MEDICAID AND CHILDREN IN FOSTER CARE 1 (2013).

35. *See* KAMALA D. ALLEN ET AL., CTR. FOR HEALTH CARE STRATEGIES, INC., IMPROVING OUTCOMES FOR CHILDREN IN CHILD WELFARE: A MEDICAID MANAGED CARE TOOLKIT 7 (2012).

36. This Medicaid screening and diagnosis federal entitlement benefit is known as “early and periodic screening, diagnostic, and treatment services” (“EPSDT”), and is mandated nationally. 42 U.S.C. §§ 1396a(a)(10)(A), 1396a(a)(43), 1396d(a)(4)(B), 1396d(r) (2011).

37. State MCO arrangements and other types of utilization controls are incredibly complex. However, about half of all states use MCOs to administer large portions of their Medicaid program. A 2012 Government Accountability Office (“GAO”) study found twelve states to be “MCO predominant” and sixteen states to be “above average” in their use of MCOs. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-12-872R, MEDICAID: STATES’ USE OF MANAGED CARE 5 fig.1 (2012).

38. *See id.* at 1 (“[W]hile states commonly contract with managed care organizations (MCO) to provide the full range of covered Medicaid services to certain enrollees, they also frequently rely on other arrangements, such as limited benefit plans, which provide a limited set of services, such as dental care or behavioral health services, or primary care case management (PCCM) programs . . . .”) (citations omitted).

providers for a number of reasons, including removal to foster care placement that is not near their home or doctor of origin, or due to multiple placement moves while in foster care.<sup>39</sup> Moreover, children placed in residential treatment centers, which represent ten percent of all children in foster care nationally,<sup>40</sup> may be required to see the healthcare providers that work for, or contract with, the agency with whom they have been placed. And although enrollment in Medicaid means access to the enforceable “early and periodic screening, diagnostic, and treatment services” entitlements,<sup>41</sup> it also means that the child may face a lack of coordinated care and provider consistency if they were not previously enrolled in Medicaid, or if they reunify with their non-Medicaid eligible family in the future.

Additionally, obtaining healthcare for children in foster care can mean navigating complex consent procedures in many states. Except for emergencies, a child too young to consent for her own medical care still needs consent from her parent or guardian.<sup>42</sup> When the state removes the child from her home, the responsibility of consenting for medical care may shift.<sup>43</sup> State laws dictate who may provide consent for children’s medical care when they are removed from their parents’ custody. Broadly speaking, these laws either dictate that biological parents maintain responsibility for consenting for a child’s medical care, or that the power to consent shifts to another entity or individual—typically, the state, foster care agency, or family court with jurisdiction.<sup>44</sup> In many states, this determination is not simple or straightforward. Consent is further complicated as children become adolescents,<sup>45</sup> although most states have a bright-line cutoff at which children are assumed old enough to consent to their own medical care.<sup>46</sup> Finally, although courts may

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39. See Ramesh Raghavan et al., *A Preliminary Analysis of the Receipt of Mental Health Services Consistent with National Standards Among Children in the Child Welfare System*, 100 AM. J. PUB. HEALTH 742, 745–47 (2010) (finding that less than ten percent of children in child welfare obtain mental healthcare consistent with national standards, and discussing the reasons for care inconsistent with national standards).

40. *Id.* at 747.

41. For more information about the EPSDT entitlement, see *supra* note 36 and accompanying text.

42. See, e.g., *Bellotti v. Baird*, 443 U.S. 622, 640 (1979) (noting that “immature minors often lack the ability to make fully informed choices that take account of both immediate and long-range consequences”); *Cardwell v. Bechtol*, 724 S.W.2d 739, 749 (Tenn. 1987) (discussing the “general rule” that parental consent is required for medical treatment of minors).

43. States clearly define what rights transfer from the child’s biological parents and legal guardians. See Camp, *supra* note 4, at 397–401.

44. See *id.* (summarizing several states’ consent procedures for children in child welfare and demonstrating how the person or entity responsible provides consent).

45. See generally Rhonda Gay Hartman, *Coming of Age: Devising Legislation for Adolescent Medical Decision-Making*, 28 AM. L.J. & MED. 409 (2002) (discussing the difficulties and challenges of adolescent consent policies).

46. See, e.g., N.Y. Pub. Health Law § 2504(1) (McKinney 2005) (permitting any person who is eighteen years of age or older to consent to routine medical treatment); COLO. REV. STAT. ANN. § 13-

recognize the right to decline medical care within the power to consent, the ability of children in foster care to refuse care is not well understood.<sup>47</sup>

## B. THE CHILDREN AND YOUTH IN FOSTER CARE

As of September 2012, there were about 400,000 children in the U.S. foster care system.<sup>48</sup> This is a low number in the modern era of child welfare, which is largely attributed to a concerted effort to increase rates of adoption, divert children from foster care by increasing in-home support, and utilize a more sophisticated response system to allegations of abuse and neglect.<sup>49</sup> The current population of children in foster care includes a large number of very young children and a large number of teenagers, particularly sixteen- and seventeen-year-olds.<sup>50</sup> These two groups of children tend to have different mental health needs and require access to other types of services than children outside of the foster care system.

It is well documented that children in foster care experience higher rates of trauma, increased mental health needs, and higher healthcare needs than children in the general population.<sup>51</sup> One recent study estimated that around seventy percent of children in foster care had experienced “complex trauma”—trauma deemed particularly harmful

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22-103(1) (2013) (permitting any person eighteen years of age or older, or any minor fifteen years of age or older—who has met specific statutory requirements—to consent to routine medical treatment); see Hartman, *supra* note 45, at 420–22 (discussing the different approaches states have taken to determine when minors are of sufficient age to provide their own consent to medical treatment).

47. Without clear policies around consent and informed consent, the child’s actual ability to consent or refuse consent is unclear and typically, undocumented. For additional information about the differences between required consent of adults and minors, see generally *Bellotti*, 443 U.S. 622.

48. CHILDREN’S BUREAU, U.S. DEP’T OF HEALTH & HUMAN SERVS., FOSTER CARE STATISTICS 2012 I (2013). Since the early 2000s, there has been a 23.7% decrease in the overall number of children in foster care, from 523,616 in 2002 to 399,546 in 2012. The decrease in the total number of children in foster care is also correlated with a shift in children who populate the system. ADMIN. FOR CHILDREN & FAMILIES, U.S. DEP’T OF HEALTH & HUMAN SERVS., RECENT DEMOGRAPHIC TRENDS IN FOSTER CARE I tbl.1 (2013). The most dramatic decrease was among African American children, with a decrease of 47.1% in foster care. *Id.* While a remarkable reduction over the course of ten years, about one-third of that change was driven by California’s reduction of children in foster care by nearly 40,000 children. *Id.* at 3 fig.2. Although there was a clear trend toward reducing the number of children in foster care during that time period, about one-fifth of states maintained nearly the same population and a separate one-fifth increased the number of children in foster care. *See id.*

49. *SEE* CHILDREN’S BUREAU, U.S. DEP’T OF HEALTH & HUMAN SERVS., THE AFCARS REPORT I (2013) (listing case plan goals, which include reunification, adoption, and guardianship). *See generally* CHILD WELFARE INFO. GATEWAY, U.S. DEP’T OF HEALTH & HUMAN SERVS., DIFFERENTIAL RESPONSE TO REPORTS OF CHILD ABUSE AND NEGLECT (2008) (discussing new types of “differential response systems” and how they have benefited the foster care system).

50. THE AFCARS REPORT, *supra* note 49, at 1 (noting that sixteen- and seventeen-year-olds account for fourteen percent of all children in foster care, ages one to twenty).

51. *See, e.g.,* JOHN A. LANDSVERK ET AL., MENTAL HEALTH CARE FOR CHILDREN AND ADOLESCENTS IN FOSTER CARE: REVIEW OF RESEARCH LITERATURE 13–19 (2006).

and perpetrated by a caregiver at a young age.<sup>52</sup> For some of those children with serious mental health diagnoses, psychotropic medications may be clinically indicated as an appropriate course of treatment. However, research shows that children with serious mental health diagnoses are not the main drivers of increasing prescriptions for antipsychotics.<sup>53</sup> On the contrary, the high rates of psychotropic medication prescription are often associated with a diagnosis of Attention Deficit Hyperactivity Disorder (“ADHD”).<sup>54</sup> For instance, one study found that ADHD without an accompanying serious second disorder (such as bipolar disorder, schizophrenia, or autism) was the reason that one-third of all youth on Medicaid receive antipsychotic medication.<sup>55</sup>

### C. PSYCHOTROPIC MEDICATIONS AND CHILDREN IN FOSTER CARE

Psychotropic medication rates for children in foster care have increased dramatically in recent years.<sup>56</sup> From 1997 to 2007, psychotropic medication prescription rates among all children in the United States increased six hundred percent.<sup>57</sup> While rates among children in Medicaid are higher than the general population,<sup>58</sup> rates among children in foster care are an additional three to five times greater.<sup>59</sup> In addition to being at risk for greater use of psychotropic medications generally, children in foster care also receive multiple psychotropic medications at higher rates.

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52. Johanna K.P. Greeson et al., *Complex Trauma and Mental Health in Children and Adolescents Placed in Foster Care: Findings from the National Child Traumatic Stress Network*, 90 CHILD WELFARE 91, 92–93 (2011).

53. According to one study that looked at rates of use of psychotropic medications among children receiving public health insurance, “[a]ntipsychotics have been used concomitantly for adults with schizophrenia, but the rare prevalence among youths is not an explanation for the observed patterns. The data reveal that youths receive antipsychotics concomitantly primarily for conduct disorders.” Susan dosReis et al., *Antipsychotic Treatment Among Youth in Foster Care*, 128 PEDIATRICS e1459, e1463–64 (2011) (describing how antipsychotics—a class of psychotropic medications—are used to treat less serious clinical diagnoses).

54. *Id.* at e1462 (describing how the driving diagnosis of psychotropic medications among children in foster care was ADHD, which accounted for 46.5% of diagnoses).

55. Stephen Crystal et al., *Broadened Use of Atypical Antipsychotics: Safety, Effectiveness, and Policy Challenges*, 28 HEALTH AFF. w770, w773 (2009).

56. See Angela Olivia Burton, “*They Use It Like Candy*”: *How the Prescription of Psychotropic Drugs to State-Involved Children Violates International Law*, 35 BROOK. J. INT’L L. 453, 476–77 (2010) (exploring the explosive growth of the use of psychotropic medications in recent decades).

57. See Camp, *supra* note 4, at 373 (“Between 1997 and 2007, the use of psychotropic medications by children in the general population increased sixfold.”).

58. See Crystal et al., *supra* note 55, at w774 exhibit 3 (describing how rates of atypical antipsychotics were about four times higher among Medicaid enrolled youth compared with privately insured youth).

59. The widely varying estimates reflect the varying types of research conducted to investigate rates of usage among children in foster care. For a summary of the existing literature, see generally U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-12-270T, FOSTER CHILDREN HHS GUIDANCE COULD HELP STATES IMPROVE OVERSIGHT OF PSYCHOTROPIC PRESCRIPTIONS (2011).

One study found that over twenty percent of children in foster care who were prescribed psychotropic medications were taking three or more psychotropic medications.<sup>60</sup>

Nearly all psychotropic medications prescribed to children are prescribed “off-label,” meaning that the drug is used in a way that has not been studied or approved by the federal agency responsible for oversight, the Food and Drug Administration (“FDA”).<sup>61</sup> However, prescribing off-label is widely accepted within the medical community.<sup>62</sup> Some off-label prescribing is perceived as necessary because the FDA “on-label” use is announced only once extensive trials and testing have concluded. Historically, testing of many medications on children was not permitted, meaning that an FDA-approved use for a pediatric population simply did not exist.<sup>63</sup> Within an outpatient pediatric setting, over sixty-two percent of prescription visits resulted in off-label prescriptions.<sup>64</sup> Among some specialists, rates were higher than ninety percent.<sup>65</sup>

Although off-label use of medication is widely accepted,<sup>66</sup> the side effects of medications on children are often poorly understood because they have historically not been widely studied. As a result, there are relatively few well-documented studies on the effects of psychotropic

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60. This number represents children being treated at community mental health centers, but does not include inpatient treatment rates, which were much higher. Daniel J. Safer et al., *Concomitant Psychotropic Medication for Youths*, 160 AM. J. PSYCHIATRY 438, 438, 442–43 (2003).

61. Michelle L. Mello, Note, *Psychotropic Medication and Foster Care Children: A Prescription for State Oversight*, 85 S. CALIF. L. REV. 395, 406–07 (2012) (citing *Blain v. Smithkline Beecham Corp.*, 240 F.R.D. 179, 182 (E.D. Pa. 2007)).

62. Off-label prescribing of psychotropic medications for children is widely documented. See, e.g., Julie Magno Zito et al., *Trends in the Prescribing of Psychotropic Medications to Preschoolers*, 283 J. AM. MED. ASS'N 1025, 1025–28 (2000) (describing widespread off-label use, particularly among young children); AM. ACAD. OF ADOLESCENT & CHILD PSYCHIATRY, A GUIDE FOR COMMUNITY CHILD SERVING AGENCIES ON PSYCHOTROPIC MEDICATIONS FOR CHILDREN AND ADOLESCENTS II (2012) (“Medication used in the treatment of youth with mental illnesses is often used ‘off-label,’ as is frequently the case in the medication treatment of pediatric physical illness. There are many medications approved for adults that are used off-label for youth. Off-label prescribing is very common . . .”).

63. *Drug Research and Children*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143565.htm> (last updated AUG. 24, 2011) (According to the FDA, “[m]ost drugs prescribed for children have not been tested in children. Before the Food and Drug Administration initiated a pediatric program, only about twenty percent of drugs approved by the FDA were labeled for pediatric use. By necessity, doctors have routinely given drugs to children ‘off label,’ which means the drug has not been approved for use in children based on the demonstration of safety and efficacy in adequate, well-controlled clinical trials.”). Despite being common practice, prescribing off-label remains problematic. One study noted that “[c]oncern about this age group relates to off-label (unlabeled) use, i.e., for treatment indications with little or no proven efficacy and lacking product package insert labeling information approved by the U.S. Food and Drug Administration.” Zito, *supra* note 62, at 1025.

64. Alicia T. F. Bazzano et al., *Off-Label Prescribing to Children in the United States Outpatient Setting*, 9 ACAD. PEDIATRICS 81, 83 (2009).

65. See *id.*

66. Camp, *supra* note 4, at 379.

medications on children. Over the last decade, this has changed as experts have begun to document the impact of increased use of psychotropic medications on children. Researchers have found increasing evidence of serious side effects of psychotropic medications on children.<sup>67</sup> Much of the research has focused on second-generation antipsychotics (“SGAs”), a commonly prescribed subset of psychotropic medications.<sup>68</sup> Many of the identified negative side effects of SGAs have been linked to metabolic disorders.<sup>69</sup> For example, one study found associations with significant weight gain for all antipsychotics studied and other serious metabolic changes in some of the antipsychotics studied.<sup>70</sup> Other research also concludes that SGAs increase the risk of obesity, Type 2 diabetes, cardiovascular conditions, and hypotension.<sup>71</sup> Those risks increase with exposure to multiple medications.<sup>72</sup> Thus, although largely unstudied, side effects of psychotropic medications for children appear serious, providing another reason to seek alternate treatment when possible.

Faced with the challenge of regulating psychotropic medications, the federal government and child welfare agencies have instituted a series of reforms, which are summarized in the next Part.

## II. FEDERAL REQUIREMENTS AND STATE ACTIONS RELATED TO PSYCHOTROPIC MEDICATION OVERSIGHT

Given the high stakes, both the federal government and, to a much lesser extent states, have begun to develop rules about how to monitor the use of psychotropic medications in the child welfare system. Although the federal government has drawn increasing attention to the need for effective monitoring systems, states seem reluctant to promulgate oversight policies.

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67. See, e.g., Burton, *supra* note 56, at 467 (discussing the side effects of psychotropic medication use in children, ranging from fairly minor ones, such as dry mouth and headaches, to more severe side effects, including thyroid dysfunction, growth retardation, heart failure, and death).

68. The existing literature focuses largely on antipsychotics, and specifically SGAs. One reason is that much of the increased use of psychotropic medications among youth in foster care is due to increased prescribing of SGAs, and SGAs also have greater risk of causing metabolic health problems in children. See dosReis et al., *supra* note 53, at e1460 (citing Christoph U. Correll, *Multiple Antipsychotic Use Associated With Metabolic and Cardiovascular Adverse Events in Children and Adolescents*, 12 EVID. BASED MENTAL HEALTH 93 (2009)).

69. *Id.*

70. Christoph U. Correll et al., *Cardiometabolic Risk of Second-Generation Antipsychotic Medications During First-Time Use in Children and Adolescents*, 302 J. AM. MED. ASS'N 1765, 1768–70 (2009).

71. Roger S. McIntyre & Jeanette M. Jerrell, *Metabolic and Cardiovascular Adverse Events Associated with Antipsychotic Treatment in Children and Adolescents*, 162 ARCHIVES OF PEDIATRIC ADOLESCENT MED. 929, 931–34 (2008).

72. *Id.*

### A. FEDERAL REQUIREMENTS

The FCA<sup>73</sup> was enacted to improve child welfare systems, including broadly strengthening healthcare services for children in foster care.<sup>74</sup> While the FCA did not explicitly address psychotropic medications, it did introduce provisions meant to improve health and mental health oversight, which was interpreted by the Children's Bureau in subsequent guidance to require states to report on psychotropic medication oversight policies.<sup>75</sup> The FCA directs states to develop "a plan for the ongoing oversight and coordination of health care services for any child in a foster care placement, which shall ensure a coordinated strategy to identify and respond to the health care needs of children in foster care placements, including mental health and dental health needs."<sup>76</sup>

The statute goes on to describe the specific information that must be included in a state's plan for oversight and coordination of healthcare services.<sup>77</sup> In their reports to the federal government, states must provide information on "initial and follow-up health screenings" for children in foster care, describe "how health needs identified through screenings will be monitored and treated," report on the sharing of medical information for children in foster care, outline "steps to ensure continuity of health care services," detail the state's approach to "the oversight of prescription medicines," and report on "how the State actively consults with and involves physicians or other appropriate medical or non-medical professionals in assessing the health and well being of children in foster care and in determining appropriate medical treatment for the children."<sup>78</sup> Additionally, state child welfare agencies must indicate "how health care experts were selected and how they and the Medicaid agency

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73. Fostering Connections to Success and Increasing Adoptions Act of 2008 ("FCA"), Pub. L. No. 110-351, § 205, 122 Stat. 3949, 3961 (codified as amended in scattered sections of 42 U.S.C.).

74. Widely lauded by child advocacy groups, the legislation was designed to "improve critical education and health care services for children in foster care and better prepare older youth for adulthood by extending federal support for transition programs to age twenty-one." CASEY FAMILY PROGRAMS, FOSTERING CONNECTIONS TO SUCCESS AND INCREASING ADOPTIONS ACT I (2009).

75. See *infra* notes 80–90 and accompanying text for a discussion of subsequent agency guidance.

76. FCA, § 205.

77. Subsequent guidance integrated the health oversight and coordination reporting into broader requirements that states must submit to the federal government. Every five years, states are required to submit a "five-year strategic plan that sets forth the vision and the goals to strengthen the States' overall child welfare system" called a Child and Family Services Plan ("CFSP"). CHILDREN'S BUREAU, U.S. DEP'T OF HEALTH & HUMAN SERVS., LOG NO. ACYF-CB-PI-10-09, PROGRAM INSTRUCTION 2 (2010). The Annual Progress and Service Reports ("APSRs") are annual updates that states create to document their progress toward reaching the goals laid out in their CFSPs. *Id.* at 2–3. States were directed by guidance issued in 2010 to include an update on the progress toward the oversight and coordination requirements in the FCA for children in foster care. *Id.* States that indicated legislation was necessary to carry out the requirements of the FCA were required to provide the federal government with an update on legislative progress. *Id.* at 8–9.

78. FCA, § 205.

were involved in developing the health care oversight and coordination plan.”<sup>79</sup>

The Children’s Bureau’s (“CB”)<sup>80</sup> 2008 Program Instruction (“PI”)<sup>81</sup> to states instructing them on how to implement the newly enacted FCA indicated that the requirement for the state’s healthcare oversight and coordination plan was effective immediately.<sup>82</sup> Subsequent PIs issued by the CB emphasized the agency’s concern about psychotropic medication oversight. In 2009, for example, the agency noted that “CB encourages States to pay particular attention to oversight of the use of psychotropic medications in treating the mental health care needs of children” in their plans for responding to children’s mental health needs and prescription medication oversight.<sup>83</sup> Following the enactment of the Patient Protection and Affordable Care Act (“ACA”),<sup>84</sup> the CB issued another PI for implementing the FCA, reiterating the need for “particular attention” to the oversight of psychotropic medications.<sup>85</sup>

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79. PROGRAM INSTRUCTIONS 10–11, *supra* note 30, at 21.

80. The CB is an agency within the U.S. Department of Health and Human Services responsible for improving the health of children and families. *What We Do*, CHILDREN’S BUREAU, U.S. DEP’T OF HEALTH & HUMAN SERVS., <http://www.acf.hhs.gov/programs/cb/about/what-we-do> (last visited Aug. 1, 2014). The statutory duties of the CB are to “investigate and report to the Secretary of Health and Human Services, upon all matters pertaining to the welfare of children and child life among all classes of our people, and [to] especially investigate the questions of infant mortality, the birth rate, orphanage, juvenile courts, desertion, dangerous occupations, accidents and diseases of children, employment, [and] legislation affecting children in the several States and Territories.” 42 U.S.C. § 192 (2011).

81. The majority of the regulatory or policy guidance related to the FCA is described as Program Instruction (“PI”) by the CB. According to the CB’s website, PIs “explain procedures and methods for operationalizing program policies, add details to program regulations or policy guide requirements, and convey to grantees program guidance information on actions they are expected or required to take.” *Program Instructions (PI)*, ADMIN. FOR CHILDREN & FAMILIES, U.S. DEP’T OF HEALTH & HUMAN SERVS., <http://www.acf.hhs.gov/programs/cb/laws-policies/program-instructions> (last visited Aug. 1, 2014).

82. CHILDREN’S BUREAU, U.S. DEP’T OF HEALTH & HUMAN SERVS., LOG NO. ACYF-CB-PI-08-05, PROGRAM INSTRUCTION 8–9 (2008). Although not discussed in this paper, similar requirements were placed upon federally recognized Indian tribes to implement oversight processes for children in their child welfare systems. *Id.* at 6–7. Further, the CB also identified the issue of psychotropic medications as a key concern and noted in a 2009 guidance that “CB encourages Tribes to pay particular attention to the oversight of the use of psychotropic medicines.” CHILDREN’S BUREAU, U.S. DEP’T OF HEALTH & HUMAN SERVS., LOG NO. ACYF-CB-PI-09-07, PROGRAM INSTRUCTION 10 (2009). Most relevant to the monitoring of psychotropic medications, in 2012, a notice was published in the Federal Register announcing a federal grant to “announce the award of a single-source program expansion supplement grant to the Tribal Law and Policy Institute in West Hollywood, CA, to support technical assistance to Tribes in the development of oversight plans for prescription medicines for children in Tribal foster care systems.” Announcement of the Award of a Single-Source Program Expansion Supplement Grant to the Tribal Law and Policy Institute in West Hollywood, CA, 77 Fed. Reg. 65,196 (Oct. 25, 2012).

83. CHILDREN’S BUREAU, U.S. DEP’T OF HEALTH & HUMAN SERVS., LOG NO. ACYF-CB-PI-09-06, PROGRAM INSTRUCTION 10-11 (2009).

84. See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended in scattered sections of 25, 26, and 42 U.S.C.).

85. PROGRAM INSTRUCTIONS 10-11, *supra* note 30, at 21.



Over a short time period, the CB's guidance to states on psychotropic medications evolved from a general charge to improve prescription drug oversight to an explicit requirement that states develop more robust psychotropic medication policies. In 2011, the provisions introduced by the FCA were amended by the CFSIIA.<sup>86</sup> The CFSIIA introduced a number of updates to the FCA and included language directly discussing psychotropic medications: under the CFSIIA, states are now required to include "protocols for the appropriate use and monitoring of psychotropic medications" in their Annual Progress and Service Reports ("ASPRS").<sup>87</sup>

In 2012, the CB issued some of its most direct language on state obligations to report on psychotropic medications, noting in a guidance document:

The [CFSIIA] also requires States to submit as part of the health care oversight plans a description of the protocols in place or planned to oversee and monitor the use of psychotropic medications among children in foster care . . . . As States develop their plans for prescription psychotropic medication management, there is also work to be done to identify effective psychosocial interventions that can improve behavioral and mental health outcomes of children receiving child welfare services.<sup>88</sup>

Around the same time, the CB also issued an Information Memorandum solely addressing the issue of psychotropic medications, and presenting a comprehensive summary of research on psychotropic medications.<sup>89</sup> Later that same year, the CB and other federal agencies co-hosted a multi-day convention of child welfare experts, researchers, practitioners, state leaders in child welfare agencies, state Medicaid agencies, and state mental health agencies, with the purpose of "[c]reating and

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86. *See generally* Child and Family Services Improvement and Innovation Act, Pub. L. No. 112-34, 125 Stat. 369 (2011) (codified as amended in scattered sections of 42 U.S.C.).

87. *Id.* § 101(b)(2) (codified at 42 U.S.C. § 422(b)(15)(A)(v)). This section was implemented to the states through an Information Memo ("IM"). *See generally* CHILDREN'S BUREAU, U.S. DEP'T OF HEALTH & HUMAN SERVS., LOG NO. ACYF-CB-IM-11-06, INFORMATION MEMORANDUM (2011) (summarizing many of the provisions in the CFSIIA). IMs "are the Children's Bureau's primary means for communicating with grantees or potential grantees on a variety of matters, such as program activities and priorities, progress reports, research findings, available funds, related regulations, and proposed and pending federal legislation affecting human services programs." *Policy/Program Issuances*, ADMIN. FOR CHILDREN & FAMILIES, U.S. DEP'T OF HEALTH & HUMAN SERVS., <http://www.acf.hhs.gov/programs/cb/laws-policies/policy-program-issuances> (last visited Aug. 1, 2014). In contrast, the other type of guidance that the CB commonly issues related to psychotropic medications are "Program Instructions," described as issuances to "clarify and explain procedures and methods for operationalizing program policies, add details to program regulations or policy guide requirements, and convey to grantees program guidance information on actions they are expected or required to take." *Id.*

88. CHILDREN'S BUREAU, U.S. DEP'T OF HEALTH & HUMAN SERVS., LOG NO. ACYF-CB-IM-12-04, INFORMATION MEMORANDUM 7 (2012).

89. *See generally* INFORMATION MEMORANDUM 12-03, *supra* note 8 (discussing issues surrounding psychotropic medication use by children in foster care).

implementing integrated oversight and monitoring protocols that ensure the appropriate use of psychotropic medications for children in foster care, [which] require[s] thoughtful collaboration across complex systems.”<sup>90</sup>

In addition to these requirements, several federal class action lawsuits against state child welfare agencies resulted in settlements that required improved state oversight.<sup>91</sup> These lawsuits alleged agency-wide failures to oversee adequate physical and mental healthcare needs of children in foster care, including psychotropic medication monitoring. In 2000, for example, Tennessee officials were sued over allegations of “systemic failure . . . to fulfill their legal obligations” to children in foster care, including mental and physical healthcare obligations.<sup>92</sup> The settlement agreement in the Tennessee suit included explicit requirements related to the state’s oversight of psychotropic medications, including that the agency, “[w]ithin six months . . . shall undertake a review of the policies and procedures surrounding the use of psychotropic medications,” and that regional health nurses submit logs of psychotropic medication approvals to the agency’s Medical Director.<sup>93</sup>

#### B. STATES’ (IN-)ACTION

Although the federal government and private litigants have sought to improve oversight of the use of psychotropic medications, state action in this area has been mixed at best. Given that several academic reports found that as of 2010 the majority of states had or were developing policies to implement federal psychotropic medication mandates,<sup>94</sup> we were interested in a more in-depth review of state requirements. To do this, we reviewed the statutes, rules, and statements of policies from

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90. The two-day conference connected state leaders with experts to jump-start improved oversight of psychotropic medications. *Because Minds Matter: Collaborating to Strengthen Management of Psychotropic Medications for Children and Youth in Foster Care*, CHILD WELFARE INFO. GATEWAY, <https://www.childwelfare.gov/systemwide/mentalhealth/effectiveness/mindsmatter.pdf> (last visited Aug. 1, 2014).

91. Some states introduced legislation and regulations to implement provisions of the FCA and CFSIIA. California was one of the only states to introduce legislation requiring a plan to improve oversight and coordination of healthcare for children in foster care. CAL WELF. & INST. CODE § 16010.2 (West 2010) (“The [State Department of Social Services], in consultation with pediatricians, other health care experts . . . and experts in and recipients of child welfare services, including parents, shall develop a plan for the ongoing oversight and coordination of health care services for a child in a foster care placement . . . consistent with . . . [the FCA].”).

92. Brian A. *ex rel.* Brooks v. Sundquist, 149 F. Supp. 2d 941, 944 (M.D. Tenn. 2000).

93. Modified Settlement Agreement at 17–18, Brian A. *ex rel.* Brooks v. Sundquist, 149 F. Supp. 2d 941 (M.D. Tenn. 2000) (No. 3:00-CV-00445).

94. *See, e.g.*, LESLIE ET AL. *supra* note 11, at 4.

sixteen states, representing almost seventy percent of the children in foster care in the United States.<sup>95</sup>

This review revealed two surprising discoveries: First, we could not locate many of the policies reported in other studies, meaning that the policies were neither broadly available nor the product of the formal rulemaking process in which the final policy would be published. Second, to the extent that policies did exist, they were extremely underdeveloped and failed to include many of the “red flag” criteria that both experts and states identified as essential to protecting children, such as the use of psychotropic medications for young children, dosage level, and whether multiple psychotropic medications were prescribed simultaneously.<sup>96</sup> Our detailed findings are available in Appendix A.

We review the highlights of our findings here. Only Illinois and Texas had policies that incorporated all three red flag criteria<sup>97</sup> in addition to a child welfare prior authorization policy.<sup>98</sup> One state, Michigan, addressed

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95. To conduct this research, we reviewed laws, rules and policies available through two sources: (1) LexisNexis’s legal database of state legal information and (2) state agency, legislative, and regulatory websites. State websites do not generally include archived materials, and we were thus confined to the materials available at the time of our searches. For each state, we searched laws and rules using LexisNexis which generally included materials from the 1990s through mid-2011. We initiated our search using keywords and phrases to search the state’s statutes and code of regulations. We recorded the number of non-unique hits in LexisNexis, conducting a preliminary assessment of the relevance of our findings. For instance, in some states, adult residential treatment is also termed “foster care.” We tried to eliminate those types of erroneous results when recording numbers of hits. The number of relevant, but non-unique hits varied for each term, from zero in some states to over two dozen in other states. We sorted the laws, rules, and policies into a priori categories, capturing the varying types of monitoring policies that could be implemented.

96. See LESLIE ET AL., *supra* note 11, at 7 tbl.1. Other efforts have also reported the status of policies in states related to psychotropic medications and children on Medicaid and/or in the child welfare system. See, e.g., Mackie et al., *supra* note 11, at 2215, 2216–18. In 2010, Medicaid and Mental Health State Agency Directors published a sixteen-state survey of antipsychotic medication use in Medicaid children and adolescents. See *generally* MEDICAID MED. DIRS. LEARNING NETWORK, *supra* note 12. And in 2011, a report by the GAO examined psychotropic policies for children in six states. See *generally* U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-12-201, FOSTER CHILDREN: HHS GUIDANCE COULD HELP STATES IMPROVE OVERSIGHT OF PSYCHOTROPIC PRESCRIPTIONS (2011) (finding that each of the six states had adopted at least one policy, though there was variability across the states). In order to identify the state policies, the GAO interviewed officials from the Center for Medicare and Medicaid Services, the Administration for Children and Families, state Medicaid agencies, and state foster care agencies. *Id.* at 4. Additionally, the GAO reviewed relevant state policies and regulations. *Id.*

97. In addition to prior authorization, we identify red flags as policies related to psychotropic medications for young children, dosage limitations, and restrictions around polypharmacy. See LESLIE ET AL., *supra* note 11, at 7 tbl.1; see also *supra* notes 11–17 and accompanying text for a more extensive discussion of these categories.

98. Illinois’ prior authorization regulation was found in the administrative code. ILL. ADMIN. CODE tit. 89, § 325.60 (2012). Other regulations are similarly codified. The prior authorization policy is identified at ILL. ADMIN. CODE tit. 89, § 325.40 (2012). Additional parameters around prescribing are located at ILL. ADMIN. CODE tit. 89, § 325 app. A (2012) (“Guidelines for the Utilization of Psychotropic Medications for Children in Foster Care”). Texas’ prior authorization regulation was found in the administrative code at 40 TEX. ADMIN. CODE § 748.2001 (2007). Texas’s policies are described in a policy document. See

all three red flag criteria.<sup>99</sup> New York and Tennessee address two of the red flags.<sup>100</sup> Tennessee's policies are likely the result of the lawsuit described above. The remaining three states with policies—Arizona, Florida, and Massachusetts—address either one of the red flag criterion or had a prior authorization policy.<sup>101</sup> Interestingly, most of the policies we identified were informally promulgated, meaning that there was no notice and comment period and the statements did not have the force of law. None of the policies related to dosage levels or age of the child were formally promulgated through a notice and comment rulemaking

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*generally* TEX. DEP'T OF FAMILY & PROTECTIVE SERVS. & UNIV. OF TEX. AT AUSTIN COLL. OF PHARMACY, PSYCHOTROPIC MEDICATION UTILIZATION PARAMETERS FOR FOSTER CHILDREN (2010).

99. Michigan's policies are evident in a form that lists out criteria triggering further review. That form is no longer publicly available. MICH. DEP'T OF HUMAN SERVS., FOSTER CARE PSYCHOTROPIC MEDICATION REPORTING FORM, DHS 0674 (on file with authors).

100. New York's policies on the child's age and polypharmacy can be found in an agency bulletin. *See* N.Y. STATE OFFICE OF CHILDREN & FAMILY SERVS., No. 08-OCFS-INF-02, INFORMATIONAL LETTER (2008), available at <http://onlinerresources.wnyc.net/pb/docs/08-ocfs-inf-02.pdf> (“[T]his Informational letter . . . provide[s] guidance on the safe and appropriate use of psychiatric medications for children and youth in the custody of [Office of Children and Family Services], local social services district commissioners or voluntary agencies who have been placed in an out-of-home setting.”). Tennessee's dosage policy states:

Medication dosages should be kept within FDA guidelines (when available). The clinical wisdom, “start low and go slow” is particularly relevant when treating children in order to minimize side effects and to observe for therapeutic effects. Any deviations from FDA guidelines should be supported by an explanation from the prescribing clinician and may warrant review by a [Department of Children's Services (“DCS”)] consultant. Unconventional treatments should be avoided. Medications that have more data regarding safety and efficacy are preferred over newly FDA-approved medications.

STATE OF TENN. DEP'T OF CHILDREN'S SERVS., PROVIDER POLICY MANUAL 2006–2007, at 94 (2007). Tennessee also addressed polypharmacy through policy: “A child on more than three psychotropic medications should be supported by an explanation from the prescribing clinician and may warrant review by a DCS consultant.” *Id.* “Anecdotally the prescribing of multiple psychotropic medications (combined treatment or polypharmacy) in the pediatric population seems on the increase. Little data exist to support advantageous efficacy for drug combinations, used primarily to treat co-morbid conditions. The current clinical best practice supports judicious use of combined medications, keeping such use to clearly justifiable circumstances.” *Id.*

101. In 2010, the Arizona Department of Health Services issued a guidance document requiring documentation for the prescription of multiple psychotropic medications, specifically describing the rationale and justification for the combined use. CENPATICO BEHAVIORAL HEALTH OF ARIZ., PROVIDER MANUAL: PSYCHOTROPIC MEDICATION: PRESCRIBING AND MONITORING 3.15.7-E (2010). Also in 2010, the Florida Department of Children and Families adopted a policy where a child psychiatrist must be retained before a prescribing practitioner may give two or more psychotropic medications to any child under the age of eleven in the custody of the Department and in out-of-home care. BREVARD FAMILY P'SHIP, POLICY & PROCEDURE MANUAL: PRE-CONSENT REVIEW FOR PSYCHOTROPIC MEDICATION TREATMENT PLANS FOR CHILDREN UNDER ELEVEN YEARS OF AGE IN OUT-OF-HOME CARE WHO ARE PRESCRIBED TWO OR MORE PSYCHOTROPIC MEDICATIONS 3 (2012). In 2008, Massachusetts adopted a regulation requiring placement agencies to seek judicial approval prior to administering antipsychotic medication to youths. 102 MASS. CODE REGS. 5.08(5) (2008).

procedure.<sup>102</sup> Nor were any of the seven policies related to polypharmacy formally codified.<sup>103</sup> Interestingly, the six states that had prior authorization policies promulgated the policies pursuant to formal rulemaking.<sup>104</sup>

What was most significant about what we found was not that states had no policies at all. Rather, it was that, with the exception of prior authorization policies, the majority failed to reflect rule of law values that should be built into the monitoring of something as important as the use of psychotropic medications for children in state foster care custody. The next Part of this Article explains rule of law values and describes how they can be applied to produce greater transparency in the development of policies on monitoring the use of psychotropic medications in the child welfare system.

### III. TRANSPARENCY AND AGENCY POLICYMAKING

Under most state rulemaking processes, administrative agencies, including child welfare agencies, are permitted to use different types of rules, policies, and guidance to interpret and enforce state laws.<sup>105</sup> The most formal approach is through legislative rulemaking, which is similar to legislation created by the legislative branches. Legislative rules are legally binding, subject to public notice and comment, and may result in criminal or civil penalties if violated.<sup>106</sup> Alternatively, interpretive rules interpret an agency's position or understanding of an existing statute or regulation and are not intended to be legally binding, which is why many

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102. States with policies around psychotropic medications for young children were: Illinois, Michigan, New York, and Texas. States with dosage policies were Illinois, Michigan, Tennessee, and Texas. See *infra* Appendix A for citations to these policies.

103. Polypharmacy is generally understood to be the use of multiple medications. However, exact definitions vary. For the purposes of this study, we used a broad definition simply meaning any policy a state enacted that addressed some type of use of multiple medications. The states in which we identified a policy related to polypharmacy were Arizona, Florida, Illinois, Michigan, New York, Tennessee, and Texas. See *infra* Appendix A.

104. The states in which we identified a rule related to prior authorization were: Arizona, California, Florida, Illinois, Massachusetts, and Texas. See ARIZ. ADMIN. CODE § 21-206.01 (2003); CAL. CODE REGS. tit. 22, § 89475 (2010); FLA. ADMIN. CODE ANN. r. 65C-35.010 (2010); ILL. ADMIN. CODE tit. 89, § 325.60 (2012); 102 MASS. CODE REGS. 5.08(5) (2008); 40 TEX. ADMIN. CODE § 748.2001 (2007).

105. See generally Todd D. Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 ADMIN. L. REV. 159 (2000) (providing a broad overview of the different ways administrative agencies issue regulations and decisions); see also Levin, *supra* note 18, at 858–84 (discussing administrative rules and guidance documents under the 2010 MSAPA); Michael Asimow, *Guidance Documents in the States: Toward a Safe Harbor*, 54 ADMIN. L. REV. 631, 632–33 (2002) (discussing the differences in adoption procedures for guidance documents and formal administrative rules).

106. See Peter L. Strauss, *The Place of Agencies in Government: Separation of Powers and the Fourth Branch*, 84 COLUM. L. REV. 573, 576 (1984) (“Validly adopted legislative rules are identical to statutes in their impact on all relevant legal actors—those subject to their constraints . . . and judges or others who may have occasion to consider them in the course of their activities.”).

states do not require notice and comment for this type of rule.<sup>107</sup> Finally, agencies may issue guidance documents in the form of interpretive rules or policy statements that, in most states, are not subject to notice and comment and are not intended to be legally binding.

One key feature of formal policymaking is transparency.<sup>108</sup> Transparency requires government institutions to be accountable, visible, and accessible to the public.<sup>109</sup> One of the most fundamental ways to promote external observation and make agencies more accountable to the public is through public disclosures.<sup>110</sup> “[R]egulations should be written to maximize consumers’ ability to understand their most important features . . . and to evaluate the relative advantages and disadvantages of the system vis à vis competitive systems.”<sup>111</sup> This need is “more true where consumers need to evaluate the range of risks” associated with a given regulation.<sup>112</sup> The range of risks from excessive use of psychotropics is extensive.<sup>113</sup> The large array of stakeholders involved in the child welfare system magnifies the need for transparency.

When the rulemaking process proceeds without transparency, the public’s ability to participate is dramatically undercut.<sup>114</sup> Lacking an understanding of the basic rationale behind a regulation, the public cannot be expected to scrutinize or understand the rule in a meaningful way.<sup>115</sup> This has a number of disadvantages. “Lack of transparency can be costly both politically and economically. It is politically debilitating because it dilutes the ability of the democratic system to judge and correct government policy by cloaking the activities of special interests and because it creates [disparities] by giving those with information something to trade.”<sup>116</sup>

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107. Administrative Procedure Act, 5 U.S.C. §§ 551–559 (2006).

108. See Thomas O. Sargentich, *The Reform of the American Administrative Process: The Contemporary Debate*, 1984 WIS. L. REV. 385, 406 (1984). (“[A]gencies [must] take a hard look at the underpinnings of their decision and provide a sufficient explanation of the reasons for their ultimate choice . . .”).

109. Mark Fenster, *Seeing the State: Transparency As Metaphor*, 62 ADMIN. L. REV. 617, 619–20 (2010).

110. See *Doe v. Reed*, 130 S. Ct. 2811, 2820 (2010) (discussing how important public disclosures are to creating governmental transparency, particularly in the case of elections).

111. See Hughes, *supra* note 23, at 832 (discussing benefits of transparency in relation to consumer cyberpayment options).

112. See *id.*

113. See *supra* notes 67–72 and accompanying text for a discussion of the side effects and other risks of psychotropic medication use in children.

114. John D. Graham, *Saving Lives Through Administrative Law and Economics*, 157 U. PA. L. REV. 395, 442 (2008).

115. *Id.*

116. John M. Ackerman & Irma E. Sandoval-Ballesteros, *The Global Explosion of Freedom of Information Laws*, 58 ADMIN. L. REV. 85, 93 (2006) (citing Daniel Kaufmann & Tara Vishwanath, *Toward Transparency: New Approaches and Their Application to Financial Markets*, 16 WORLD BANK RES. OBSERVER 41, 44 (2001)).

Within the context of formal policymaking, transparency typically involves a public notice and comment period, during which experts and the public at large can give feedback to the relevant agency on a proposed course of action.<sup>117</sup> While agencies typically have no obligation to follow any particular course of commentary, such commentary can lead to better policy outcomes.<sup>118</sup> Formal, publicly available rules can ensure consistency in approaches to treatment that can result in long-term efficiencies for practitioners and perhaps better outcomes for children subject to those rules. This will, of course, depend on the quality of the rule in the first place. Because problematic formal rules can be more effectively challenged in judicial proceedings *ex post* their fate and durability will also generally be a matter of public record. Public discourse surrounding the litigation of a disputed rule can, itself, heighten awareness of the underlying problem, making improved rulemaking more plausible.<sup>119</sup>

Some scholars argue that agencies need flexibility in their day-to-day management responsibilities and that the formal policymaking process is neither efficient nor realistic given the scope of issues that require agency policymaking.<sup>120</sup> To be sure, formal policymaking can add months or years to the articulation of agency policy. Informal policymaking also offers flexibility generally unavailable in formal policymaking, allowing agencies to function more smoothly.

Scholars have wrestled with the tension between the costs and benefits of informal agency policymaking.<sup>121</sup> Some of the debate focuses on whether judicial review of agency policies—whether they have been promulgated formally or informally—should be *ex ante* or *ex post*. More recently, scholars have tried to change the discussion from how courts decide whether a policy is formal or informal to requiring agencies to justify their choice of policy mechanism up front. For example, M. Elizabeth Magill has proposed that agencies should be required to justify their choice and the factors they considered in coming to their decision.<sup>122</sup> Nina A. Mendelson has proposed instead that Congress amend the federal APA to allow stakeholders to petition agencies to amend or repeal informal policies.<sup>123</sup> Mark Seidenfeld, by contrast,

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117. Rakoff, *supra* note 105, at 163–64.

118. See Fenster, *supra* note 109, at 619–20 (noting that in order for government institutions to be held accountable and perform well, the institution must be visible to external observation; in other words, it must be transparent).

119. See M. Elizabeth Magill, *Agency Choice of Policymaking Form*, 71 U. CHI. L. REV. 1383, 1391 (2004) (noting that most formal administrative adjudication involves a “trial-like hearing”).

120. See Strauss, *supra* note 106, at 595, 666.

121. See Seidenfeld, *supra* note 23, at 364–66.

122. *Id.*

123. Nina A. Mendelson, *Regulatory Beneficiaries and Informal Agency Policymaking*, 92 CORNELL L. REV. 397, 438 (2007).

contends that the proposals suggested by Magill and Mendelson would “bog down the issuance of guidance documents.” He instead advocates for “reasoned decisionmaking” through which agencies justify their policy in light of their consequences, which he argues would urge agencies to consider outflows from their policymaking more clearly.<sup>124</sup>

Finally, it is worth noting that states face distinct challenges in administrative rulemaking as compared to those faced by the federal government. First, most states tend to have less rigorous standards for formal policymaking. Within federal agencies, for example, a rule may be found invalid if it is determined to be “arbitrary and capricious” and not rationally related to the content of the legislation it is meant to interpret.<sup>125</sup> For states, the standard of judicial review often varies from the federal standard in terms of both the deference given agencies and the analysis of reviewable rules.<sup>126</sup> Similarly, while federal policymaking standards have been broadly litigated and spawned much analysis, many states have not had a comparable level of judicial review and public wrestling with state standards. Second, and perhaps more importantly, states have far more limited resources at their disposal for policymaking than federal agencies.<sup>127</sup> This may be more acute for state human services agencies like child welfare, which is historically underfunded and lacks significant investment in human capital.

#### IV. STATE POLICYMAKING ON PSYCHOTROPIC MEDICATIONS FOR CHILDREN IN FOSTER CARE

The issue of high rates of psychotropic medication use by children in foster care has been festering for years. The federal government, as well as media and professional associations, recently began to bring attention to the need for improved monitoring of psychotropic medications.<sup>128</sup> Yet,

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<sup>124</sup> Seidenfeld, *supra* note 23, at 367, 373–75.

<sup>125</sup> See, e.g., *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 39–40 (1983).

<sup>126</sup> See, e.g., Bernard W. Bell, *The Model APA and the Scope of Judicial Review: Importing Chevron into State Administrative Law*, 20 WIDENER L.J. 801, 804–05 (2011) (discussing Oregon’s judicial review standards and grouping of statutory terms into three categories: “terms of precise meaning,” “inexact terms,” and “terms of delegation”); see also Arthur Earl Bonfield, *The Federal APA and State Administrative Law*, 72 VA. L. REV. 297, 336 (1986) (“Differences between the details of state administrative law and the federal APA on other subjects—such as adjudication and judicial review—are as numerous and significant as those just noted in the rulemaking context.”).

<sup>127</sup> See Jeffrey M. Hirsch, *Taking States Out of the Workplace*, YALE L.J. F. (Apr. 3, 2008), <http://www.yalelawjournal.org/forum/taking-states-out-of-the-workplace> (“Most state policymakers lack the time, resources, and expertise of their federal counterparts.”).

<sup>128</sup> See *supra* notes 6, 37, 59 for the GAO reports relevant to oversight of psychotropic medications and foster care. The media has also covered the use of psychotropic medication in children in foster care. See, e.g., Ana M. Valdes, *Psychotropic Drug Use Higher for Foster Kids; a Five-State Study that Includes Florida Shows a Wide Disparity*, PALM BEACH POST, Dec. 2, 2011, at A1; *Doctors Put Foster Children at Risk with Mind-Altering Drugs* (ABC television broadcast Dec. 1,



states have been slow to implement policies or document significant decreases in prescribing rates. There could be many reasons for this slow movement toward change, including the lack of alternative non-pharmacological therapeutic interventions, the disconnect between child welfare systems and the healthcare providers who serve children in foster care, and the lack of internal health experts in child welfare systems.<sup>129</sup>

Based on our review, the majority of policies implemented by states regarding oversight of psychotropic medications for children in foster care have been issued informally, which means they have been subject to little, if any, public discourse or scrutiny, and are non-binding, which means that recourse for non-compliance is more limited.<sup>130</sup> Our review of psychotropic medication policies for children in foster care revealed another weakness of using informal policy: the inability to verify agency guidance documents, since most states we reviewed do not make their documents available through their websites or other public databases. Thus, a possible explanation for the differences in reported results in our study compared to earlier studies could be that the key informants interviewed had access to policies that were not publicly available, or at least easily publicly accessible. This also reveals an inherent weakness in studies that rely on key informant interviews as a core source of data related to policy: the informants' statements are not always verifiable through public searches of published policy statements, meaning the public may not be able to access the policies, or they may be largely unknown outside of certain segments of a specific agency. This is an important contrast to formal policies, which are codified in statutes or regulations that are publicly accessible.

We do not mean to suggest that the findings from our review should be read as contradicting earlier studies. Those studies capture an important policy reality at the state agency executive level that could, in fact, be closer to the norm. But, in the absence of a formal promulgation process, it is difficult to know whether stakeholders other than those at the state agency had a chance to comment on, or are even aware of, the policy. More importantly, it is difficult to understand what recourse, if any, is available if the policy is not followed.

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2011), available at <http://abcnews.go.com/Health/doctors-put-foster-children-risk-mind-altering-drugs/story?id=15064560>; *Foster Kids Prescribed Psychotropic Drugs* (ABC television broadcast Dec. 2, 2011), available at <http://abcnews.go.com/2020/video/foster-kids-prescribed-psychotropic-drugs-heavy-duty-drug-treatments-neglect-2020-15077792>.

129. See Camp, *supra* note 4, at 373–75, 382–88, 397–401 (describing both the disconnect between mental health and healthcare in foster care, as well as the reimbursement incentives for continued medication use).

130. See *supra* notes 18–21 and accompanying text for information about informal policy making; see also Appendix B, *infra*, for various state definitions of informal policy making and whether those states require a notice and comment period for informally adopted policies and rules.

Transparency is not, however, without its costs.<sup>131</sup> In the context of child welfare, there is a presumption that sensitive information about or pertaining to minors should remain confidential.<sup>132</sup> Also, matters involving the healthcare of children must include zones of discretion, whereby qualified professionals may exercise judgment about appropriate courses of action unburdened by concerns of being second-guessed by bureaucracies unfamiliar with or indifferent to the particulars of the case at hand. Nevertheless, we concur with the scholars who advocate more responsibility on the part of agencies to make their reasoning with regard to policymaking transparent. The vast disparity in prescription rates between children in and out of foster care custody remains cause for concern. Some type of “reasoned decisionmaking” should be required with regard to psychotropic medications so that agencies are intentional and up front about their use of informal versus formal policy.

In furtherance of the 2008 FCA and the 2011 CFSIIA, the CB decided in 2012 that it would require states to issue “protocols for the appropriate use and monitoring of psychotropic medications.”<sup>133</sup> These protocols would, among other things, govern assessment, individual medication decisionmaking (such as consent), communication between stakeholders, and sharing information related to psychotropic prescriptions among clinicians, child welfare staff, and consumers.<sup>134</sup> While this sounds like a step toward transparency, it is not sufficient because, as our study has shown, the mere fact that a state should have policies about prescribing psychotropic medications to children does not guarantee that those policies themselves will be formalized or publicly available. It is therefore incumbent on the federal government and state child welfare agencies to determine the most effective mechanisms for monitoring this issue, and making monitoring policies broadly known.

#### CONCLUSION

Our review found that few state child welfare agencies within our study period had publicly available, comprehensive policies addressing psychotropic medication prescriptions for children in foster care. To the

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131. See *supra* notes 109–16 and accompanying text for a discussion of the advantages and disadvantages of providing transparency in the administrative rulemaking process.

132. See *generally Confidentiality in Public Child Welfare: Frequently Asked Questions*, NAT'L ASS'N OF PUB. CHILD WELFARE ADM'RS, <http://www.duluth.umn.edu/sw/cw/lowo/tabs/4/ConfidentialityFAQs.pdf> (last visited Aug. 1, 2014) (providing a broad overview of the confidentiality practices related to child welfare). The tension between transparency and privacy is evident as child welfare systems consider reform. See Erik Schelzig, *Tennessee Fights Transparency for Child Welfare Agency*, THE DAILY NEWS (Jan. 8, 2013), <http://www.memphisdailynews.com/news/2013/jan/8/tennessee-fights-transparency-for-child-welfare-agency>.

133. See INFORMATION MEMORANDUM I2-03, *supra* note 8, at 1.

134. *Id.* at 12–13.

extent policies did exist, they were informal, were not developed through a public notice and comment process, and had little, if any, redress available if the policies were not followed. What this means is that in many states, policymakers, providers, families, children and youth, and citizens have little information about psychotropic medication policies specifically regarding monitoring for children in foster care. Without such information, it is difficult to understand and assess the ability of individual states to oversee psychotropic medications. Moreover, as long as practice is so distinct from publicly accessible requirements, states will face challenges in implementing and demonstrating adherence to federal or more local requirements. Equally important, states may also confront challenges in coordinating services between agencies and in identifying promising practices for the challenging task of overseeing psychotropic medication use by children in foster care.

The newly articulated federal guidelines for child welfare agencies related to psychotropic medications provide states with a starting point for reassessing their approach to psychotropic medication oversight. But they are only a starting point. State child welfare agencies presently have the opportunity to implement reforms and make those reforms publicly accessible. This Article seeks to encourage states to do so and to thoughtfully consider the purpose of oversight measures and the need for broad dissemination of promulgated policies that provide for stakeholder participation, ratification, and process for redress where non-compliance occurs.

## APPENDIX A: STATE APPROACHES TO MONITORING

State	Young Children	Dosage Level	Polypharmacy	Prior Authorization per Child Welfare
AZ	None	None	Yes (2010) (P) <sup>i</sup>	Yes (2003) (R) <sup>ii</sup>
CA	None	None	None	Yes (2010) (R) <sup>iii</sup>
FL	None	None	Yes (2010) (P) <sup>iv</sup>	Yes (2010) (R) <sup>v</sup>
GA	None	None	None	None
IL	Yes (2008) (P) <sup>vi</sup>	Yes (2008) (P) <sup>vii</sup>	Yes (2008) (P) <sup>viii</sup>	Yes (1995) (R) <sup>ix</sup>
KY	None	None	None	None
MA	None	None	None	Yes (2008) (R) <sup>x</sup>
MD	None	None	None	None
MI	Yes (2011) (P) <sup>xi</sup>	Yes (2011) (P) <sup>xii</sup>	Yes (2011) (P) <sup>xiii</sup>	None
NC	None	None	None	None
NY	Yes (2008) (P) <sup>xiv</sup>	None	Yes (2008) (P) <sup>xv</sup>	None
OH	None	None	None	None
PA	None	None	None	None
TN	None	Yes (2007) (P) <sup>xvi</sup>	Yes (2007) (P) <sup>xvii</sup>	None
TX	Yes (2010) (P) <sup>xviii</sup>	Yes (2010) (P) <sup>xix</sup>	Yes (2010) (P) <sup>xx</sup>	Yes (2007) (R) <sup>xxi</sup>
VA	None	None	None	None

(P) Informal guidance document, including policy statements and interpretive rules.

(R) Formal legislative regulation, adopted in compliance with state APA requirements.

APPENDIX B: SUMMARY OF STATE FORMAL AND INFORMAL  
RULE-MAKING DEFINITIONS

State	MSAPA Adopted				Legislative Rules Defined ("Formal Policy")	Policy Document / Statement / Interpretive Rule Definition ("Informal Policy")	Inform. Notice/ Cmt. Required?
	46	6I	8I	10			
AZ <sup>xxii</sup>		X	X		An agency statement of general applicability that implements, interprets or prescribes law or policy, or describes the procedure or practice requirements of an agency. Rules include prescribing fees or the amendment or repeal of a prior rule but do not include intraagency memoranda that are not delegation agreements.	A written expression that informs the general public of an agency's current approach to, or opinion of, the requirements of the federal or state constitution, federal or state statute, administrative rule or regulation, or final judgment of a court of competent jurisdiction, including, where appropriate, the agency's current practice, procedure or method of action based upon that approach or opinion.	No. <sup>xxiii</sup>
CA <sup>xxiv</sup>	X		X		Every rule, regulation, order, or standard of general application or the amendment, supplement, or revision of any rule, regulation, order, or standard adopted by any state agency to implement, interpret, or make specific the law enforced or administered by it, or to govern its procedure.	Any guideline, criterion, bulletin, manual, instruction, order, standard of general application, or other rule, unless the guideline, criterion, bulletin, manual, instruction, order, standard of general application, or other rule has been adopted as a regulation and filed with the Secretary of State.	Yes. <sup>xxv</sup>
FL <sup>xxvi</sup>		X	X		Each agency statement of general applicability that implements, interprets, or prescribes law or policy or	Internal management memoranda that do not affect either the private interests of any person or	No. <sup>xxvii</sup>

				describes the procedure or practice requirements of an agency and includes any form that imposes any requirement or solicits any information not specifically required by statute or by an existing rule.	any plan or procedure important to the public and which have no application outside the agency issuing the memorandum.	
GA <sup>xxviii</sup>		X		Each agency regulation, standard, or statement of general applicability that implements, interprets, or prescribes law or policy or describes the organization, procedure, or practice requirements of any agency.	Statements concerning only the internal management of an agency and not affecting private rights or procedures available to the public; declaratory rulings; intra-agency memoranda; statements of policy or interpretations that are made in the decision of a contested case. <sup>xxix</sup>	No. <sup>xxx</sup>
IL <sup>xxxi</sup>	X	X		Each agency statement of general applicability that implements, applies, interprets, or prescribes law or policy.	Statements concerning only the internal management of an agency and not affecting private rights or procedures available to persons or entities outside the agency, informal advisory rulings issued under Section 5-150, intra-agency memoranda, or guidance documents prepared by IEPA.	No. <sup>xxxii</sup>
KY <sup>xxxiii</sup>				Each statement of general applicability promulgated by an administrative body that implements, <i>interprets, or prescribes law or policy</i> , or describes the organization, procedure, or practice requirements of any administrative body.	Statements concerning only the internal management of an administrative body and not affecting the private rights or procedures to the public; declaratory rulings; and intradepartmental memoranda not in conflict with KRS 13A. 130. <sup>xxxiv</sup>	Yes. <sup>xxxv</sup>
MA <sup>xxxvi</sup>			X	The whole or any part of every rule, regulation, standard or other requirement of general application and future effect,	Advisory rulings issued under section eight; or regulations concerning only the internal management or	No. <sup>xxxviii</sup>

				including the amendment or repeal thereof, adopted by an agency to implement or interpret the law enforced or administered by it, but does not include advisory rulings or regulations concerning internal management.	discipline of the adopting agency or any other agency, and not substantially affecting the rights of or the procedures available to the public or that portion of the public affected by the agency's activities. <sup>xxxvii</sup>	
MD <sup>xxxix</sup>	X			A statement or an amendment or repeal of a statement that has general application; has future effect; is adopted by an officer or unit authorized by law to adopt regulations, govern organization of the unit, govern the procedure of the unit, govern practice before the unit; and is in any form, including a guideline, a rule, a statement of interpretation, or a statement of policy.	A statement that concerns only internal management of the unit and does not affect the rights of the public or the procedures available to them directly, or a declaratory ruling of the unit as to a regulation.	Yes. <sup>xl</sup>
MI <sup>xli</sup>	X			An agency regulation, statement, standard, policy, ruling, or instruction of general applicability that implements or applies law enforced or administered by the agency, or that prescribes the organization, procedure, or practice of the agency, including the amendment, suspension, or rescission of the law enforced or administered by the agency.	An intergovernmental, interagency, or intraagency memorandum, directive, or communication that does not affect the rights of, or procedures and practices available to, the public. A form with instructions, an interpretive statement, a guideline, an informational pamphlet, or other material that does not have the force and effect of law but is merely explanatory.	No. <sup>xlii</sup>
NC <sup>xliii</sup>	X	X		Any agency regulation, standard, or statement of general applicability that implements or interprets an enactment of the General Assembly or Congress or a regulation adopted by a federal agency or that describes the	Nonbinding interpretative statements within the delegated authority of an agency that merely define, interpret, or explain the meaning of a statute or rule. Statements of agency policy made in the context	No. <sup>xliv</sup>

				procedure or practice requirements of an agency. The term includes the establishment of a fee and the amendment or repeal of a prior rule.	of another proceeding.	
NY <sup>xlv</sup>	X			The whole or part of each agency statement, regulation or code of general applicability that implements or applies law, or prescribes a fee charged by or paid to any agency or the procedure or practice requirements of any agency, including the amendment, suspension or repeal thereof.	Forms and instructions, interpretive statements, and statements of general policy that, in themselves, have no legal effect but are merely explanatory.	No. <sup>xlvi</sup>
OH <sup>xlvii</sup>	X			Any rule, regulation, or standard, having a general and uniform operation, adopted, promulgated, and enforced by any agency under the authority of the laws governing such agency, and includes any appendix to a rule.	Any internal management rule of an agency.	Yes. <sup>xlviii</sup>
PA <sup>xlix</sup>	X		X <sup>1</sup>	Any regulation except a proclamation, executive order, executive directive, or other similar document promulgated by the Governor. The term includes a regulation that may be promulgated by an agency only with the approval of the Governor.	Any document, except an adjudication or a regulation, promulgated by an agency, which sets forth substantive or procedural personal or property rights, privileges, immunities, duties, liabilities or obligations of the public or any part thereof, and includes, any document interpreting or implementing any act of Assembly enforced or administered by such agency.	No. <sup>li</sup>
TN <sup>lii</sup>	X		X	Each agency statement of general applicability that implements or prescribes law or policy or describes the	Intraagency memoranda; general policy statements that are substantially repetitious of existing law.	No. <sup>liii</sup>



				procedures of any agency.	“Policy” means a set of decisions, procedures, and practices pertaining to the internal operation or actions of an agency.	
TX <sup>liv</sup>				A state agency statement of general applicability that: implements, interprets, or prescribes law or policy or describes the procedure or practice requirements of a state agency.	A statement regarding only the internal management or organization of a state agency and that does not affect private rights or procedures.	No. <sup>lv</sup>
VA <sup>lvi</sup>	X			Any statement of general application, having the force of law, affecting the rights or conduct of any person, adopted by an agency in accordance with the authority conferred on it by applicable basic laws.	Any document developed by a state agency or staff that provides information or guidance of general applicability to the staff or public to interpret or implement statutes or the agency's rules or regulations.	No. <sup>lvii</sup>

i Provider manuals were created from templates issued by the Arizona Department of Health Services, Division of Behavioral Health Services. *See, e.g.*, CENPATICO BEHAVIORAL HEALTH OF ARIZ., PROVIDER MANUAL: PSYCHOTROPIC MEDICATION: PRESCRIBING AND MONITORING 3.15.7-E (2010).

ii ARIZ. ADMIN. CODE § R9-21-206.01 (2003).

iii CAL. CODE REGS. tit. 22, § 89475 (2010).

iv STATE OF FLA. DEP'T OF CHILDREN AND FAMILIES, PRE-CONSENT REVIEW FOR PSYCHOTROPIC MEDICATION TREATMENT PLANS FOR CHILDREN UNDER ELEVEN (11) YEARS OF AGE IN OUT-OF-HOME CARE WHO ARE PRESCRIBED TWO (2) OR MORE PSYCHOTROPIC MEDICATIONS (2010), *available at* [http://centerforchildwelfare2.fmhi.usf.edu/kb/DCF\\_Pol/Family%20Safety%20CFOP's/CFOP175-98Pre-ConsentReview.pdf](http://centerforchildwelfare2.fmhi.usf.edu/kb/DCF_Pol/Family%20Safety%20CFOP's/CFOP175-98Pre-ConsentReview.pdf).

v FLA. ADMIN. CODE ANN. r. 65C-35.010 (2010).

vi Factors that trigger case review include a heightened level of medications for children six or younger, or the presence of any non-stimulant medication for children under four years old. *See* ILL. ADMIN. CODE tit. 89, § 325 app. A (2012) (“Guidelines for the Utilization of Psychotropic Medications for Children in Foster Care”).

vii *Id.* § 325.40.

viii There are additional parameters around polypharmacy prescriptions. *Id.* § 325 app. A.

ix An administrative rule requires prior approval from an authorized agent before a physician can prescribe a psychotropic medication to any child for whom the department is legally responsible. *Id.* § 325.60.

x 102 MASS. CODE REGS. 5.08(5) (2008).

xi *See* MICH. DEP'T OF HUMAN SERVS., FORM DHS-1643: PSYCHOTROPIC MEDICATION INFORMED CONSENT (2014) (on file with authors).

xii *See id.*

xiii *See id.*

xiv *See generally* N.Y. STATE OFFICE OF CHILDREN & FAMILY SERVS., *supra* note 100.

xv *Id.* at 11–13.

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- XVI STATE OF TENN. DEP'T OF CHILDREN'S SERVS., *supra* note 100, at 94.
- XVII *Id.*
- XVIII *See generally* TEX. DEP'T OF FAMILY & PROTECTIVE SERVS. & UNIV. OF TEX. AT AUSTIN COLL. OF PHARMACY, *supra* note 98.
- XIX *Id.* at 12–18.
- XX *Id.* at 4, 8.
- XXI 40 TEX. ADMIN. CODE § 748.2001 (2007).
- XXII ARIZ. REV. STAT. ANN. § 41-1001 (2013).
- XXIII Asimow, *supra* note 105, at 642 n.53 (noting that Arizona's broad definition of "substantive policy statement" creates an exception to the normal rulemaking requirements).
- XXIV CAL. GOV'T CODE § 11342.600 (West 2014).
- XXV *Id.* § 11340.5. *See* Asimow, *supra* note 105, at 644 ("More than any other state, California prohibits the adoption of guidance documents without APA compliance and strongly enforces this prohibition both through court decisions and an administrative determination mechanism.").
- XXVI FLA. STAT. ANN. § 120.52 (2013).
- XXVII *See* Asimow, *supra* note 105, at 641 (noting that Florida construes "rule" in a manner that covers only quasi-legislative action that has the force of law, therefore implicitly exempting "guidance documents" and other policy statements from the formal public notice and comment period). A "policy statement will not be treated as [a] rule because [it is] not intended to create rights or require compliance or otherwise to have the direct and consistent effect of law." *Id.* at 641 n.45. *But see* Jenkins v. State, 855 So. 2d 1219, 1225 (Fla. Dist. Ct. App. 2003) ("An agency statement or policy is a rule if its effect requires compliance, creates certain rights while adversely affecting others, or otherwise has the direct and consistent effect of law.").
- XXVIII GA. CODE ANN. § 50-13-2 (2013); *id.* § 50-13-4.
- XXIX *Id.* § 50-13-2.
- XXX *See* Asimow, *supra* note 105, at 642 (Georgia has "adopt[ed] the federal exception for interpretive rules and policy statements").
- XXXI ILL. ADMIN. CODE. tit. 100, § 1.70 (2012).
- XXXII *See* Asimow, *supra* note 105, at 640 (Illinois has applied the 1961 exception for "intra-agency memoranda" to their interpretive rules and guidance documents). *See also* People v. Carpenter, 895 N.E.2d 24, 33 (Ill. App. Ct. 2008) (holding that implementations of existing regulations are not subject to APA requirements).
- XXXIII KY. REV. STAT. ANN. § 13A.010 (West 2014).
- XXXIV *Id.*
- XXXV Asimow, *supra* note 105, at 651 (providing "that the term regulation includes manuals, policies, instructions, guides to enforcement, interpretive bulletins, interpretations, and the like that have the effect of rules, orders, regulations, or standards of general application"). *See also* KY. REV. STAT. ANN. § 13A.010 ("An administrative body shall not by internal policy, memorandum, or other form of action: modify a statute or administrative regulation; expand upon or limit a statute or administrative regulation . . .").
- XXXVI MASS. GEN. LAWS ch. 30A, § 1 (2014); *id.* § 8.
- XXXVII *Id.* § 1.
- XXXVIII *See* Asimow, *supra* note 105, at 641 (noting that the Massachusetts Supreme Court has held "the legislature could not possibly have intended the rulemaking procedure apply to every guidance document"). *See also* Mass. Gen. Hosp. v. Rate Setting Comm'n, 359 N.E.2d 41 (1977) (holding that advisory or information pronouncements may be lawfully issued by an agency in relation to a regulation or statute without going through the procedures required for promulgation of a regulation).
- XXXIX MD. CODE ANN., STATE GOVT § 10-101(G)(1) (West 2014).
- XL *See* Asimow, *supra* note 105, at 641 (noting that Maryland construes "rule" in a manner that covers only quasi-legislative action that has the force of law, therefore implicitly exempting "guidance documents" and other policy statements from the formal public notice and comment period). Despite the language of the statute, which plainly equates rules/regulations with interpretive rules, Asimow asserts that Maryland courts have seemingly upheld the legitimacy of policy statements passed without notice or comment periods. *Id.* (citing Dep't of Health & Mental Hygiene v. Chimes, Inc., 681 A.2d 484, 488-90 (Md. 1996)). *But see* Delmarva Power & Light Co. v. Pub. Serv. Comm'n of Md., 370 Md.

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I, 34, 803 A.2d 460, 479 (2002) (distinguishing *Chimes* and concluding that agencies may not adopt standards that constitute regulations under the APA without complying with APA requirements).

XLI MICH. COMP. LAWS ANN. § 24.207 (2014).

XLII See Asimow, *supra* note 105, at 642 (enacting legislation creating explicit rulemaking exceptions for certain guidance documents).

XLIII N.C. GEN. STAT. § 150B-2 (2014).

XLIV See Asimow, *supra* note 105, at 642 (enacting legislation creating explicit rulemaking exceptions for certain types of guidance documents).

XLV N.Y. COMP. CODES R. & REGS. tit. x, § 102(a) (2014).

XLVI See Asimow, *supra* note 105, at 642 (enacting legislation creating explicit rulemaking exceptions for types of certain guidance documents). See also *Pharmacists Soc’y, State of N.Y., Inc. v. Pataki*, 58 A.D.3d 924, 926 (N.Y. App. Div. 2009) (holding that interpretive statements are exempt under New York’s APA).

XLVII OHIO REV. CODE ANN. § 119.01 (West 2014).

XLVIII See Asimow, *supra* note 105, at 638 (noting that Ohio has no functioning exception from the notice and comment requirements required of “rules” for guidance documents).

XLIX 2 PA. CONS. STAT. ANN. § 101 (West 2007).

L Pennsylvania is the only state that has introduced legislation proposing to adopt the 2010 Revised Model State Administrative Procedure Act. *State Administrative Procedure Act, Revised Model*, Unif. Law Comm’n, <http://www.uniformlaws.org/Act.aspx?title=State%20Administrative%20Procedure%20Act,%20Revised%20Model> (last visited Aug. 1, 2014).

LI See Asimow, *supra* note 105, at 642 (enacting legislation creating explicit rulemaking exceptions for certain guidance documents. See also *Success Against All Odds v. Dep’t of Pub. Welfare of the Commonwealth of Pa.*, 700 A.2d 1340 (Pa. Commw. Ct. 1997) (Administrative agency may render interpretive law so long as interpretation is one that reviewing court determines is consistent with meaning of statute with respect to which it is rendered). For a discussion of how Pennsylvania interprets and affords deference to agency rulemaking, see *Nw. Youth Servs., Inc. v. Commonwealth of Pa., Dep’t of Pub. Welfare*, 66 A.3d 301 (Pa. 2013).

LII TENN. CODE ANN. § 4-5-102 (2014).

LIII See Asimow, *supra* note 105, at 642 (enacting legislation creating explicit rulemaking exceptions for certain guidance documents). See also *Mandela v. Campbell*, 972 S.W.2d 531, 534 (Tenn. 1998) (noting that “a policy is not a rule under the UAPA if the policy concerns internal management of state government and if the policy does not affect the private rights, privileges, or procedures available to the public”).

LIV TEX. GOV’T CODE ANN. § 2001.003 (West 2013).

LV *Brinkley v. Tex. Lottery Comm’n*, 986 S.W.2d 764, 769 (Tex. App. 1999) (“If every expression by the agency as to ‘law,’ ‘policy,’ and procedural ‘requirements’ requires the promulgation of a formal rule, the agency could no longer exercise its “informed discretion” to choose adjudication as a means of making law and policy, rather than rulemaking, a choice we have repeatedly said an agency has when it possesses both adjudicatory and rulemaking powers.”).

LVI VA. CODE ANN. § 2.2-4001 (2014).

LVII Asimow, *supra* note 105, at 644 (“Guidance documents need not be adopted with notice and comment, but they must be filed with the Registrar for publication. . . .”). See also *Davenport v. Summit Contractors, Inc.*, 612 S.E.2d 239, 243 (Va. Ct. App. 2005) (quoting *Jackson v. W.*, 419 S.E.2d 385, 389 (Va. Ct. App. 1992) (guidance documents are not “subject to the scrutiny associated with promulgated regulations, [and therefore] agency guidelines ‘do not purport to be a substitute for the statute’”).



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